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Modification of the existing maximum residue levels for fludioxonil in certain small fruits and berries

European Food Safety Authority (EFSA),
Maria Anastassiadou, Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Agro GmbH submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRL) for the active substance fludioxonil in blueberries, gooseberries, currants and cranberries. The data submitted in support of the intended northern Europe (NEU) outdoor and EU indoor use were found sufficient to derive MRL proposals of 4 mg/kg for cranberries, gooseberries, currants and blueberries. 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.

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Correspondence: pesticides.mrl@efsa.europa.eu

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Agro GmbH submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance fludioxonil in blueberries, gooseberries, currants and cranberries. 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 10 November 2020. To accommodate for the intended northern Europe (NEU) outdoor and European Union (EU) indoor uses of fludioxonil, the EMS proposed to raise the existing MRLs from 3 to 4 mg/kg in currants and from 2 to 4 mg/kg in blueberries, gooseberries and cranberries.

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, data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fludioxonil following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and root crops; in addition, metabolism studies for seed treatment in root crops, cereals/grasses 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. For the current application, as the proposed use of fludioxonil is on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed by the EU pesticides peer review and the MRL review 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. For fruit crops, the conversion factor of 1 from enforcement to risk assessment was derived in the MRL review.

EFSA concluded that for the crops under assessment, metabolism of fludioxonil in primary 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 at or above the limit of quantification (LOQ) of 0.01 mg/kg.

The data submitted were found sufficient to derive an MRL proposal of 4.0 mg/kg for fludioxonil in cranberries, gooseberries, currants and blueberries in support of the NEU outdoor and EU indoor Good Agricultural Practices (GAPs). Residue trial samples were not analysed according to risk assessment residue definition, but this was not considered as a data gap since the metabolism of fludioxonil in fruit crops indicates insignificant concentrations of metabolites containing 2,2-difluorobenzo[1,3] dioxole-4 carboxylic acid moiety.

Specific studies investigating the magnitude of fludioxonil residues in processed commodities are not required, as significant residues are not expected in raw agricultural commodities (RAC) due to the low contribution of residues in the crops under assessment to the total consumer exposure.

Residues of fludioxonil in commodities of animal origin were not assessed since the crops under assessment are 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 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure to fludioxonil in blueberries, cranberries, gooseberries and currants, EFSA used the supervised trials median residue (STMR) value as derived from the trials in black currants and blueberries from the more critical indoor GAP. For the remaining crops, the STMR values as reported by the MRL review and in succeeding reasoned opinions were used; for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by the

JMPR were taken into account in the risk assessment. For animal commodities the input values were the MRLs as implemented in the Commission Regulation (EU) 2020/1633 following the evaluation of the Article 12 confirmatory data (EFSA, 2019d). The crops on which no EU uses were reported in the framework of the MRL review or in subsequent EFSA reasoned opinions have not been taken into account in the exposure calculation, assuming that these crops are not treated with fludioxonil.

The long-term exposure accounted for a maximum of 21% of the ADI (NL toddler diet); the individual contributions of residues in blueberries, currants, gooseberries and cranberries to the total consumer exposure were < 0.1% of the ADI. An acute exposure calculation was not required since for the active substance, no ARfD has been derived.

EFSA concluded that the long-term intake of residues of fludioxonil resulting from the existing and the intended uses is unlikely to present a risk to consumer health. 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.

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fludioxonil[(F)]				
0154010	Blueberries	2	4	MRL proposal for the intended EU indoor and NEU outdoor use. Risk for consumers unlikely.
0154020	Cranberries	2	4	
0154030	Currants	3	4	
0154040	Gooseberries	2	4	

MRL: maximum residue level; NEU: northern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for fludioxonil in blueberries, gooseberries, currants and cranberries. The detailed description of the intended uses of fludioxonil, which are 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)-1*H*-pyrrole-3-carbonitrile (IUPAC). The chemical structures of the active substance and its main metabolite are reported in Appendix E.

Fludioxonil was evaluated in the framework of Directive 91/414/EEC[1] with Denmark designated as rapporteur Member State (RMS) for the representative uses as a foliar application 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 (2007). Fludioxonil was approved[2] for the use as a fungicide on 1 November 2008. The process of renewal of the first approval is currently ongoing.

