REASONED OPINION

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Modification of the existing maximum residue level for fludioxonil in Florence fennels

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

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Belgium Federal Public Service for Health, Food chain safety and Environment (Belgium FPS Health) submitted a request to modify the existing maximum residue level (MRL) for the active substance fludioxonil in Florence fennels. The data submitted in support of the request were found to be sufficient to derive an MRL proposal of 1.5 mg/kg for Florence fennels. Adequate analytical methods for enforcement are available to control the residues of fludioxonil on the commodity 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, the Federal Public Service of Belgium, (FPS) Health, Food chain safety and Environment submitted an application to modify the existing maximum residue level (MRL) for the active substance fludioxonil in fennel. The FPS Health (acting as evaluating Member State (EMS)) drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 11 July 2018. To accommodate for the intended use of fludioxonil, the EMS proposed to raise the existing MRL from 0.05 mg/kg to 1.5 mg/kg.

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

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

The metabolism of fludioxonil following foliar and or seed applications was investigated in crops belonging to the groups of fruit crops, root crops, leafy crops, pulses and oilseeds, and cereals.

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 the crops assessed in this application, 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 applicable.

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 Florence fennels (limit of quantification (LOQ)).

The available residue trials are sufficient to derive a MRL proposal of 1.5 mg/kg for Florence fennels.

Specific studies investigating the magnitude of fludioxonil residues in processed commodities are not required considering the low contribution of residues in Florence fennels to the total calculated 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 resulting from the intended use of fludioxonil in Florence fennels, the supervised trials median residue (STMR) values derived from the residue trials on celery, and for other crops based on earlier reasoned opinions were used. 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.

The long-term exposure accounted for 20% of the ADI (NL toddler); the contribution of Florence fennels was low (maximum 0.1% of the ADI).

An acute exposure calculation was not required since for the active substances no ARfD has been derived due to its low acute toxicity.

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

The peer review 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 should be taken as provisional and 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.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Fludioxanil[(F)]				
0270040	Florence fennels	0.05	1.5	The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely

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

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Assessment

The European Food Safety Authority (EFSA) received a request to assess the application to modify the existing maximum residue level (MRL) for fludioxonil in Florence fennels. The detailed description of the intended use of fludioxonil 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) for representative uses as 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 fungicide on 1 November 2008. In accordance with Commission Implementing Regulation (EU) No 540/2011[3] fludioxonil is approved under Regulation (EC) No 1107/2009[4], repealing Council Directive 91/414/EEC.

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[5]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the MRLs have been modified, taking into account the proposals derived by EFSA. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for fludioxonil, which have been considered in recent MRL regulations.[6]

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service of Belgium, (FPS) Health, Food chain safety and Environment submitted an application to modify the existing MRL for the active substance fludioxonil in Florence fennel. The FPS Health (acting as evaluating Member State (EMS)) drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 July 2018. To accommodate for the intended use of fludioxonil, the EMS proposed to raise the existing MRL from 0.05 mg/kg to 1.5 mg/kg.

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 (Belgium, 2018), 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), as well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2012, 2013, 2016a,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[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].

[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] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[5] 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.

[6] 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

[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.

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

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

The evaluation report submitted by the EMS (Belgium, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) 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 was evaluated in the framework of the peer review under Directive 91/414/EEC and in the framework of the MRL review (EFSA, 2007, 2011). Metabolism studies with foliar application on fruit crops (grape, peach and tomato), leafy crops (lettuce) and root crops (spring onions) as well as for seed treatment on root crops (potato), pulses and oilseeds (soybeans, cotton) and cereals (wheat, rice) are available.

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, a large number of metabolites are formed, individually occurring at low levels (each < 10% of TRR). The metabolic pattern was considered as qualitatively similar in all crop groups investigated. 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 considered to be similar in all crops. (EFSA, 2007, 2011).

1.1.2. Nature of residues in rotational crops

Florence fennels can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use of the active substance on primary crops had to be assessed. According to the soil degradation studies evaluated in the framework of the peer review, the highest DT_{90} value of fludioxonil exceeds the trigger value of 100 days (EFSA, 2007).

