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Modification of the existing maximum residue levels for fludioxonil in rhubarbs

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) 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.

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

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) 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[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fludioxonil[(F)]				
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

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

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for 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)-1*H*-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/EEC[1] 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 approved[2] 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 396/2005[3]. 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 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997c–g, 2000, 2010a,b, 2017; OECD, 2007, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

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 trails 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 3 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.

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Abbreviations

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[a]	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			Unit	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			
Rhubarbs	NEU	F	*Botrytis cinerea*	WG	25 (% w/w)	Foliar spray	–	1–2	10	–	200–800	0.25	kg a.i./ha	14	Treatment as soon as the first symptoms are observed The formulation contains 25% fludioxonil 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-^{14}C] (EFSA, 2007, 2011)
		Tomato	Foliar, 3 × 0.75 kg a.s./ha	0, 40	Radiolabelling: [pyrrole-4-^{14}C] (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-^{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, 2011)
		Potato	Seed, 2.5 g a.s./100 kg seed	0, 40, 71, 95	Radiolabelling: [pyrrole-4-^{14}C] (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-^{14}C] (EFSA, 2011)
	Cereals/ grass	Rice	Seed, 6.5 g a.s./100 kg seed	0, 38, 76, 152	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011)
		Wheat	Seed, 3.9- 7.4 g a.s./100 kg seed	48, 83, 106	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011)
	Pulses/ oilseeds	Cotton	Seed, 2.5 or 5 g a.s./100 kg seed	186	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011)
		Soybean	Seed, 5 g a.s./100 kg seed	28, 38, 133	Radiolabelling: [pyrrole-4-^{14}C] (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-^{14}C] (EFSA, 2007, 2011)
		Turnips	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
		Radishes	0.062 kg a.s./ha	32, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
			1.117 kg a.s./ha	30, 90, 210	Radiolabelling: [phenyl-^{14}C] (EFSA, 2007, 2011)
	Leafy crops	Lettuce	0.75 kg a.s./ha	90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
	Pulses and oilseeds	Mustard	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
			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, 2011)
		Spring wheat	0.124 kg a.s./ha	33, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
			0.062 kg a.s./ha	32, 90	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)
			1.117 kg a.s./ha	30, 90, 210	Radiolabelling: [phenyl-^{14}C] (EFSA, 2007, 2011)
		Corn	0.75 kg a.s./ha	140, 320, 345	Radiolabelling: [pyrrole-^{14}C] (EFSA, 2007, 2011)

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Radiolabeling: [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, 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.1.1.2. 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 (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,	−16	24	Months	Fludioxonil	EFSA (2011)
		Corn meal	−20	24	Months	Fludioxonil	EFSA (2011)
		Sorghum hay	−20	24	Months	Fludioxonil	EFSA (2011)

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[e]
Rhubarbs	NEU	0.074; 0.15[d]; 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-difluoro-benzo[1,3]dioxole-4-carboxylic moiety were identified (EFSA, 2011).

B.1.2.2. Residues in rotational crops

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

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[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fludioxonil[(F)]				
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

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)

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Fludioxonil (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:		Source of ARfD:	
Year of evaluation:		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 : ---