The European Union (EU) MRLs for fludioxonil are established in Annex II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011a) 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 recent MRL regulations.[4]

The evaluation of the confirmatory data following the MRL review under Article 12 of Regulation (EC) No 396/2005 has been recently completed (EFSA, 2019d) and the MRL proposals were implemented[5] in the Commission Regulation (EU) 2020/1633[6]; it is noted that for various commodities of animal origin the implemented MRLs were different than EFSA proposals and were based on the risk management decision. In addition, EFSA recently assessed the MRL application on the modification of fludioxonil MRL in elderberries (EFSA, 2020b), but the MRL proposal of this assessment has not yet been taken over in the MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Agro GmbH submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for the active substance fludioxonil in blueberries, gooseberries, currants and cranberries. 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 10 November 2020. To accommodate for the intended northern Europe (NEU) outdoor and European Union (EU) indoor uses of fludioxonil, the EMS proposed to raise the existing MRLs from 3 to 4 mg/kg in currants and from 2 to 4 mg/kg in blueberries, gooseberries and cranberries.

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

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2020), 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, 2007), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011a), as well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2011b, 2012, 2013, 2016a,b, 2019b,d,e, 2020a,b) and the EFSA scientific report (EFSA, 2019c).

[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, 16.03.2005, p. 1–16.
[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
[5] The MRLs are applicable as from 25/5/2021.
[6] Commission Regulation (EU) 2020/1633 of 27 October 2020 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products. OJ L 367/1, 5.11.2020, p. 1–38.

For this application, the data requirements established in Regulation (EU) No 544/2011[7] 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 546/2011[8].

As the procedure for the renewal of the approval of the active substance 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, is presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2020) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fludioxonil in primary crops (fruit crops, root crops, leafy crops, cereals/grass and pulses/oilseeds) was evaluated in the framework of the EU peer review and in the MRL review (EFSA, 2007, 2011a). Following foliar application, the major component of residues 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. Based on the metabolism study in spring onions, for root crop group a conversion factor of 2.8 from enforcement to risk assessment was proposed by the MRL review. Following seed application, uptake and translocation of fludioxonil was low. The metabolism was qualitatively similar in all crops (EFSA, 2007, 2011a). For cereals (seed treatment), fruits and leafy crops, a conversion factor (CF) of 1 was derived, which gave an indication that no significant concentrations of metabolites containing the 2,2-difluorobenzo[1,3]dioxole-4 carboxylic moiety are expected (EFSA, 2011a).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Not relevant for the current application, since the crops under assessment are not considered to be rotational crops.

1.1.3. Nature of residues in processed commodities

In the framework of the EU pesticides peer review and the MRL review (EFSA, 2007, 2011a) 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.

1.1.4. Methods of analysis in plants

Analytical methods for enforcement purposes were assessed by the EU pesticides peer review and further discussed in the MRL review (EFSA, 2007, 2011a). Fully validated multiresidue DFG S19 and

[7] 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.

[8] 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.

QuEChERS methods applying high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available for the analysis of fludioxonil in high water, high acid, high oil content commodities and in dry commodities at the limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2007, 2011a). It is concluded that for blueberries, currants, gooseberries and cranberries (high acid content commodities), adequate analytical methods for monitoring of residues are available.

1.1.5. Storage stability of residues in plants

The storage stability of fludioxonil in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and MRL review (EFSA, 2007, 2011a). It was demonstrated that fludioxonil was stable upon storage at $\leq -20°C$ 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/high starch content (cereal grains, maize grains, potato tubers) commodities and other matrices (straw, corn meal, sorghum hay).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review and MRL review (EFSA, 2007, 2011a):

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

The same residue definitions are applicable to rotational crops and processed products. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the EU pesticides peer review and the MRL review.

Taking into account the proposed uses on the crops as assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended **NEU outdoor use** of fludioxonil on blueberries, currants, gooseberries and cranberries, the applicant referred to Good Agricultural Practice (GAP)-compliant residue trials performed on red currants (five trials), black currants (four trials) and blueberries (four trials), which were evaluated recently by EFSA for an MRL application on elderberries (EFSA, 2020b).

The applicant proposes to use these residue trials also in support of the intended NEU use on currants, blueberries, gooseberries and cranberries. The number of trials is sufficient to derive an MRL proposal of 4 mg/kg for currants and blueberries. According to EU guidance document (European Commission, 2017), an extrapolation from merged currant and blueberry residue data to gooseberries and cranberries is acceptable, resulting in an MRL proposal of 4 mg/kg.

Additionally, in support of the intended **EU indoor use**, the applicant submitted six GAP-compliant indoor trials on black currants (four trials) and blueberries (two trials) which were all performed in Germany from 2016 to 2017, to support the indoor use of fludioxonil on blueberries, currants, gooseberries and cranberries. The number of trials is sufficient to derive an MRL proposal of 4 mg/kg for currants and blueberries. The applicant proposes to combine available residue data on black currants and blueberries and to extrapolate to gooseberries and cranberries. According to the EU guidance document (European Commission, 2017), such an extrapolation is acceptable and is sufficiently supported by residue data. An MRL proposal of 4 mg/kg is thus derived also for gooseberries and cranberries.

