REASONED OPINION

EFSA Journal

APPROVED: 7 August 2019

doi: 10.2903/j.efsa.2019.5812

Evaluation of confirmatory data following the Article 12 MRL review for fludioxonil

European Food Safety Authority (EFSA),
Maria Anastassiadou, 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, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

The applicant Syngenta submitted a request to the competent national authority in France to evaluate the confirmatory data that were identified in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. The applicant provided residue trials on strawberries representative for an adjusted Good Agricultural Practice (GAP) and a new feeding study in ruminants. The data gaps identified in the MRL review were considered satisfactorily addressed, except for the southern adjusted GAP on strawberries. The new residue data confirm the existing tentative MRL for strawberries; EFSA proposed – based on the new feeding study in ruminants – amendments of the existing MRLs for certain animal products for further risk management consideration. EFSA updated the most recent consumer risk assessment for fludioxonil and concluded that the long-term dietary intake is unlikely to present a risk to consumer health.

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Keywords: fludioxonil, confirmatory data, pesticide, MRL review, risk assessment

Requestor: European Commission

Question numbers: EFSA-Q-2018-00903

Correspondence: pesticides.mrl@efsa.europa.eu

Acknowledgement: EFSA wishes to acknowledge the contribution of Marianna Raczyk and Silvia Ruocco to this opinion.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review for fludioxonil. EFSA Journal 2019;17(8):5812, 31 pp. https://doi.org/10.2903/j.efsa.2019.5812

ISSN: 1831-4732

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

Summary

In 2011, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) six additional residue trials supporting the northern outdoor Good Agricultural Practice (GAP), four additional residue trials supporting the southern outdoor GAP and six residue trials supporting the indoor GAP on strawberries;
2) eight residue trials on melons supporting the import tolerance GAP on cucurbits with inedible peel;
3) three additional residue trials supporting the northern outdoor GAP and three additional residue trials supporting the southern outdoor GAP on celery;
4) a livestock feeding study for meat ruminants at higher dose levels, taking into account the calculated dietary burdens where levels of fludioxonil and metabolites containing the 2,2-difluorobenzo [1,3]dioxole-4 carboxylic moiety are preferably reported separately.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 79/2014, including footnotes related to data gaps number 1 and 4, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 30 January 2016.

The data gaps number 2 and 3 became obsolete since new uses were assessed by EFSA which were fully supported by data. When the revised MRLs for cucurbits with inedible peel and celeries have been implemented in the EU MRL legislation by Commission Regulation (EU) No 834/2013 and Commission Regulation (EU) No 241/2013, the footnotes were deleted.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Syngenta submitted an application to the competent national authority in France (rapporteur Member State, RMS) to evaluate the confirmatory data for data gaps number 1 and 4 identified during the MRL review.

The RMS included the assessment of this new information in the Renewal Assessment Report (RAR), prepared under the framework of the peer review on fludioxonil for renewal of approval according to Article 13 of Regulation (EU) No 844/2012.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition for plant products: Fludioxonil **Enforcement residue definition for animal products:** Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (F) **N.B.** EFSA noted an inaccuracy regarding the residue definition for animal products currently implemented in Regulation (EC) No 396/2005 (the last part of the residue definitions 'expressed as fludioxonil' is missing). Thus, when implementing the current MRL recommendations, the residue definition should be updated as reported above				
0152000	Strawberries	4 (ft 1)	4	The data gap identified by EFSA during the MRL review for additional residue trials was addressed The MRL derived for the adjusted indoor GAP with a longer PHI of 3 days corresponds to the current MRL. Thus, no modification of the MRL is necessary. Risk for consumer is unlikely The adjusted NEU GAP, which is sufficiently supported by data, would require a lower MRL. The original GAPs assessed in the framework of the MRL review with a shorter PHI of 1 day and the adjusted SEU GAP are not sufficiently supported by data