Residues in rotational crops were investigated in the framework of the peer review under Directive 91/414/EEC and in the framework of the MRL review (EFSA, 2007, 2011). Uptake of the parent fludioxonil in rotational leafy vegetables (lettuce, mustard), root and tuber vegetables (sugar beet, turnip, radish), cereals (wheat, maize) following bare soil applications was investigated in four studies with plant back intervals ranging from 30 to 345 days. It was concluded that the metabolic pathway of fludioxonil in rotational crops is similar to that in primary crops.

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 with an limit of quantification (LOQ) of 0.01 mg/kg in high water-, high acid-, high oil content and in dry commodities (EFSA, 2007, 2011).

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

1.1.5. Stability of residues in plants

Fludioxonil was demonstrated to be stable upon storage at $\leq -18°C$ 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 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' for risk assessment.

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

For the use on Florence fennels, EFSA concludes that the residue definitions for enforcement and risk assessment agreed in the peer review and in the MRL review are applicable. If residue definitions will be modified in the framework of the renewal of the approval, the MRL proposal derived in this opinion as well as the risk assessment need to be reconsidered.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended northern Europe (NEU) outdoor use of fludioxonil on Florence fennels, the applicant referred to residue trials on celery which were submitted to EFSA by the EMS France and subsequently assessed in the reasoned opinion on the setting of MRLs for fludioxonil in celery (EFSA, 2012; France 2012). The applicant proposes to extrapolate the residue data from celery to Florence fennels.

In the previous assessment, in total, four NEU residue trials on celery, compliant with the intended NEU good agricultural practice (GAP) on Florence fennels, were available and assessed by EFSA. The residue trails performed in France in 2005, 2009 and 2010 analysing for the parent compound only, were compliant with the intended Belgian GAP. 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 residues for the risk assessment residue definition (EFSA, 2012).

An MRL proposal of 1.5 mg/kg was derived for the northern EU GAP. The proposed extrapolation of residue data from celery to Florence fennels is acceptable according to the EU guidance documents (European Commission, 2017).

Residue trial data were considered valid both with regard to analytical part and the storage stability (EFSA, 2012).

EFSA concludes that an MRL of 1.5 mg/kg for fludioxonil in Florence fennels would be required in support of the intended GAP in Belgium.

1.2.2. Magnitude of residues in rotational crops

During the peer review, a rotational crop study with non-radiolabelled fludioxonil was submitted. After treatment of bare soil with 0.62–1.12 kg/ha, lettuce (leafy vegetables), sugar beets (root and tuber vegetables), winter wheat and corn (cereals) were planted at plant-back intervals of 30, 90 and $>$ 140 days. The application rate was 2.26 times the seasonal application rate intended in Florence fennels. Residues of parent fludioxonil and its metabolites oxidised to CGA 192155 were analysed in the harvested samples. Based on this study, it was concluded that residues exceeding 0.01 mg/kg are not expected in rotational crops sown 30 days after a total of four applications at 282 g a.s./kg on bare soil (EFSA, 2007).

Since the application rate requested in the framework of this MRL application is lower than the dose rates investigated in the rotational crop studies, EFSA concluded that fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP.

1.2.3. Magnitude of residues in processed commodities

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

1.2.4. Proposed MRLs

The submitted data are sufficient to propose an MRL of 1.5 mg/kg for fludioxonil in Florence fennels in support of the intended GAP in Belgium.

2. Residues in livestock

Florence fennels or its by-products are not used as livestock feed items and therefore the assessment of the nature and magnitude of fludioxonil in livestock was not undertaken in the framework of this application.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2018).

For the calculation of the chronic exposure resulting from the intended use of fludioxonil in Florence fennels, 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); 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 Florence fennels was low (maximum 0.1% of the ADI).

An acute exposure calculation was not required since for the active substance no acute reference dose (ARfD) has been derived due to its low acute toxicity.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for Florence fennels.

