Modification of the existing maximum residue levels for fludioxonil in rhubarbs

EFSA (European Food Safety Authority),
Maria Anastasiadou, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue level (MRL) for the active substance fludioxonil in rhubarbs. The data submitted in support of the request were found to be sufficient to derive an MRL proposal of 0.7 mg/kg for rhubarbs. Adequate analytical methods for enforcement are available to control the residues of fludioxonil 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 use of fludioxonil according to the reported agricultural practice is unlikely to present a risk to consumer health.

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

Requestor: European Commission
Question number: EFSA-Q-2019-00350
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgments: EFSA wishes to acknowledge the contribution of Marianna Raczyk and Silvia Ruocco to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned Opinion on the modification of the existing maximum residue levels for fludioxonil in rhubarbs. EFSA Journal 2019;17(9):5815, 24 pp. https://doi.org/10.2903/j.efsa.2019.5815

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to set a maximum residue level (MRL) for the active substance fludioxonil 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 fludioxonil, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) 0.01 to 0.7 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 assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fludioxonil following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and root and tuber crops; in addition, metabolism studies for seed treatment in root crops, cereals and pulses/oilseeds are available.

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

In rotational crops, the metabolic pathway of fludioxonil is similar to that in primary crops.

Based on the metabolic pattern identified in metabolism studies, the residue definitions for plant products were proposed as ‘fludioxonil’ for enforcement and as ‘sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil’ for risk assessment.

EFSA concluded that for rhubarb, metabolism of fludioxonil 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 appropriate.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in rhubarbs (limit of quantification (LOQ)).

The data submitted in support of this MRL application were found sufficient to derive an MRL proposal of 0.7 mg/kg in rhubarbs, which was derived by extrapolation from residue trials on celeries.

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

The occurrence of fludioxonil residues in rotational crops was investigated in the framework of the European Union (EU) pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Residues of fludioxonil in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of fludioxonil 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 0.37 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.

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 fludioxonil in rhubarbs, EFSA used the supervised trials median residue (STMR) value from the trials in celeries. 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 fludioxonil 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. The long-term exposure accounted for 20% of the ADI (NL toddler); the contribution of rhubarbs was low (maximum 0.02% of the ADI).

An acute exposure calculation was not required since for the active substances no ARfD has been derived.

EFSA concluded that the proposed use of fludioxonil on rhubarbs will not result in a risk to consumer health.
The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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<sup>(a)</sup> | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------|-------------------------|-------------------------|-----------------------|
| 0270070           | Rhubarbs   | 0.01*                   | 0.70                    | The submitted data are sufficient to derive an MRL proposal for the NEU use by extrapolation from results on celeries. Risk for consumers unlikely |

Enforcement residue definition: Fludioxonil<sup>(F)</sup>

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.
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 ............................................................................. 7
1.1.4. Methods of analysis in plants ....................................................................................................... 7
1.1.5. Storage stability of residues in plants ............................................................................................ 7
1.1.6. Proposed residue definitions ....................................................................................................... 7
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 .................................................................................... 8
1.2.3. Magnitude of residues in processed commodities ........................................................................ 8
1.2.4. Proposed MRLs ........................................................................................................................... 8
2. Residues in livestock .......................................................................................................................... 8
3. Consumer risk assessment ............................................................................................................... 8
4. Conclusion and Recommendations ................................................................................................. 9
References............................................................................................................................................... 9
Abbreviations .......................................................................................................................................... 10
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) ................................................................. 18
Appendix D – Input values for the exposure calculations................................................................. 20
Appendix E – Input values for the exposure calculations................................................................. 24
Assessment

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

Fludioxonil is the ISO common name for 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Fludioxonil was evaluated in the framework of Directive 91/414/EEC1 with Denmark designated as rapporteur Member State (RMS); the representative uses assessed were foliar applications on table and wine grapes and seed treatment on wheat. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2007). Fludioxonil was approved2 for the use as a fungicide 1 November 2008. The process of renewal of the first approval is currently ongoing.

The EU MRLs for fludioxonil are established in Annexes II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for fludioxonil. The proposals from these reasoned opinions have been considered in MRL regulations.4

In accordance with Article 6 of Regulation (EC) No 396/2005, Agriculture and Horticulture Development Board (AHDB) submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to modify the existing MRL for the active substance fludioxonil 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 fludioxonil, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) 0.01 to 0.7 mg/kg, by extrapolating results from four residue trials in celeries 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 (Denmark, 2005, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on fludioxonil (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil (EFSA, 2011), as well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2012, 2013, 2016a,b, 2019a,b) including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997c–q, 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 546/20116.

As the procedure for the renewal of the approval of fludioxonil 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.

The evaluation report submitted by the EMS (United Kingdom, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo version 3) are considered as supporting

---

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 Commission Directive 2007/76/EC of 20 December 2007 amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb as active substances, OJ L 337, 21.12.2007, p. 100–104.
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/eu-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.
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 fludioxonil in primary crops (fruit crops, leafy crops, root and tuber crops, cereals and pulses/oilseeds) was evaluated in the framework of the EU peer review and in the MRL review (EFSA, 2007, 2011).