All the residue trial samples were analysed for fludioxonil and no information was provided on metabolites containing 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid moiety. Since metabolism of fludioxonil in fruit crops indicates insignificant concentrations of metabolites containing 2,2-difluorobenzo[1,3] dioxole-4 carboxylic acid moiety (see Section 1.1.1), the lack of this information is

not considered a data gap and the default conversion factor of 1 from enforcement to risk assessment is applicable according to the proposal of the MRL review (EFSA, 2011a).

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Germany, 2020).

Summary of residue trials is available in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current application since the crops under assessment are not considered to be rotational crops.

1.2.3. Magnitude of residues in processed commodities

Studies to assess the magnitude of fludioxonil residues in the crops under assessment during processing were not provided for the current application and are not considered necessary, as the consumer exposure to fludioxonil residues resulting from the consumption of the evaluated crops were < 0.1% of the acceptable daily intake (ADI).

1.2.4. Proposed MRLs

EFSA concluded that the submitted data are sufficient to derive an MRL proposal of 4 mg/kg as well as the risk assessment values for blueberries, currants, gooseberries and cranberries in support of the intended NEU outdoor and EU indoor use of fludioxonil (see Appendix B.4). In Section 3, EFSA assessed whether residues on the crops under assessment resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant for the current application since the crop group of berries are not used as livestock feed item.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 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, 2019a).

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 ADI of 0.37 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary (European Commission, 2007).

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required.

Long-term (chronic) dietary risk assessment

For the calculation of the chronic exposure resulting from the residues of fludioxonil in blueberries, gooseberries, currants and cranberries, EFSA used the supervised trials median residue (STMR) value derived from the residue trials on black currants and blueberries from the indoor GAP, which represented the worst case scenario regarding the risk assessment values (see Section B.1.2.1).

The consumer exposure as performed in the recent EFSA reasoned opinion on fludioxonil (EFSA, 2020b) was updated with the STMR values for the crops under assessment. For several commodities the Codex MRLs are implemented in the EU MRL legislation and therefore for these crops, the STMR values derived by the JMPR were taken into account in the risk assessment (FAO, 2012, 2013, 2019). Although for elderberries the MRL as derived in the recent EFSA assessment (EFSA, 2020b) has not yet been taken over into the EU regulation, this crop was considered in the exposure assessment. For animal commodities the input values were the MRLs as implemented in the Commission Regulation (EU) 2020/1633 following the evaluation of the Article 12 confirmatory data (EFSA, 2019d).

The crops on which no EU uses were reported in the framework of the MRL review or in subsequent EFSA reasoned opinions have not been taken into account in the exposure calculation, assuming that these crops are not treated with fludioxonil. The complete list of input values is presented in Appendix D.1.

The calculated long-term exposure accounted for a maximum of 21% of the ADI (NL toddler diet); the individual contributions of residues in blueberries, currants, gooseberries and cranberries to the total consumer exposure were 0.1% of the ADI (See Appendix B.3).

EFSA concluded that the long-term intake of residues of fludioxonil resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

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 for fludioxonil in blueberries, currants, gooseberries and cranberries, as extrapolated from residue trials on black currants and blueberries, in support of the intended NEU outdoor and EU indoor GAP.

EFSA concluded that the proposed use of fludioxonil on the crops under assessment 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.

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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
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
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
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
PF	processing factor
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
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				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Currants (red, black and white), gooseberries (green, red and yellow), blueberries, cranberries	EU	G	*Botrytis cinerea*	WG	250 g/kg	Foliar treatment – broadcast spraying	From BBCH 59	3*	7–10	–	1,000	250	g a.s./ha	7	750 g a.s./ha max seasonal rate
Currants (red, black and white), gooseberries (green, red and yellow), blueberries, cranberries	NEU	F	*Colletotrichum*	WG	250 g/kg	Foliar treatment – broadcast spraying	From BBCH 59	3*	10–14	–	1,000	250	g a.s./ha	7	750 g a.s./ha max seasonal rate