	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	20%	NL toddler	75.67	7%	Apples	3%	Oranges	3%	Pears		
	19%	DE child	70.41	8%	Apples	6%	Oranges	1%	Potatoes		
	11%	NL child	42.11	4%	Apples	2%	Oranges	1%	Potatoes		
	11%	IE adult	39.74	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits		
	9%	FR child 3 15 yr	31.69	5%	Oranges	1%	Apples	0.6%	Potatoes		
	8%	FR toddler 2 3 yr	28.79	2%	Oranges	2%	Apples	1%	Mandarins		
	7%	GEMS/Food G11	26.24	2%	Potatoes	1%	Oranges	1.0%	Apples		
	7%	ES child	26.11	3%	Oranges	0.9%	Lettuces	0.7%	Potatoes		
	7%	SE general	25.59	2%	Potatoes	1%	Oranges	0.9%	Lettuces		
	7%	GEMS/Food G07	25.56	2%	Oranges	2%	Potatoes	0.6%	Apples		
	7%	UK toddler	25.11	3%	Oranges	1%	Potatoes	1%	Apples		
	7%	DE women 14-50 yr	24.97	3%	Oranges	2%	Apples	0.4%	Potatoes		
	6%	GEMS/Food G10	23.54	2%	Oranges	1%	Potatoes	0.7%	Lettuces		
	6%	DE general	22.27	2%	Oranges	2%	Apples	0.5%	Potatoes		
	6%	GEMS/Food G08	21.65	2%	Potatoes	0.8%	Apples	0.7%	Oranges		
	6%	GEMS/Food G06	21.54	1%	Oranges	0.8%	Potatoes	0.6%	Tomatoes		
	5%	PT general	20.27	2%	Potatoes	0.9%	Oranges	0.7%	Apples		
	5%	ES adult	20.09	2%	Oranges	1%	Lettuces	0.5%	Apples		
	5%	UK infant	20.07	2%	Oranges	1%	Potatoes	1.0%	Apples		
	5%	GEMS/Food G15	19.16	1%	Potatoes	1.0%	Oranges	0.7%	Apples		
	5%	NL general	18.71	1%	Oranges	1.0%	Potatoes	0.9%	Apples		
	5%	DK child	17.49	1%	Apples	1.0%	Potatoes	0.4%	Carrots		
	5%	FI 3 yr	16.99	2%	Potatoes	0.6%	Apples	0.6%	Mandarins		
	4%	IT toddler	15.75	0.7%	Oranges	0.7%	Lettuces	0.6%	Apples		
	4%	RO general	15.69	2%	Potatoes	0.9%	Apples	0.4%	Oranges		
	4%	IT adult	15.23	0.8%	Lettuces	0.5%	Oranges	0.5%	Apples		
	4%	FI 6 yr	14.13	2%	Potatoes	0.5%	Mandarins	0.4%	Apples		
	4%	FR infant	13.81	1%	Apples	0.8%	Potatoes	0.4%	Spinaches		
	4%	PL general	13.51	1%	Potatoes	1%	Apples	0.2%	Pears		
	3%	UK vegetarian	12.37	1%	Oranges	0.6%	Potatoes	0.4%	Apples		
	3%	LT adult	11.60	1%	Potatoes	1%	Apples	0.1%	Lettuces		
	3%	FR adult	11.27	0.8%	Oranges	0.5%	Apples	0.3%	Potatoes		
	3%	UK adult	9.50	0.8%	Oranges	0.6%	Potatoes	0.3%	Lettuces		
	3%	DK adult	9.45	0.6%	Apples	0.5%	Potatoes	0.2%	Oranges		
	2%	FI adult	9.03	0.6%	Oranges	0.5%	Potatoes	0.4%	Apples		
	0.8%	IE child	2.95	0.2%	Potatoes	0.2%	Apples	0.1%	Oranges		

Conclusion:

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.

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 of IESTI calculation only for crops with GAPs under assessment