Following foliar application, the major component was parent fludioxonil, accounting for up to 73% of the total radioactive residue (TRR) in tomatoes. Besides the parent compound, a large number of metabolites are formed, individually occurring at low levels (each < 10% of TRR). Compared to other crop groups, however, the metabolism was more extensive in root vegetables (spring onions) where fludioxonil was detected for a maximum of 31% TRR and the remaining radioactive residues composed of several metabolites (each < 7% of the TRR) containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. Following seed application, uptake and translocation of fludioxonil was low. The metabolism was qualitatively similar in all crops (EFSA, 2007, 2011).

1.1.2. Nature of residues in rotational crops

Not relevant for the current application since rhubarb is not considered to be a rotational crop (OECD, 2007).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fludioxonil residues was investigated under standard hydrolysis conditions, indicating that fludioxonil is hydrolytically stable under the representative processing conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2007, 2011).

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, 2007, 2011).

Fully validated multiresidue DFG S19 and QuEChERS methods in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available for the analysis of fludioxonil. The limit of quantification (LOQ) of 0.01 mg/kg was validated in high water-, high acid-, high oil content and in dry commodities (EFSA, 2007, 2011).

For rhubarb, a matrix with a high acid content, adequate analytical methods are available which allow quantification of fludioxonil residues at or above the LOQ of 0.01 mg/kg.

1.1.5. Storage stability of residues in plants

Fludioxonil was demonstrated to be stable upon storage at ≤ -20°C for at least 24 months in commodities of high water (tomato, apple, fresh peas, maize forage), high acid (grapes) and high oil (rapeseed, corn oil) content, as well as in dry/starch (cereal grains, maize grains, potato tubers) commodities and other matrices (straw, corn meal, sorghum hay) (EFSA, 2007, 2011).

1.1.6. Proposed residue definitions

Based on the metabolism studies, the residue definition was proposed during the EU peer review and MRL review as 'fludioxonil' for monitoring and as 'sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil or risk assessment.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the EU peer review and the MRL review.

EFSA concludes that the residue definitions for enforcement and risk assessment agreed in the EU peer review and in the MRL review are appropriate for rhubarbs.
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 fludioxonil on rhubarbs, the applicant referred to residue trials with fludioxonil and cyprodinil on celery which were submitted to EFSA by the EMS France and subsequently assessed in the reasoned opinion on the setting of MRLs for in celery (EFSA, 2012; France, 2012). The applicant proposed to derive an MRL proposal for fludioxonil in rhubarbs by extrapolation from celery.

In total, four NEU residue trials on celery, compliant with the intended NEU GAP on rhubarbs, are available. The residue trials performed in France in 2005, 2009 and 2010 were analysed for the parent compound only.

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 fludioxonil was measured in the whole product (stems plus leaves).

The trials were valid with regard to the analytical method used and the storage stability.

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 rhubarbs. EFSA agrees with this proposed refinement.

Taking into account the finding of the metabolism studies, in the green parts of the crops no significant concentrations of the metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic moiety are expected. Therefore, a default conversion factor of 1 was applied to derive the risk assessment value STMR for the risk assessment residue definition (EFSA, 2012).

EFSA concludes that an MRL of 0.7 mg/kg for fludioxonil in rhubarb is required in support of the intended GAP in the United Kingdom.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current application since rhubarb is not considered to be a rotational crop (OECD, 2007).

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of fludioxonil residues in processed commodities have not been submitted and are not required considering the low contribution of residues in rhubarb to the total calculated consumer exposure.

1.2.4. Proposed MRLs

The submitted data are sufficient to propose an MRL of 0.7 mg/kg for fludioxonil in rhubarbs, as extrapolated from residue trials on celery, in support of the intended NEU GAP.

2. Residues in livestock

Not relevant for the current application since rhubarb is not used as livestock feed item.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018). For the calculation of the chronic exposure resulting from the intended use of fludioxonil in rhubarbs, EFSA used the supervised trials median residue (STMR) value 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 and in succeeding reasoned opinions were used (EFSA, 2011, 2012, 2013, 2016a,b, 2019b); for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by JMPR were taken into account in the risk assessment (FAO, 2012, 2013). Crops for which no EU uses have been assessed in the EU and crops for which no import tolerance/Codex MRLs are established in the EU MRL legislation have not
been taken into account in the exposure calculation, assuming that these crops are not treated with fludioxonil. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The long-term exposure accounted for 20% of the acceptable daily intake (ADI; NL toddler); the contribution of rhubarbs was low (maximum 0.02% of the ADI). An acute exposure calculation was not required since for the active substance no acute reference dose (ARfD) has been derived.

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 0.7 mg/kg for fludioxonil in rhubarbs, as extrapolated from residue trials on celery, in support of the intended NEU GAP.

EFSA concluded that the proposed use of fludioxonil on rhubarbs will not result in a long-term consumer exposure exceeding the ADI value for fludioxonil and therefore is unlikely to pose a risk to consumers’ health. The MRL recommendations are summarised in Appendix B.4.

References

Denmark, 2005. Draft assessment report on the active substance fludioxonil prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, June 2005.

Denmark, 2007. Final addendum to the draft assessment report on the active substance fludioxonil prepared by the rapporteur Member State Denmark in the framework of Council Directive 91/414/EEC, June 2007.