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

*: The GAP for which a higher MRL is needed relates to a maximum of two treatments per season against grey mold (Botrytis cinerea). However, as the plant protection product may be used for the control of further pests on the crops in the same growing season, a maximum number of three treatments have to be taken into account in estimating the corresponding MRLs which are applied for.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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-^{14}C] (EFSA, 2007, 2011a)
		Tomato	Foliar, 3 Cabrera 0.75 kg a.s./ha	0, 40	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2007)
		Peach	Foliar, 3 Cabrera 0.28 kg a.s./ha 3 Cabrera 2.8 kg a.s./ha 2.1 + 6.3 kg a.s./ha	28 28 30, 114	Radiolabelling: [phenyl-U-^{14}C] (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-^{14}C] (EFSA, 2011a)
		Potato	Seed, 2.5 g a.s./100 kg seed	0, 40, 71, 95	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
	Leafy crops	Lettuce	Foliar, 3 Cabrera 0.2 kg a.s./ha 3 × 0.6 kg a.s./ha	0, 6, 13	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
	Cereals/ grass	Rice	Seed, 6.5 g a.s./100 kg seed	0, 38, 76, 152	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
		Wheat	Seed, 3.9- 7.4 g a.s./100 kg seed	48, 83, 106	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
	Pulses/ oilseeds	Cotton	Seed, 2.5 or 5 g a.s./100 kg seed	186	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
		Soybean	Seed, 5 g a.s./100 kg seed	28, 38, 133	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011a)
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-^{14}C] (EFSA, 2007, 2011a)
		Turnips	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
		Radishes	0.062 kg a.s./ha	32, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
			1.117 kg a.s./ha	30, 90, 210	Radiolabelling: [phenyl-^{14}C] (EFSA, 2007, 2011a)
	Leafy crops	Lettuce	0.75 kg a.s./ha	90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
	Pulses and oilseeds	Mustard	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
			0.062 kg a.s./ha	32, 90	
			1.117 kg a.s./ha	30, 90, 210	
	Cereal (small grain)	Winter wheat	0.75 kg a.s./ha	140, 320, 345	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
		Spring wheat	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
			0.062 kg a.s./ha	32, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)
			1.117 kg a.s./ha	30, 90, 210	Radiolabelling: [phenyl-^{14}C] (EFSA, 2007, 2011a)
		Corn	0.75 kg a.s./ha	140, 320, 345	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011a)

Processed commodities (hydrolysis study)	**Conditions**	**Stable?**	**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2007)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2007)
	Sterilisation (20 min, 120°C, pH 6)	Yes	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2007)

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2011a)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2011a)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2011a)
Plant residue definition for monitoring (RD-Mo)	Fludioxonil	
Plant residue definition for risk assessment (RD-RA)	EU pesticides peer review, MRL review (EFSA, 2007, 2011a): Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil Conversion factors (CF) for risk assessment (EFSA, 2011a): Root crops: 2.8 Fruit crops, leafy crops and cereals (soil treatment): 1	
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. QuEChERS method also available for high acid and high water content commodities: HPLC–MS/MS, LOQ of 0.01 mg/kg (EFSA, 2011a).	

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; MRL: maximum residue level; LOQ: limit of quantification; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Tomato, apples, peas	–18	24	Months	Fludioxonil	EFSA (2007)
		Maize forage	–20	24	Months	Fludioxonil	EFSA (2007)
	High oil content	Rapeseed, corn oil	–18	24	Months	Fludioxonil	EFSA (2007)
	Dry/High starch	Cereal grains, maize grains,	–18	24	Months	Fludioxonil	EFSA (2007)
		Potato tubers	–20	24	Months	Fludioxonil	EFSA (2007)
	High acid content	Grapes	< –20	24	Months	Fludioxonil	EFSA (2011a)
	Others	Cereal straw	–16	24	Months	Fludioxonil	EFSA (2007)
		Corn meal	–20	24	Months	Fludioxonil	EFSA (2007)
		Sorghum hay	–20	24	Months	Fludioxonil	EFSA (2007)

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)	CF[d]
Blueberries, currants, gooseberries, and cranberries	NEU	0.15; 0.26[e]; 0.31; 0.31; 0.37; 0.60; 0.62; 0.63[e]; 1.30; 1.40; 1.40[f]; 1.60; 2.00	Residue trials on red and black currants and blueberries compliant with NEU GAP. Extrapolation to gooseberries, and cranberries possible.	4	2	0.62	1
Blueberries, currants, gooseberries, and cranberries	Indoor	0.22[e]; 0.27; 0.92; 0.93; 1.20; 2.20	Residue trials on black currants and blueberries compliant with Indoor GAP. Extrapolation to gooseberries, and cranberries possible.	4	2.2	0.93	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 and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Residues higher at a longer PHI interval of 10 days.
(f): Residues higher at a longer PHI interval of 14 days.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	The occurrence of fludioxonil residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops (EFSA, 2007) For the current assessment, residues in rotational crops are not relevant since the crops under consideration are normally not grown in rotation.
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Not relevant for the current assessment since the crops under consideration are normally not grown in a crop rotation.