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

The MRL recommendation is 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
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
FPS	Federal Public Service of Belgium
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
Mo	monitoring
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
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
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		
Florence fennels (0270040)	BE NEU	F	*Botrytis cinerea*, *Sclerotinia sclerotiorum*	WG	250 g/kg	Spray	14–49	2	10–14	–	–	250	g a.s./ha	14	Extrapolation from celeries (0270030) to Florence fennel (0270040)

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

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

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

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

(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/Source
	Fruit crops	Grape	Foliar, 3 × 0.5 kg a.s./ha	0, 14, 35 (maturity)	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011)
		Tomato	Foliar, 3 × 0.75 kg a.s./ha	0, 40	Radiolabelling: [pyrrole-4-^{14}C] (EFSA, 2011)
		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, 2011)
	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	EFSA (2011)
		Turnips	0.124 kg a.s./ha	33, 90	EFSA (2011)
		Radishes	0.062 kg a.s./ha	32, 90	EFSA (2011)
	Leafy crops	Lettuce	0.75 kg a.s./ha	90	EFSA (2011)
	Pulses and oilseeds	Mustard	0.124 kg a.s./ha	33, 90	EFSA (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	EFSA (2011)
		Spring wheat	0.124 kg a.s./ha	32, 90	EFSA (2011)
			0.062 kg a.s./ha	33, 90	
			1.117 kg a.s./ha	30, 90, 210	
		Corn	0.75 kg a.s./ha	140, 320, 345	EFSA (2011)

Processed commodities (hydrolysis study)	Conditions	Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)	Yes	Denmark (2005)
	Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes	Denmark (2005)
	Sterilisation (20 min, 120°C, pH 6)	Yes	Denmark (2005)

Can a general residue definition be proposed for primary crops?	yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
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; PBI: plant-back interval; a.s.: active substance; 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, fresh peas, maize forage	−18	24	Months	Fludioxonil	Denmark (2005)
	High oil content	Rapeseed, corn oil	−18	24	Months	Fludioxonil	Denmark (2005)
	Dry/High starch	Cereal grains, maize grains, potato tubers	−18	24	Months	Fludioxonil	Denmark (2005)
	High acid content	Grapes	−18	28	Months	Fludioxonil	Denmark (2005)
	Others	Cereal straw,	−18	24	Months	Fludioxonil	Denmark (2005)
		Corn meal	−18	26	Months	Fludioxonil	Denmark (2005)
		Sorghum hay	−18	24	Months	Fludioxonil	Denmark (2005)

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)
Florence fennels	NEU	**Mo = RA:** 0.074; 0.31; 0.32; 0.62[(d)]	Residue trials on celery compliant with GAP. Extrapolation to fennel possible	**1.5**	**0.62**	**0.32**

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification.
(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 according to the residue definition.
(d): Separate analyses for leaves and stalks, value for celery stems derived by calculation.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Based on four metabolism studies fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Based on the rotational crop study (bare soil: 2.26N) fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP

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

Acute risk assessment not relevant since no ARfD has been considered necessary (EFSA, 2007).

ADI	0.37 mg/kg bw per day (EFSA, 2007)
Highest IEDI, according to EFSA PRIMo	20% ADI (NL toddler) Contribution of crops assessed: Florence fennels: 0.01% of ADI (IT adult)
Assumptions made for the calculations	The calculation is based on the median residue levels derived for raw agricultural commodities for which MRLs have been established in the EU MRL legislation The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; 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: Fludioxanil[(F)]				
0270040	Florence fennels	0.05	1.5	The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely

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

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.0; 2017/12/11

Fludioxonil

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

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	Exposure (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	72.24	6%	Apples	3%	Oranges	2%	Pears	0.0%	0.0%
	18%	DE child	67.75	7%	Apples	6%	Oranges	1%	Potatoes		0.0%
	11%	NL child	40.64	3%	Apples	2%	Oranges	1%	Potatoes	0.0%	0.0%
	11%	IE adult	39.62	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits		0.0%
	8%	FR child 3–15 years	31.22	5%	Oranges	1.0%	Apples	0.6%	Potatoes	0.0%	0.0%
	8%	FR toddler 2–3 years	27.92	2%	Oranges	2%	Apples	1%	Mandarins	0.0%	0.0%
	7%	GEMS/Food G11	25.86	2%	Potatoes	1%	Oranges	0.9%	Apples		0.0%
	7%	ES child	25.70	3%	Oranges	0.9%	Lettuces	0.7%	Potatoes	0.0%	
	7%	SE general	25.47	2%	Potatoes	1%	Oranges	0.9%	Lettuces		0.0%
	7%	GEMS/Food G07	25.37	2%	Oranges	2%	Potatoes	0.6%	Apples	0.0%	0.0%
	7%	UK toddler	24.66	3%	Oranges	1%	Potatoes	1.0%	Apples	0.0%	
	7%	DE women 14–50 years	24.36	3%	Oranges	1%	Apples	0.4%	Potatoes	0.0%	0.0%
	6%	GEMS/Food G10	23.41	2%	Oranges	1%	Potatoes	0.7%	Lettuces	0.0%	0.0%
	6%	DE general	21.69	2%	Oranges	1%	Apples	0.5%	Potatoes	0.0%	0.0%
	6%	GEMS/Food G08	21.45	2%	Potatoes	0.7%	Apples	0.7%	Oranges		0.0%
	6%	GEMS/Food G06	21.41	1%	Oranges	0.8%	Potatoes	0.6%	Tomatoes	0.0%	0.0%
	5%	PT general	20.01	2%	Potatoes	0.9%	Oranges	0.6%	Apples		0.0%
	5%	ES adult	19.83	2%	Oranges	1%	Lettuces	0.4%	Apples	0.0%	
	5%	UK infant	19.44	2%	Oranges	1%	Potatoes	0.9%	Apples	0.0%	
	5%	GEMS/Food G15	18.89	1%	Potatoes	1.0%	Oranges	0.6%	Apples		0.0%
	5%	NL general	18.37	1%	Oranges	1.0%	Potatoes	0.8%	Apples	0.0%	0.0%
	5%	FI 3 years	16.91	2%	Potatoes	0.6%	Mandarins	0.5%	Apples		
	5%	DK child	16.86	1%	Apples	1.0%	Potatoes	0.4%	Carrots		
	4%	RO general	15.32	2%	Potatoes	0.8%	Apples	0.4%	Oranges	0.0%	
	4%	IT toddler	15.23	0.7%	Oranges	0.7%	Lettuces	0.5%	Apples		0.0%
	4%	IT adult	14.66	0.8%	Lettuces	0.5%	Oranges	0.5%	Apples		0.0%
	4%	FI 6 years	14.09	2%	Potatoes	0.5%	Mandarins	0.3%	Apples		
	4%	FR infant	13.34	1.0%	Apples	0.8%	Potatoes	0.4%	Spinaches	0.0%	0.0%
	4%	PL general	13.06	1%	Potatoes	1%	Apples	0.2%	Pears		0.0%
	3%	UK vegetarian	12.27	1%	Oranges	0.6%	Potatoes	0.3%	Apples	0.0%	0.0%
	3%	LT adult	11.17	1%	Potatoes	1%	Apples	0.1%	Lettuces		
	3%	FR adult	11.12	0.8%	Oranges	0.4%	Apples	0.3%	Potatoes	0.0%	0.0%
	3%	UK adult	9.45	0.8%	Oranges	0.6%	Potatoes	0.3%	Lettuces	0.0%	0.0%
	2%	DK adult	9.20	0.5%	Apples	0.5%	Potatoes	0.2%	Oranges		
	2%	FI adult	8.96	0.6%	Oranges	0.5%	Potatoes	0.3%	Apples		
	0.8%	IE child	2.85	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 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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment[a]
Citrus fruits	5.3	STMR (EFSA, 2011)
Pistachios	0.06	STMR (EFSA, 2011)
Pome fruits	2.1	STMR (EFSA, 2011)
Apricots	1.06	STMR (EFSA, 2011)
Cherries (sweet)	0.80	STMR (EFSA, 2011)
Peaches	3.65	STMR (EFSA, 2011)
Plums	1.06	STMR (EFSA, 2011)
Table grapes	0.38	STMR (EFSA, 2011)
Wine grapes	0.33	STMR (EFSA, 2011)
Strawberries	0.7	STMR (EFSA, 2011)
Blackberries, raspberries	1	STMR (EFSA, 2011)
Cranberries, currants, gooseberries	0.37	STMR (EFSA, 2011)
Elderberries	0.24	STMR (EFSA, 2011)
Kiwi fruits (green, red, yellow)	7.3	STMR (EFSA, 2011)
Avocados	0.05	STMR (FAO, 2013)
Mangoes	0.02	$STMR_{edible\ portion}$ (FAO, 2012)
Granate apples/pomegranates	0.95	STMR (EFSA, 2011)
Pineapples	2.14	STMR (EFSA, 2016a)
Potatoes	1.5	STMR (FAO, 2013)
Sweet potatoes, yams	3.76	STMR (EFSA, 2011)
Beetroots, carrots	1.13	STMR (EFSA, 2011)
Celeriacs/turnip rooted celeries	0.21	STMR (EFSA, 2011)
Horseradishes	1.13	STMR (EFSA, 2011)
Parsnips	1.13	STMR (EFSA, 2011)
Parsley roots/Hamburg roots parsley	1.13	STMR (EFSA, 2011)
Radishes	0.1	STMR × CF (2.8) (EFSA, 2013)
Salsifies	1.13	STMR (EFSA, 2011)
Garlic	0.06	STMR (EFSA, 2011)
Onions	0.11	STMR (EFSA, 2011)
Shallots	0.06	STMR (EFSA, 2011)
Spring onions/green onions and Welsh onions	1.65	STMR (EFSA, 2011)
Tomatoes	0.66	STMR (FAO, 2013)
Sweet peppers/bell peppers	0.21	STMR (EFSA, 2011)
Aubergines/egg plants	0.12	STMR (EFSA, 2011)
Cucurbits - edible peel	0.1	STMR (EFSA, 2011)
Cucurbits - inedible peel	0.01	$STMR_{edible\ portion}$ (EFSA, 2013)
Sweet corn	0.01	STMR (EFSA, 2011)
Broccoli	0.23	STMR (EFSA, 2011)
Head cabbages	0.24	STMR (EFSA, 2011)
Chinese cabbages/pe-tsai	1.2	STMR (EFSA, 2011)
Lettuces	8.3	STMR (FAO, 2013)
Lettuce and other salad plants including Brassicaceae, (except lettuce)	6.13	STMR (EFSA, 2016b)
Spinaches	5.8	STMR (FAO, 2013)
Purslanes	6.13	STMR (EFSA, 2016b)