EFSA (European Food Safety Authority), 2007. Conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil. EFSA Journal 2007;5(8):RN-110, 85 pp. https://doi.org/10.2903/j.efsa.2007.110r

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(8):2335, 86 pp. https://doi.org/10.2903/j.efsa.2011.2335

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the modification of the existing MRLs for fludioxonil in celery, celery leaves and radishes. EFSA Journal 2012;10(12):3014, 26 pp. https://doi.org/10.2903/j.efsa.2012.3014

EFSA (European Food Safety Authority), 2013. Modification of the existing MRLs for fludioxonil in cucurbits inedible peel and radishes. EFSA Journal 2013;11(2):3113, 25 pp. https://doi.org/10.2903/j.efsa.2013.3113

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the review of the setting of an import tolerance for fludioxonil in pineapples. EFSA Journal 2016;14(1):4372, 19 pp. https://doi.org/10.2903/j.efsa.2016.4372

EFSA (European Food Safety Authority), 2016b. Reasoned opinion on the modification of the MRLs for fludioxonil in various crops. EFSA Journal 2016;14(3):4445, 20 pp. https://doi.org/10.2903/j.efsa.2016.4445

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Lostia A, Magrans JO, Medina P, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Reasoned opinion on the modification of the existing maximum residue level for fludioxonil in Florence fennels. EFSA Journal 2019;17(5):5673, 22 pp. https://doi.org/10.2903/j.efsa.2019.5673

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Lostia A, Magrans JO, Medina P, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019b. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for fludioxonil. EFSA Journal 2019;17(9):5812, 31 pp. https://doi.org/10.2903/j.efsa.2019.5812

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 2, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/V/95-rev. 5, 22 July 1997.
European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2007. Review report for the active substance fludioxonil. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 1 June 2012 in view of the approval of fludioxonil as fludioxonil in accordance with Regulation (EC) No 1107/2009. SANCO/10692/2012 Rev 12, 1 June 2012, 7 pp.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO/825/00-rev. 10.3, 13 June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2012. Fludioxonil. In: Pesticide residues in food – 2012. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 215, 161–163.

FAO (Food and Agriculture Organization of the United Nations), 2013. Fludioxonil. In: Pesticide residues in food – 2013. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 219, 203–209.

France, 2012. Evaluation report on the setting of MRLs for fludioxonil in celery prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005. 20 February 2012, 25 pp.

OECD (Organisation for Economic Co-operation and Development), 2007. OECD Guideline for the testing of Chemicals: No 504 Residues in Rotational Crops. 8 January 2007.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

United Kingdom, 2019. Evaluation report on the modification of MRLs for fludioxonil in rhubarbs. 31 pp.

**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| a.i. | active ingredient |
| 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 |
| CF | conversion factor for enforcement to risk assessment residue definition |
| CXL | Codex maximum residue limit |
| DAR | draft assessment report |
| DAT | days after treatment |
| EMS | evaluating Member State |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| HPLC-MS/MS | high-performance liquid chromatography with tandem mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| InChIKey | International Chemical Identifier Key |
| ILV | independent laboratory validation |
| 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
RAC  raw agricultural commodity
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
TAR  total applied radioactivity
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<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Unit | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|------------------------|------------------------------------|-------------|----------------|-------------------------------|------|----------------|---------|
| Rhubarbs              | NEU                     | F                      | Botrytis cinerea                   | WG          | 25 (% w/w) | Foliar spray                  | 0.25 kg a.i./ha | 14 | Treatment as soon as the first symptoms are observed. The formulation contains 25% fluioxonil and 37.5% cyprodinil. |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule; a.i.: active ingredient.

(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                      | Grape       | Foliar, 3 × 0.5 kg a.s./ha | 0, 14, 35 (maturity) | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007, 2011) |
|                                  | Tomato      | Foliar, 3 × 0.75 kg a.s./ha | 0, 40 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007) |
|                                  | Peach       | Foliar, 3 × 0.28 kg a.s./ha 3 × 2.8 kg a.s./ha 2.1 + 6.3 kg a.s./ha | 28 28 30, 114 | Radiolabelling: [phenyl-U-14C] (EFSA, 2007) |
| Root crops                       | Spring onion| Foliar, 0.6-0.9 kg a.s./ha 2.8-3.4 kg a.s./ha | 0, 7, 14, 28 | Radiolabelling: [phenyl-U-14C] (EFSA, 2011) |
|                                  | Potato      | Seed, 2.5 g a.s./100 kg seed | 0, 40, 71, 95 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Leafy crops                      | Lettuce     | Foliar, 3 × 0.2 kg a.s./ha 3 × 0.6 kg a.s./ha | 0, 6, 13 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Cereals/grass                    | Rice        | Seed, 6.5 g a.s./100 kg seed | 0, 38, 76, 152 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Pulses/oilseeds                  | Cotton      | Seed, 2.5 or 5 g a.s./100 kg seed | 186 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
|                                  | Soybean     | Seed, 5 g a.s./100 kg seed | 28, 38, 133 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                    | Sugar beets | 0.75 kg a.s./ha | 140, 320, 345 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    | Turnips     | 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    | Radishes    | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    |             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [phenyl-14C] (EFSA, 2007, 2011) |
| Leafy crops                        | Lettuce     | 0.75 kg a.s./ha | 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
| Pulses/oilseeds                    | Mustard     | 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    |             | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    |             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
| Cereal (small grain)               | Winter wheat| 0.75 kg a.s./ha | 140, 320, 345 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    | Spring wheat| 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    |             | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                    |             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [phenyl-14C] (EFSA, 2007, 2011) |
| Corn                               | 0.75 kg a.s./ha | 140, 320, 345 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
### 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              | Tomato, apples, peas       | -18    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   |                                 | Maize forage               | -20    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   | High oil content                | Rapeseed, corn oil         | -18    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   | Dry / High starch               | Cereal grains, maize grains| -18    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   |                                 | Potato tubers              | -20    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   | High acid content               | Grapes                     | < -20  | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   | Others                          | Cereal straw, Corn meal    | -16    | 24 Months              | Fludioxonil                        | EFSA (2011)    |
|                                   |                                 | Sorghum hay                | -20    | 24 Months              | Fludioxonil                        | EFSA (2011)    |