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	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	21% ADI (NL toddler) Contribution of crops assessed: Blueberries: < 0.1% of ADI Cranberries: < 0.1% of ADI Gooseberries: < 0.1% of ADI Currants: < 0.1% of ADI
Assumptions made for the calculations	Calculations were performed with PRIMo rev. 3.1. For blueberries, currants, gooseberries and cranberries the median residue value (STMR) as derived from the residue trials on black currants and blueberries from the indoor trials was used as an input value. Additionally, the median residue levels for the crops assessed in the MRL review and in reasoned opinions issued after the MRL review and safe CXLs implemented in the EU legislation were included in the calculation. Although not yet implemented into the EU legislation, for

elderberries the STMR value as derived in recent EFSA assessment (EFSA, 2020b) was used as input value.
For animal commodities, the input values were the MRLs as implemented in the Commission Regulation (EU) 2020/1633 following the evaluation of Article 12 confirmatory data (EFSA, 2019d).
For mangoes and cucurbits with inedible peel, the STMR for pulp (peeled commodity) was used as an input value. The median residue for root crops and certain oilseeds (EFSA, 2020a) was multiplied by the conversion factor for risk assessment of 2.8 derived from metabolism study on spring onions 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; STMR: supervised trials median residue; CXL: codex maximum residue limit; GAP: Good Agricultural Practice.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fludioxonil[(F)]				
0154010	Blueberries	2	4	The submitted data are sufficient to derive an MRL proposal for the intended EU indoor and NEU outdoor use. Risk for consumers unlikely.
0154020	Cranberries	2	4	
0154030	Currants	3	4	
0154040	Gooseberries	2	4	

MRL: maximum residue level; NEU: northern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Fludioxonil (R) (F)

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.37	ARfD (mg/kg bw):	not necessary
Source of ADI:	EC	Source of ARfD:	
Year of evaluation:	2007	Year of evaluation:	

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
21%	NL toddler	77.18	7%	Apples	3%	Oranges	3%	Pears		21%
19%	DE child	70.90	8%	Apples	6%	Oranges	1%	Potatoes		19%
12%	NL child	42.82	4%	Apples	2%	Oranges	1%	Potatoes		12%
11%	IE adult	39.96	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits		11%
9%	FR child 3 15 yr	32.18	5%	Oranges	1%	Apples	0.6%	Potatoes		9%
8%	FR toddler 2 3 yr	29.41	2%	Oranges	2%	Apples	1%	Mandarins		8%
7%	GEMS/Food G11	26.45	2%	Potatoes	1%	Oranges	1.0%	Apples		7%
7%	ES child	26.39	3%	Oranges	0.9%	Lettuces	0.7%	Potatoes		7%
7%	SE general	25.93	2%	Potatoes	1%	Oranges	0.9%	Lettuces		7%
7%	GEMS/Food G07	25.84	2%	Oranges	2%	Potatoes	0.6%	Apples		7%
7%	UK toddler	25.60	3%	Oranges	1%	Potatoes	1%	Apples		7%
7%	DE women 14-50 yr	25.28	3%	Oranges	2%	Apples	0.4%	Potatoes		7%
6%	GEMS/Food G10	23.75	2%	Oranges	1%	Potatoes	0.7%	Lettuces		6%
6%	DE general	22.57	2%	Oranges	2%	Apples	0.5%	Potatoes		6%
6%	GEMS/Food G08	21.89	2%	Potatoes	0.8%	Apples	0.7%	Oranges		6%
6%	GEMS/Food G06	21.66	1%	Oranges	0.8%	Potatoes	0.6%	Tomatoes		6%
6%	UK infant	20.89	2%	Oranges	1%	Potatoes	1.0%	Apples		6%
5%	PT general	20.29	2%	Potatoes	0.9%	Oranges	0.7%	Apples		5%
5%	ES adult	20.22	2%	Oranges	1%	Lettuces	0.5%	Apples		5%
5%	GEMS/Food G15	19.39	1%	Potatoes	1.0%	Oranges	0.7%	Apples		5%
5%	NL general	18.94	1%	Oranges	1.0%	Potatoes	0.9%	Apples		5%
5%	DK child	17.79	1%	Apples	1.0%	Potatoes	0.4%	Carrots		5%
5%	FI 3 yr	17.06	2%	Potatoes	0.6%	Apples	0.6%	Mandarins		5%
4%	RO general	15.97	2%	Potatoes	0.9%	Apples	0.4%	Oranges		4%
4%	IT toddler	15.77	0.7%	Oranges	0.7%	Lettuces	0.6%	Apples		4%
4%	IT adult	15.24	0.8%	Lettuces	0.5%	Oranges	0.5%	Apples		4%
4%	FI 6 yr	14.17	2%	Potatoes	0.5%	Mandarins	0.4%	Apples		4%
4%	FR infant	14.16	1%	Apples	0.8%	Potatoes	0.4%	Spinaches		4%
4%	PL general	13.56	1%	Potatoes	1%	Apples	0.2%	Pears		4%
3%	UK vegetarian	12.46	1%	Oranges	0.6%	Potatoes	0.4%	Apples		3%
3%	LT adult	11.70	1%	Potatoes	1%	Apples	0.1%	Lettuces		3%
3%	FR adult	11.39	0.8%	Oranges	0.5%	Apples	0.3%	Potatoes		3%
3%	DK adult	9.59	0.6%	Apples	0.5%	Potatoes	0.2%	Oranges		3%
3%	UK adult	9.58	0.8%	Oranges	0.6%	Potatoes	0.3%	Lettuces		3%
2%	FI adult	9.06	0.6%	Oranges	0.5%	Potatoes	0.4%	Apples		2%
0.8%	IE child	3.04	0.2%	Potatoes	0.2%	Apples	0.1%	Oranges		0.8%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fludioxonil (R) (F) is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details –acute risk assessment/children	Details –acute risk assessment/adults