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

Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[1]	
				Input value (mg/kg)	Comment
110010	Grapefruits	10	Existing EU MRL	5.3	STMR-RAC
110020	Oranges	10	Existing EU MRL	5.3	STMR-RAC
110030	Lemons	10	Existing EU MRL	5.3	STMR-RAC
110040	Limes	10	Existing EU MRL	5.3	STMR-RAC
110050	Mandarins	10	Existing EU MRL	5.3	STMR-RAC
110990	Other citrus fruit	10	Existing EU MRL	5.3	STMR-RAC
120100	Pistachios	0.2	Existing EU MRL	0.06	STMR-RAC
130010	Apples	5	Existing EU MRL	2.3	STMR-RAC
130020	Pears	5	Existing EU MRL	2.3	STMR-RAC
130030	Quinces	5	Existing EU MRL	2.3	STMR-RAC
130040	Medlar	5	Existing EU MRL	2.3	STMR-RAC
130050	Loquats/Japanese medlars	5	Existing EU MRL	2.3	STMR-RAC
140010	Apricots	5	Existing EU MRL	1.06	STMR-RAC
140020	Cherries (sweet)	5	Existing EU MRL	0.8	STMR-RAC
140030	Peaches	10	Existing EU MRL	3.65	STMR-RAC
140040	Plums	5	Existing EU MRL	1.06	STMR-RAC
151010	Table grapes	5	Existing EU MRL	0.38	STMR-RAC
151020	Wine grapes	4	Existing EU MRL	0.33	STMR-RAC
152000	Strawberries	4	EFSA (2019b)	0.31	STMR-RAC
153010	Blackberries	5	Existing EU MRL	1	STMR-RAC
153020	Dewberries	5	Existing EU MRL	1	STMR-RAC
153030	Raspberries (red and yellow)	5	Existing EU MRL	1	STMR-RAC
153990	Other cane fruit	5	Existing EU MRL	1	STMR-RAC
154010	Blueberries	2	Existing EU MRL	0.37	STMR-RAC
154020	Cranberries	2	Existing EU MRL	0.37	STMR-RAC
154030	Currants (red, black and white)	2	Existing EU MRL	0.37	STMR-RAC
154040	Gooseberries (green, red and yellow)	2	Existing EU MRL	0.37	STMR-RAC
154080	Elderberries	0.8	Existing EU MRL	0.24	STMR-RAC
162010	Kiwi fruits (green, red, yellow)	15	Existing EU MRL	7.3	STMR-RAC
163010	Avocados	0.4	Existing EU MRL	0.05	STMR-RAC
163030	Mangoes	2	Existing EU MRL	0.02	STMR-RAC
163050	Granate apples/pomegranates	3	Existing EU MRL	0.95	STMR-RAC
163080	Pineapples	7	Existing EU MRL	2.14	STMR-RAC
211000	Potatoes	5	Existing EU MRL	1.5	STMR-RAC
212020	Sweet potatoes	10	Existing EU MRL	3.76	STMR-RAC
212030	Yams	10	Existing EU MRL	3.76	STMR-RAC
213010	Beetroots	1	Existing EU MRL	1.148	STMR-RAC*CF
213020	Carrots	1	Existing EU MRL	1.148	STMR-RAC*CF
213030	Celeriacs/turnip rooted celeries	0.2	Existing EU MRL	0.196	STMR-RAC*CF
213040	Horseradishes	1	Existing EU MRL	1.148	STMR-RAC*CF
213060	Parsnips	1	Existing EU MRL	1.148	STMR-RAC*CF
213070	Parsley roots/Hamburg roots parsley	1	Existing EU MRL	1.148	STMR-RAC*CF
213080	Radishes	0.3	Existing EU MRL	0.098	STMR-RAC*CF
213090	Salsifies	1	Existing EU MRL	1.148	STMR-RAC*CF
220010	Garlic	0.02	Existing EU MRL	0.056	STMR-RAC*CF

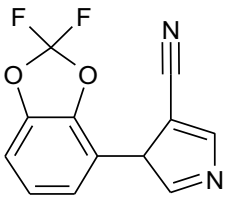
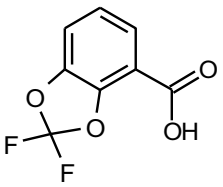
Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[1]	
				Input value (mg/kg)	Comment
220020	Onions	0.5	Existing EU MRL	0.056	STMR-RAC*CF
220030	Shallots	0.02	Existing EU MRL	0.056	STMR-RAC*CF
220040	Spring onions/green onions and Welsh onions	5	Existing EU MRL	0.532	STMR-RAC*CF
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	Existing EU MRL	0.32	STMR-RAC
270070	Rhubarbs	0.70	Proposed MRL	0.23	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
300990	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 CGA 173506	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile N#Cc1c[NH]cc1c1cccc2OC(F)(F)Oc12 MUJOIMFVNIBMKC-UHFFFAOYSA-N	
CGA 192155	2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid O=C(O)c1cccc2OC(F)(F)Oc12 ZGAQVJDFFVTWJK-UHFFFAOYSA-N	

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).