**Table:**

- **Processed commodities (hydrolysis study):**
  - Pasteurisation (20 min, 90°C, pH 4)
  - Baking, brewing and boiling (60 min, 100°C, pH 5)
  - Sterilisation (20 min, 120°C, pH 6)

- **Conditions:**
  - Pasteurisation: Yes, Radiolabelling: [pyrrole-4-14C] (EFSA, 2007)
  - Baking, brewing and boiling: Yes, Radiolabelling: [pyrrole-4-14C] (EFSA, 2007)
  - Sterilisation: Yes, Radiolabelling: [pyrrole-4-14C] (EFSA, 2007)

- **Can a general residue definition be proposed for primary crops?**
  - Yes (EFSA, 2011)

- **Rotational crop and primary crop metabolism similar?**
  - Yes (EFSA, 2011)

- **Residue pattern in processed commodities similar to residue pattern in raw commodities?**
  - Yes (EFSA, 2011)

- **Plant residue definition for monitoring (RD-Mo):**
  - Fludioxonil

- **Plant residue definition for risk assessment (RD-RA):**
  - Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil

- **Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs):**
  - Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg
  - Confirmatory method available
  - ILV available (EFSA, 2011)

**DAT:** days after treatment; a.s.: active substance; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(e)</sup> |
|-----------|-----------------------------|---------------------------------------------------------------|----------------|------------------------|----------------|----------------|--------------|
| Rhubarbs  | NEU                         | 0.074; 0.15<sup>(d)</sup>; 0.31; 0.31                        | Residue trials on celeries compliant with NEU GAP Extrapolation to rhubarb possible (European Commission, 2017) | 0.7         | 0.31            | 0.23           | 1            |

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.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. The conversion factor was derived from metabolism studies, where in the green parts of the crops no significant concentrations of the metabolites containing the 2,2-difuoro-benzo[1,3]dioxole-4-carboxylic moiety were identified (EFSA, 2011).
### B.1.2.2. Residues in rotational crops

| Question                                                                 | Answer                                                                 |
|-------------------------------------------------------------------------|------------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | Fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP (EFSA, 2007) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No | Not relevant since rhubarb is not considered to be a rotational crop |

GAP: Good Agricultural Practice.

### 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

| Parameter                                                                 | Calculation                                                                 |
|--------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| ARfD                                                                     | Not relevant since no ARfD has been considered necessary. (European Commission, 2007) |
| Highest IESTI, according to EFSA PRIMo                                   | Not applicable                                                               |
| Assumptions made for the calculations                                     | Not applicable                                                               |
| ADI                                                                       | 0.37 mg/kg bw per day (European Commission, 2007)                           |
| Highest IEDI, according to EFSA PRIMo 3                                  | 20% ADI (NL toddler)                                                        |
| Contribution of crops assessed:                                            | Rhubarbs: 0.02% of ADI                                                      |
| Assumptions made for the calculations                                     | Calculations were performed with PRIMo rev. 3. The calculation was performed using the median residue concentration measured in the valid residue trials used to derive the MRL proposal for rhubarbs. Additionally, the median residue levels for the crops assessed in the MRL review and in reasoned opinions issued after the MRL review and for safe CXLs implemented in the EU legislation were included in the calculation. The median residue refers to the edible part of mangoes and cucurbits with inedible peel. The median residue for root crops was multiplied by the conversion factor for risk assessment of 2.8 derived from metabolism study during the EU pesticides peer review. The contributions of commodities where no GAP was reported in the framework of the MRL review or in the following EFSA evaluations were not included in the calculation |

ARfD: acute reference dose; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; MRL: maximum residue level; GAP: Good Agricultural Practice; CXL: Codex maximum residue limit.
**B.4. Recommended MRLs**

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|-----------|------------------------|------------------------|-----------------------|
| 0270070          | Rhubarbs  | 0.01*                  | 0.70                   | The submitted data are sufficient to derive an MRL proposal for the NEU use by extrapolation from results on celeries. Risk for consumers unlikely |

*Enforcement residue definition:* Fludioxonil<sup>(F)</sup>

- 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.
### Appendix C – Pesticide Residue Intake Model (PRiMo)

#### Fludioxonil (F)

| Toxicological reference values | LOQ (mg/kg) range from | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|--------------------------------|------------------------|------------------------|-----------------|
| 0.00                           | 0.01                   | 0.37                   | not necessary   |