As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
Expand/collapse list							

Conclusion:

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Chronic risk assessment			Acute risk assessment	
		Source	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil.						
Blueberries	4	Intended indoor use	0.93	STMR	Acute risk assessments not relevant	
Cranberries	4	Intended indoor use	0.93	STMR		
Currants (red, black and white)	4	Intended indoor use	0.93	STMR		
Gooseberries (green, red and yellow)	4	Intended indoor use	0.93	STMR		
Citrus fruits	10	(EFSA, 2011a)	5.3	STMR		
Pistachios	0.2	(EFSA, 2011a)	0.06	STMR		
Pome fruits	5	(EFSA, 2011a)	2.3	STMR		
Apricots	5	(EFSA, 2011a)	1.06	STMR		
Cherries (sweet)	5	(EFSA, 2011a)	0.8	STMR		
Peaches	10	(EFSA, 2011a)	3.65	STMR		
Plums	5	(EFSA, 2011a)	1.06	STMR		
Table grapes	5	(EFSA, 2011a)	0.38	STMR		
Wine grapes	4	(EFSA, 2011a)	0.33	STMR		
Strawberries	4	(EFSA, 2019d)	0.31	STMR		
Blackberries	5	(EFSA, 2011a)	1	STMR		
Dewberries	5	(EFSA, 2011a)	1	STMR		
Raspberries (red and yellow)	5	(EFSA, 2011a)	1	STMR		
Other cane fruit	5	(EFSA, 2011a)	1	STMR		
Elderberries	4[(a)]	(EFSA, 2020b)	0.62	STMR		
Kiwi fruits (green, red, yellow)	15	(EFSA, 2011a)	7.3	STMR		
Avocados	1.5	(FAO, 2019)	0.45	STMR (Whole fruit)		
Mangoes	2	(FAO, 2012)	0.02	STMR		
Granate apples/ pomegranates	3	(EFSA, 2011a)	0.95	STMR		
Guavas	0.5	(FAO, 2019)	0.125	STMR		
Pineapples	7	(EFSA, 2016a)	2.14	STMR		
Potatoes	5	(FAO, 2013)	1.5	STMR		
Sweet potatoes	10	(EFSA, 2011a)	3.76	STMR		
Yams	10	(EFSA, 2011a)	3.76	STMR		
Beetroots	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		
Carrots	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		
Celeriacs/turnip rooted celeries	0.2	(EFSA, 2011a)	0.196	STMR (0.07) × CF (2.8)		
Horseradishes	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		