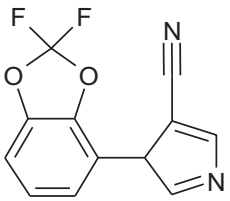
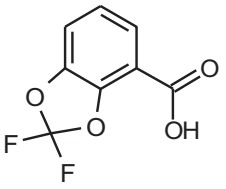
Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment[a]
Chards/beet leaves	6.13	STMR (EFSA, 2016b)
Herbs and edible flowers	6.13	STMR (EFSA, 2016b)
Beans, peas (with pods)	0.48	STMR (EFSA, 2011)
Beans (without pods)	0.02	STMR (EFSA, 2016b)
Peas (without pods)	0.04	STMR (EFSA, 2016b)
Lentils (fresh)	0.02	STMR (EFSA, 2011)
Asparagus	0.01	STMR (EFSA, 2011)
Celeries	0.32	STMR (EFSA, 2012)
Florence fennels	0.32	STMR (Section B.1.2)
Beans (dry)	0.04	STMR (FAO, 2013)
Lentils, peas, lupins/lupini beans	0.02	STMR (EFSA, 2011)
Poppy seeds, sunflower seeds, rapeseeds/canola seeds, soybeans	0.01	STMR (EFSA, 2011)
Cotton seeds	0.02	STMR (EFSA, 2011)
Cereals	0.01	STMR (EFSA, 2011)
Ginseng root	0.8	STMR × CF[b] (2.8) (FAO, 2013)
Liquorice, ginger, turmeric/curcuma, other spices (roots)	1	MRL
Sugar beet roots	0.01	STMR (EFSA, 2011)
Bovine, sheep, goat: Muscle/meat[a]	0.06	STMR (EFSA, 2011)
Bovine, sheep, goat: fat tissue, liver, kidney	0.16	STMR (EFSA, 2011)
Poultry muscle/meat[a]	0.01	STMR (EFSA, 2011)
Poultry: fat tissue, liver, kidney	0.05	STMR (EFSA, 2011)
Milk	0.01	STMR (EFSA, 2011)
Eggs	0.05	STMR (EFSA, 2011)

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; MRL: maximum residue level.

(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticides, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat, respectively (FAO, 2016).

(b): 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, 2007).

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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).