Source of ADI: EFSA PRiMo revision 3.0; 2017/12/11
Year of evaluation: 2017/12/11

#### Calculated exposure (% of ADI)

| Component/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) | Expsoure (% of ADI) MS Diet |
|-------------------------------|-----------------------------|---------------------------------------------|------------------------------------------|------------------------------------------|-----------------------------|
| Pears                         | 20%                         | 75.67                                       | 7%                                       | 3%                                       | 75.67                        |
| Potatoes                      | 19%                         | 70.41                                       | 8%                                       | 6%                                       | 70.41                        |
| Potatoes                      | 11%                         | 42.11                                       | 4%                                       | 2%                                       | 42.11                        |
| Potatoes                      | 11%                         | 39.74                                       | 4%                                       | 1%                                       | 39.74                        |
| Grapefruits                   | 9%                          | 31.69                                       | 4%                                       | 1%                                       | 31.69                        |
| Potatoes                      | 8%                          | 31.69                                       | 4%                                       | 1%                                       | 31.69                        |
| Mandarins                     | 8%                          | 28.79                                       | 2%                                       | 2%                                       | 28.79                        |
| Potatoes                      | 7%                          | 26.24                                       | 2%                                       | 1%                                       | 26.24                        |
| Potatoes                      | 7%                          | 26.11                                       | 2%                                       | 1%                                       | 26.11                        |
| Potatoes                      | 7%                          | 25.59                                       | 2%                                       | 1%                                       | 25.59                        |
| Potatoes                      | 7%                          | 25.56                                       | 2%                                       | 1%                                       | 25.56                        |
| Potatoes                      | 7%                          | 25.11                                       | 2%                                       | 1%                                       | 25.11                        |
| Potatoes                      | 5%                          | 22.27                                       | 2%                                       | 1%                                       | 22.27                        |
| Potatoes                      | 5%                          | 22.07                                       | 2%                                       | 1%                                       | 22.07                        |
| Potatoes                      | 5%                          | 19.16                                       | 2%                                       | 1%                                       | 19.16                        |
| Potatoes                      | 5%                          | 18.71                                       | 2%                                       | 1%                                       | 18.71                        |
| Potatoes                      | 5%                          | 16.99                                       | 2%                                       | 1%                                       | 16.99                        |
| Potatoes                      | 5%                          | 15.75                                       | 2%                                       | 1%                                       | 15.75                        |
| Potatoes                      | 4%                          | 14.13                                       | 2%                                       | 1%                                       | 14.13                        |
| Potatoes                      | 4%                          | 11.27                                       | 2%                                       | 1%                                       | 11.27                        |
| Potatoes                      | 3%                          | 9.50                                        | 2%                                       | 1%                                       | 9.50                         |
| Potatoes                      | 2%                          | 7.23                                        | 2%                                       | 1%                                       | 7.23                         |
| Potatoes                      | 1%                          | 6.72                                        | 2%                                       | 1%                                       | 6.72                         |
| Potatoes                      | 0.8%                        | 5.98                                        | 2%                                       | 1%                                       | 5.98                         |
| Potatoes                      | 0.5%                        | 5.01                                        | 2%                                       | 1%                                       | 5.01                         |
| Potatoes                      | 0.3%                        | 4.07                                        | 2%                                       | 1%                                       | 4.07                         |
| Potatoes                      | 0.1%                        | 2.95                                        | 2%                                       | 1%                                       | 2.95                         |

**Note:** The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Fludioxonil (F) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results of IESTI calculation only for crops with GAPs under assessment

| IESTI | IESTI |
|-------|-------|
| Results for children | Results for adults |
| No. of commodities for which ARfD/ADI is exceeded (IESTI): | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
| [Unprocessed commodities](#) | [Processed commodities](#) |
| Highest % of ARfD/ADI Commodities | MRL/input for RA Exposure (mg/kg) (µg/kg bw) |
| Highest % of ARfD/ADI Commodities | MRL/input for RA Exposure (mg/kg) (µg/kg bw) |