Commodity	Existing/ Proposed MRL (mg/kg)	Chronic risk assessment			Acute risk assessment	
		Source	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Parsnips	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		
Parsley roots/ Hamburg roots parsley	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		
Radishes	0.3	(EFSA, 2013)	0.098	STMR (0.035) × CF (2.8)		
Salsifies	1	(EFSA, 2011a)	1.148	STMR (0.410) × CF (2.8)		
Garlic	0.5	(EFSA, 2011a)	0.112	STMR (0.02) × CF (2.8)		
Onions	0.5	(EFSA, 2011a)	0.112	STMR (0.02) × CF (2.8)		
Shallots	0.5	(EFSA, 2011a)	0.112	STMR (0.02) × CF (2.8)		
Spring onions/ green onions and Welsh onions	5	(EFSA, 2011a)	0.532	STMR (0.19) × CF (2.8)		
Tomatoes	3	(EFSA, 2013)	0.66	STMR		
Sweet peppers/ bell peppers	1	(EFSA, 2011a)	0.21	STMR		
Aubergines/egg plants	0.4	(EFSA, 2011a)	0.12	STMR		
Cucumbers	0.4	(EFSA, 2011a)	0.1	STMR		
Gherkins	0.4	(EFSA, 2011a)	0.1	STMR		
Courgettes	0.4	(EFSA, 2011a)	0.1	STMR		
Other cucurbits - edible peel	0.4	(EFSA, 2011a)	0.1	STMR		
Melons	0.3	(EFSA, 2013)	0.01	STMR edible portion		
Pumpkins	0.3	(EFSA, 2013)	0.01	STMR edible portion		
Watermelons	0.3	(EFSA, 2013)	0.01	STMR edible portion		
Other cucurbits - inedible peel	0.3	(EFSA, 2013)	0.01	STMR edible portion		
Sweet corn	0.01*	(EFSA, 2011a)	0.01	STMR		
Broccoli	0.7	(EFSA, 2011a)	0.23	STMR		
Head cabbages	2	(EFSA, 2011a)	0.24	STMR		
Chinese cabbages/pe-tsai	10	(EFSA, 2011a)	1.2	STMR		
Lamb's lettuce/ corn salads	20	(EFSA, 2016b)	6.13	STMR		
Lettuces	40	(FAO, 2013)	8.3	STMR		
Escaroles/broad-leaved endives	20	(EFSA, 2016b)	6.13	STMR		
Cress and other sprouts and shoots	20	(EFSA, 2016b)	6.13	STMR		
Land cress	20	(EFSA, 2016b)	6.13	STMR		
Roman rocket/ rucola	20	(EFSA, 2016b)	6.13	STMR		

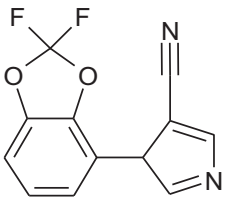
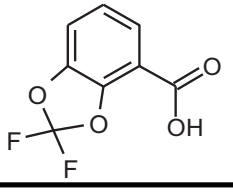
Commodity	Existing/ Proposed MRL (mg/kg)	Chronic risk assessment			Acute risk assessment	
		Source	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Red mustards	20	(EFSA, 2016b)	6.13	STMR		
Baby leaf crops (including brassica species)	20	(EFSA, 2016b)	6.13	STMR		
Other lettuce and other salad plants	20	(EFSA, 2016b)	6.13	STMR		
Spinaches	30	(FAO, 2013)	5.8	STMR		
Purslanes	20	(EFSA, 2016b)	6.13	STMR		
Chards/beet leaves	20	(EFSA, 2016b)	6.13	STMR		
Other spinach and similar	20	(EFSA, 2016b)	6.13	STMR		
Chervil	20	(EFSA, 2016b)	6.13	STMR		
Chives	20	(EFSA, 2016b)	6.13	STMR		
Celery leaves	20	(EFSA, 2016b)	6.13	STMR		
Parsley	20	(EFSA, 2016b)	6.13	STMR		
Sage	20	(EFSA, 2016b)	6.13	STMR		
Rosemary	20	(EFSA, 2016b)	6.13	STMR		
Thyme	20	(EFSA, 2016b)	6.13	STMR		
Basil and edible flowers	20	(EFSA, 2016b)	6.13	STMR		
Laurel/bay leaves	20	(EFSA, 2016b)	6.13	STMR		
Tarragon	20	(EFSA, 2016b)	6.13	STMR		
Other herbs	20	(EFSA, 2016b)	6.13	STMR		
Beans (with pods)	1	(EFSA, 2011a)	0.48	STMR		
Beans (without pods)	0.4	(EFSA, 2016b)	0.02	STMR		
Peas (with pods)	1	(EFSA, 2011a)	0.48	STMR		
Peas (without pods)	0.3	(EFSA, 2016b)	0.04	STMR		
Lentils (fresh)	0.05	(EFSA, 2011a)	0.02	STMR		
Asparagus	0.01*	(EFSA, 2011a)	0.01	STMR		
Celeries	1.5	(EFSA, 2012)	0.32	STMR		
Florence fennels	1.5	(EFSA, 2019b,d, 2020a,b)	0.32	STMR		
Rhubarbs	0.7	(EFSA, 2019e)	0.23	STMR		
Beans	0.5	(FAO, 2013)	0.04	STMR		
Lentils	0.4	(EFSA, 2011a)	0.02	STMR		
Peas	0.4	(EFSA, 2011a)	0.02	STMR		
Lupins/lupini beans	0.4	(EFSA, 2011a)	0.02	STMR		
Other pulses	0.4	(EFSA, 2011a)	0.02	STMR		
Linseeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Peanuts/ groundnuts	0.01*	(EFSA, 2011a)	0.01	STMR		
Poppy seeds	0.01*	(EFSA, 2011a)	0.01	STMR		

Commodity	Existing/ Proposed MRL (mg/kg)	Chronic risk assessment			Acute risk assessment	
		Source	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Sesame seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Sunflower seeds	0.01*	(EFSA, 2011a)	0.01	STMR		
Rapeseeds/canola seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Soyabeans	0.2	(EFSA, 2011a)	0.01	STMR		
Mustard seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Cotton seeds	0.01*	(EFSA, 2011a)	0.02	STMR		
Pumpkin seeds	0.01*	(EFSA, 2011a)	0.01	STMR		
Safflower seeds	0.01*	(EFSA, 2011a)	0.01	STMR		
Borage seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Gold of pleasure seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Hemp seeds	0.3	(EFSA, 2019d)	0.028	STMR (0.01) × CF (2.8)		
Castor beans	0.01*	(EFSA, 2011a)	0.01	STMR		
Other oilseeds	0.01*	(EFSA, 2011a)	0.01	STMR		
Barley	0.01*	(EFSA, 2011a)	0.01	STMR		
Buckwheat and other pseudo-cereals	0.01*	(EFSA, 2011a)	0.01	STMR		
Maize/corn	0.01*	(EFSA, 2011a)	0.01	STMR		
Common millet/ proso millet	0.01*	(EFSA, 2011a)	0.01	STMR		
Oat	0.01*	(EFSA, 2011a)	0.01	STMR		
Rice	0.01*	(EFSA, 2011a)	0.01	STMR		
Rye	0.01*	(EFSA, 2011a)	0.01	STMR		
Sorghum	0.01*	(EFSA, 2011a)	0.01	STMR		
Wheat	0.01*	(EFSA, 2011a)	0.01	STMR		
Other cereals	0.01*	(EFSA, 2011a)	0.01	STMR		
Ginseng root	4	(FAO, 2013)	0.8	STMR (0.286) × CF (2.8)		
Sugar beet roots	0.01*	(EFSA, 2011a)	0.01	STMR		
Swine: Muscle/ meat	0.02	(EFSA, 2019d)	0.02	MRL		
Swine: Fat tissue	0.02	(EFSA, 2019d)	0.02	MRL		
Swine: Liver	0.1	(EFSA, 2019d)	0.1	MRL		
Swine: Kidney	0.1	(EFSA, 2019d)	0.1	MRL		
Swine: Edible offals (other than liver and kidney)	0.1	(EFSA, 2019d)	0.1	MRL		
Bovine, sheep, goat, equine: Muscle/meat	0.02	(EFSA, 2019d)	0.02	MRL		
Bovine, sheep, goat, equine: Fat tissue	0.02	(EFSA, 2019d)	0.02	MRL		

Commodity	Existing/ Proposed MRL (mg/kg)	Chronic risk assessment			Acute risk assessment	
		Source	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Bovine, sheep, goat, equine: Liver	0.1	(EFSA, 2019d)	0.1	MRL		
Bovine, sheep, goat, equine: Kidney	0.1	(EFSA, 2019d)	0.1	MRL		
Bovine sheep, goat, equine: Edible offals (other than liver and kidney)	0.1	(EFSA, 2019d)	0.1	MRL		
Poultry: Muscle/ meat	0.01*	(EFSA, 2019d)	0.01*	MRL		
Poultry: Fat tissue	0.01*	(EFSA, 2019d)	0.01*	MRL		
Poultry: Liver	0.1	(EFSA, 2019d)	0.1	MRL		
Poultry: Kidney	0.1	(EFSA, 2019d)	0.1	MRL		
Poultry: Edible offals (other than liver and kidney)	0.1	(EFSA, 2019d)	0.1	MRL		
Milk: Cattle, sheep, goat, horse, others	0.04	(EFSA, 2019d)	0.04	MRL		
Eggs: Chicken, duck, goose, quail, others	0.02	(EFSA, 2019d)	0.02	MRL		

STMR: supervised trials median residue; CF: conversion factor.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): MRL not yet taken over in the EU MRL legislation (EFSA, 2020b).

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
Fludioxonil CGA 173506	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile N#Cc1c[NH]cc1c1cccc2OC(F)(F)Oc12 MUJOIMFVNIBMKC-UHFFFAOYSA-N	
CGA 192155	2,2-difluoro-2*H*-1,3-benzodioxole-4-carboxylic acid O=C(O)c1cccc2OC(F)(F)Oc12 ZGAQVJDFFVTWJK-WXRBYKJCNA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(b): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).