### Details – acute risk assessment/children

### Details – acute risk assessment/adults

### Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation):
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Code  | Commodity                      | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment<sup>(1)</sup> | Input value (mg/kg) | Comment |
|-------|--------------------------------|------------------------|--------------------|--------------------------------------|---------------------|---------|
| 110010 | Grapefruits                    | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 110020 | Oranges                        | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 110030 | Lemons                         | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 110040 | Limes                          | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 110050 | Mandarins                      | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 110990 | Other citrus fruit             | 10                     | Existing EU MRL    | STMR-RAC                            | 5.3                 | STMR-RAC |
| 120100 | Pistachios                     | 0.2                    | Existing EU MRL    | STMR-RAC                            | 0.06                | STMR-RAC |
| 130010 | Apples                         | 5                      | Existing EU MRL    | STMR-RAC                            | 2.3                 | STMR-RAC |
| 130020 | Pears                          | 5                      | Existing EU MRL    | STMR-RAC                            | 2.3                 | STMR-RAC |
| 130030 | Quinces                        | 5                      | Existing EU MRL    | STMR-RAC                            | 2.3                 | STMR-RAC |
| 130040 | Medlar                         | 5                      | Existing EU MRL    | STMR-RAC                            | 2.3                 | STMR-RAC |
| 130050 | Loquats/Japanese medlars       | 5                      | Existing EU MRL    | STMR-RAC                            | 2.3                 | STMR-RAC |
| 140010 | Apricots                       | 5                      | Existing EU MRL    | STMR-RAC                            | 1.06                | STMR-RAC |
| 140020 | Cherries (sweet)               | 5                      | Existing EU MRL    | STMR-RAC                            | 0.8                 | STMR-RAC |
| 140030 | Peaches                        | 10                     | Existing EU MRL    | STMR-RAC                            | 3.65                | STMR-RAC |
| 140040 | Plums                          | 5                      | Existing EU MRL    | STMR-RAC                            | 1.06                | STMR-RAC |
| 151010 | Table grapes                   | 5                      | Existing EU MRL    | STMR-RAC                            | 0.38                | STMR-RAC |
| 151020 | Wine grapes                    | 4                      | Existing EU MRL    | STMR-RAC                            | 0.33                | STMR-RAC |
| 152000 | Strawberries                   | 4                      | EFSA (2019b)       | STMR-RAC                            | 0.31                | STMR-RAC |
| 153010 | Blackberries                   | 5                      | Existing EU MRL    | STMR-RAC                            | 1                   | STMR-RAC |
| 153020 | Dewberries                     | 5                      | Existing EU MRL    | STMR-RAC                            | 1                   | STMR-RAC |
| 153030 | Raspberries (red and yellow)   | 5                      | Existing EU MRL    | STMR-RAC                            | 1                   | STMR-RAC |
| 153990 | Other cane fruit               | 5                      | Existing EU MRL    | STMR-RAC                            | 1                   | STMR-RAC |
| 154010 | Blueberries                    | 2                      | Existing EU MRL    | STMR-RAC                            | 0.37                | STMR-RAC |
| 154020 | Cranberries                    | 2                      | Existing EU MRL    | STMR-RAC                            | 0.37                | STMR-RAC |
| 154030 | Currants (red, black and white)| 2                      | Existing EU MRL    | STMR-RAC                            | 0.37                | STMR-RAC |
| 154040 | Gooseberries (green, red and yellow)| 2 | Existing EU MRL | STMR-RAC | 0.37 | STMR-RAC |
| 154080 | Elderberries                   | 0.8                    | Existing EU MRL    | STMR-RAC                            | 0.24                | STMR-RAC |
| 162010 | Kiwi fruits (green, red, yellow)| 15                     | Existing EU MRL    | STMR-RAC                            | 7.3                 | STMR-RAC |
| 163010 | Avocados                       | 0.4                    | Existing EU MRL    | STMR-RAC                            | 0.05                | STMR-RAC |
| 163030 | Mangoes                        | 2                      | Existing EU MRL    | STMR-RAC                            | 0.02                | STMR-RAC |
| 163050 | Granate apples/pomegranates    | 3                      | Existing EU MRL    | STMR-RAC                            | 0.95                | STMR-RAC |
| 163080 | Pineapples                     | 7                      | Existing EU MRL    | STMR-RAC                            | 2.14                | STMR-RAC |
| 211000 | Potatoes                       | 5                      | Existing EU MRL    | STMR-RAC                            | 1.5                 | STMR-RAC |
| 212020 | Sweet potatoes                 | 10                     | Existing EU MRL    | STMR-RAC                            | 3.76                | STMR-RAC |
| 212030 | Yams                           | 10                     | Existing EU MRL    | STMR-RAC                            | 3.76                | STMR-RAC |
| 213010 | Beetroots                      | 1                      | Existing EU MRL    | STMR-RAC                            | 1.148               | STMR-RAC+CF |
| 213020 | Carrots                        | 1                      | Existing EU MRL    | STMR-RAC                            | 1.148               | STMR-RAC+CF |
| 213030 | Celerics/turnip rooted celeries| 0.2                    | Existing EU MRL    | STMR-RAC                            | 0.196               | STMR-RAC+CF |
| 213040 | Horseradishes                  | 1                      | Existing EU MRL    | STMR-RAC                            | 1.148               | STMR-RAC+CF |
| 213060 | Parsnips                       | 1                      | Existing EU MRL    | STMR-RAC                            | 1.148               | STMR-RAC+CF |
| 213070 | Parsley roots/Hamburg roots parsley| 1 | Existing EU MRL | STMR-RAC | 1.148 | STMR-RAC+CF |
| 213080 | Radishes                       | 0.3                    | Existing EU MRL    | STMR-RAC                            | 0.098               | STMR-RAC+CF |
| 213090 | Salsifises                     | 1                      | Existing EU MRL    | STMR-RAC                            | 1.148               | STMR-RAC+CF |
| 220010 | Garlic                         | 0.02                   | Existing EU MRL    | STMR-RAC                            | 0.056               | STMR-RAC+CF |
| Code    | Commodity                                | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment[^1] | Input value (mg/kg) | Comment   |
|---------|------------------------------------------|-----------------------|--------------------|-------------------------------|---------------------|-----------|
| 220020  | Onions                                   | 0.5                   | Existing EU MRL    |                               | 0.056               | STMR-RAC*CF |
| 220030  | Shallots                                 | 0.02                  | Existing EU MRL    |                               | 0.056               | STMR-RAC*CF |
| 220040  | Spring onions/green onions and Welsh onions | 5                    | Existing EU MRL    |                               | 0.532               | STMR-RAC*CF |
| 231010  | Tomatoes                                 | 3                     | Existing EU MRL    |                               | 0.66                | STMR-RAC   |
| 231020  | Sweet peppers/bell peppers               | 1                     | Existing EU MRL    |                               | 0.21                | STMR-RAC   |
| 231030  | Aubergines/egg plants                    | 0.4                   | Existing EU MRL    |                               | 0.12                | STMR-RAC   |
| 232010  | Cucumbers                                | 0.4                   | Existing EU MRL    |                               | 0.1                 | STMR-RAC   |
| 232020  | Gherkins                                 | 0.4                   | Existing EU MRL    |                               | 0.1                 | STMR-RAC   |
| 232030  | Courgettes                               | 0.4                   | Existing EU MRL    |                               | 0.1                 | STMR-RAC   |
| 232990  | Other cucurbits - edible peel            | 0.4                   | Existing EU MRL    |                               | 0.1                 | STMR-RAC   |
| 233010  | Melons                                   | 0.3                   | Existing EU MRL    |                               | 0.01                | STMR-RAC   |
| 233020  | Pumpkins                                 | 0.3                   | Existing EU MRL    |                               | 0.01                | STMR-RAC   |
| 233030  | Watermelons                              | 0.3                   | Existing EU MRL    |                               | 0.01                | STMR-RAC   |
| 233990  | Other cucurbits - inedible peel          | 0.3                   | Existing EU MRL    |                               | 0.01                | STMR-RAC   |
| 234000  | Sweet corn                               | 0.01                  | Existing EU MRL    |                               | 0.01                | STMR-RAC   |
| 241010  | Broccoli                                 | 0.7                   | Existing EU MRL    |                               | 0.23                | STMR-RAC   |
| 242020  | Head cabbages                            | 2                     | Existing EU MRL    |                               | 0.24                | STMR-RAC   |
| 243010  | Chinese cabbages/pe-tsai                 | 10                    | Existing EU MRL    |                               | 1.2                 | STMR-RAC   |
| 251010  | Lamb's lettuce/corn salads               | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251020  | Lettuces                                 | 40                    | Existing EU MRL    |                               | 8.3                 | STMR-RAC   |
| 251030  | Escaroles/broad-leaved endives           | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251040  | Cress and other sprouts and shoots       | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251050  | Land cress                               | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251060  | Roman rocket/rucola                      | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251070  | Red mustards                             | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251080  | Baby leaf crops (including brassica species) | 20                   | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 251990  | Other lettuce and other salad plants     | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 252010  | Spinaches                                | 30                    | Existing EU MRL    |                               | 5.8                 | STMR-RAC   |
| 252020  | Purslanes                                | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 252030  | Chards/beet leaves                       | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 252990  | Other spinach and similar                | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256010  | Chervil                                  | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256020  | Chives                                   | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256030  | Celery leaves                            | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256040  | Parsley                                  | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256050  | Sage                                     | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256060  | Rosemary                                 | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256070  | Thyme                                    | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256080  | Basil and edible flowers                 | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256090  | Laurel/bay leaves                        | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256100  | Tarragon                                 | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 256990  | Other herbs                              | 20                    | Existing EU MRL    |                               | 6.13                | STMR-RAC   |
| 260010  | Beans (with pods)                        | 1                     | Existing EU MRL    |                               | 0.48                | STMR-RAC   |
| 260020  | Beans (without pods)                     | 0.4                   | Existing EU MRL    |                               | 0.02                | STMR-RAC   |
| 260030  | Peas (with pods)                         | 1                     | Existing EU MRL    |                               | 0.48                | STMR-RAC   |
| 260040  | Peas (without pods)                      | 0.3                   | Existing EU MRL    |                               | 0.04                | STMR-RAC   |
| Code   | Commodity                | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment(1) | Input value (mg/kg) | Comment        |
|--------|--------------------------|------------------------|--------------------|----------------------------|---------------------|-----------------|
| 260050 | Lentils (fresh)          | 0.05                   | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 270010 | Asparagus                | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 270030 | Celeries                 | 1.5                    | Existing EU MRL    |                            | 0.32                | STMR-RAC        |
| 270040 | Florence fennels         | 1.5                    | Proposed MRL       |                            | 0.32                | STMR-RAC        |
| 300010 | Beans                    | 0.5                    | Existing EU MRL    |                            | 0.04                | STMR-RAC        |
| 300020 | Lentils                  | 0.4                    | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 300030 | Peas                     | 0.4                    | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 300040 | Lupins/lupini beans      | 0.4                    | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 300090 | Other pulses             | 0.4                    | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 401030 | Poppy seeds              | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 401050 | Sunflower seeds          | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 401060 | Rapeseeds/canola seeds   | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 401070 | Soya beans               | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 401090 | Cotton seeds             | 0.01                   | Existing EU MRL    |                            | 0.02                | STMR-RAC        |
| 401130 | Gold of pleasure seeds   | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500010 | Barley                   | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500020 | Buckwheat and other pseudo-cereals | 0.01 | Existing EU MRL | | 0.01 | STMR-RAC |
| 500030 | Maize/corn               | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500040 | Common millet/proso millet | 0.01                  | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500050 | Oat                      | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500060 | Rice                     | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500070 | Rye                      | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500080 | Sorghum                  | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 500090 | Wheat                    | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 633020 | Ginseng root             | 4                      | Existing EU MRL    |                            | 0.8                 | STMR-RAC*CF     |
| 840010 | Liquorice                | 1                      | Existing EU MRL    |                            | 1                   | MRL             |
| 840020 | Ginger                   | 1                      | Existing EU MRL    |                            | 1                   | MRL             |
| 840030 | Turmeric/curcuma         | 1                      | Existing EU MRL    |                            | 1                   | MRL             |
| 840990 | Other spices (roots)     | 1                      | Existing EU MRL    |                            | 1                   | MRL             |
| 900010 | Sugar beet roots         | 0.01                   | Existing EU MRL    |                            | 0.01                | STMR-RAC        |
| 1011010 | Swine: Muscle/meat      | 0.01                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1011020 | Swine: Fat tissue       | 0.01                  | EFSA (2019b)       |                            | 0.003               | STMR-RAC        |
| 1011030 | Swine: Liver            | 0.02                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1011040 | Swine: Kidney           | 0.03                  | EFSA (2019b)       |                            | 0.02                | STMR-RAC        |
| 1012010 | Bovine: Muscle/meat     | 0.01                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1012020 | Bovine: Fat tissue      | 0.01                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1012030 | Bovine: Liver           | 0.06                  | EFSA (2019b)       |                            | 0.04                | STMR-RAC        |
| 1012040 | Bovine: Kidney          | 0.07                  | EFSA (2019b)       |                            | 0.05                | STMR-RAC        |
| 1013010 | Sheep: Muscle/meat      | 0.01                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1013020 | Sheep: Fat tissue       | 0.01                  | EFSA (2019b)       |                            | 0.003               | STMR-RAC        |
| 1013030 | Sheep: Liver            | 0.02                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1013040 | Sheep: Kidney           | 0.03                  | EFSA (2019b)       |                            | 0.02                | STMR-RAC        |
| 1014010 | Goat: Muscle/meat       | 0.01                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1014020 | Goat: Fat tissue        | 0.01                  | EFSA (2019b)       |                            | 0.003               | STMR-RAC        |
| 1014030 | Goat: Liver             | 0.02                  | EFSA (2019b)       |                            | 0.01                | STMR-RAC        |
| 1014040 | Goat: Kidney            | 0.03                  | EFSA (2019b)       |                            | 0.02                | STMR-RAC        |
| Code   | Commodity         | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment$^{(1)}$ |
|--------|-------------------|------------------------|--------------------|-------------------------------|
|        |                   |                        |                    | Input value (mg/kg) | Comment            |
| 1016010 | Poultry: Muscle/meat | 0.01                   | EFSA (2019b)       | 0.01             | STMR-RAC           |
| 1016020 | Poultry: Fat tissue | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1016030 | Poultry: Liver     | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1016040 | Poultry: Kidney    | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1020010 | Milk: Cattle       | 0.02                   | EFSA (2019b)       | 0.02             | STMR-RAC           |
| 1020020 | Milk: Sheep        | 0.02                   | EFSA (2019b)       | 0.02             | STMR-RAC           |
| 1020030 | Milk: Goat         | 0.02                   | EFSA (2019b)       | 0.02             | STMR-RAC           |
| 1020040 | Milk: Horse        | 0.02                   | EFSA (2019b)       | 0.02             | STMR-RAC           |
| 1020990 | Milk: Others       | 0.02                   | EFSA (2019b)       | 0.02             | STMR-RAC           |
| 1030010 | Eggs: Chicken      | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1030020 | Eggs: Duck         | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1030030 | Eggs: Goose        | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1030040 | Eggs: Quail        | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |
| 1030990 | Eggs: Others       | 0.05                   | EFSA (2019b)       | 0.05             | STMR-RAC           |

MRL: maximum residue level; STMR: supervised trials median residue; CF: conversion factor; RAC: raw agricultural commodity. A CF of 2.8 (derived from the metabolism study on spring onions) was used for residues resulting from foliar application on root crops (EFSA, 2011).
## Appendix E – Used compound codes

| Code/trivial name\(^{(a)}\) | IUPAC name/SMILES notation/InChiKey\(^{(b)}\) | Structural formula\(^{(c)}\) |
|---------------------------|---------------------------------------------|-----------------------------|
| Fludioxonil              | 4-(2,2-diﬂuoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile N#Cc1c[NH]cc1c1cccc2OC(F)(F)Oc12 MUJOIMFVNIBMKC-UHFFFAOYSA-N | ![Structural formula](image) |
| CGA 173506               |                                             |                             |
| CGA 192155               | 2,2-diﬂuoro-benzo[1,3]dioxole-4 carboxylic acid O=\(\text{O}\)c1cccc2OC(F)(F)Oc12 ZGAQVJDFVTWJK-UHFFFAOYSA-N | ![Structural formula](image) |
|                          |                                             |                             |

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

\(^{(a)}\): The metabolite name in bold is the name used in the conclusion.

\(^{(b)}\): ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).

\(^{(c)}\): ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).