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Conclusion/recommendation
1011010	Swine, muscle	0.01* (c)	0.01*	Based on the updated dietary burden calculation and the new feeding study, the MRL required for swine products were recalculated The new assessment confirmed the existing MRLs for swine muscle; a lower MRL would be sufficient for fat, liver and kidney The option to lower existing EU MRL should be further discussed by risk managers. A risk for consumer is unlikely
1011020	Swine, fat	0.05* (c)	0.01* Further risk management consideration required	
1011030	Swine, liver	0.05* (c)	0.02 Further risk management consideration required	
1011040	Swine, kidney	0.05* (c)	0.03 Further risk management consideration required	
1011050	Swine edible offal	0.05* (c)	Further risk management consideration required	The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1011990	Swine, other products	0.05* (c)	Further risk management consideration required	
1012010	Bovine, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for bovine tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers. Risk for consumer is unlikely
1012020	Bovine, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1012030	Bovine, liver	0.2 (ft 2)	0.06 Further risk management consideration required	
1012040	Bovine, kidney	0.2 (ft 2)	0.07 Further risk management consideration required	
1012050	Bovine, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1012990	Bovine, other products	0.05* (ft 2)	Further risk management consideration required	
1013010	Sheep, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for sheep tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers Risk for consumer is unlikely
1013020	Sheep, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1013030	Sheep, liver	0.2 (ft 2)	0.02 Further risk management consideration required	
1013040	Sheep, kidney	0.2 (ft 2)	0.03 Further risk management consideration required	
1013050	Sheep, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactory addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1013990	Sheep, other products	0.05* (ft 2)	Further risk management consideration required	

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
1014010	Goat, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for goat tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers Risk for consumer is unlikely
1014020	Goat, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1014030	Goat, liver	0.2 (ft 2)	0.02 Further risk management consideration required	
1014040	Goat, kidney	0.2 (ft 2)	0.03 Further risk management consideration required	
1014050	Goat, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1014990	Goat, other products	0.05* (ft 2)	Further risk management consideration required	
1020010	Cattle milk	0.01* (d)	Further risk management considerations required 0.02	The new feeding study suggests a higher MRL for milk. A risk for consumer is unlikely
1020020	Sheep milk	0.01* (d)		
1020030	Goat milk	0.01* (d)		

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; NEU: northern Europe; SEU: southern 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.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): Although formally, no data gap was identified for swine products, EFSA re-assessed the MRLs, since the new feeding study in ruminants allowed to update the MRLs.
(d): Although formally, no data gap was identified for milk, EFSA re-assessed the MRLs, since the new feeding study allowed to update the MRLs for milk.
(F): Fat soluble.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 1).
ft 2: The European Food Safety Authority identified some information on a livestock feeding study as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 4).

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Assessment

The review of existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/2005[1] (MRL review) has been performed in 2011. The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified (EFSA, 2011). The Good Agricultural Practices (GAPs) for strawberries assessed in the framework of the MRL review, that were not fully supported by data and for which confirmatory data were requested, are listed in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 79/2014[2], including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 30 January 2016.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016) the applicant, Syngenta, submitted an application to the competent national authority in France (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant amended the GAPs for strawberries by proposing a longer preharvest interval (PHI) of 3 days compared to the GAP assessed in the MRL review (hereafter referred to as adjusted GAPs); in addition, a new feeding study in ruminants was provided. The data gaps identified for cucurbits with inedible peel and celery were assessed by EFSA in previous reasoned opinions (EFSA, 2012, 2013).

The RMS assessed the new information provided by the applicant in the Renewal Assessment Report (RAR), prepared under the framework of the peer review on fludioxonil for renewal of approval according to Article 13 of Regulation (EU) No 844/2012.[3]

EFSA based its assessment on the information provided in the RAR submitted by the RMS (France, 2018), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and additional assessments performed after the MRL review (EFSA, 2011, 2012, 2013, 2016a,b, 2018, 2019).

For this application, the data requirements established in Regulation (EU) No 544/2011[4] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 79/2014 are applicable. 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[5].

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

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

The RAR submitted by the RMS (France, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

[1] 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.

[2] Commission Regulation (EU) No 79/2014 of 29 January 2014 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, chlorpropham, esfenvalerate, fludioxonil and thiobencarb in or on certain products. OJ L 27, 30.1.2014, p. 9–55.

[3] The peer review of fludioxonil was initiated on 17 July 2018. On 2 May 2019, the assessment was stopped, requesting additional data in relation to assessment of endocrine properties in accordance with the new scientific criteria introduced by Regulation (EU) No 2018/605 (Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36). EFSA agreed with the European Commission that the confirmatory data following the MRL review should be evaluated in a separate reasoned opinion to avoid further delays.

[4] 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.

[5] 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.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

Not relevant for the current assessment.

1.1.2. Nature of residues in rotational crops

Not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

Not relevant for the current assessment.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

1.1.6. Proposed residue definitions

The previously derived residue definitions are still applicable.

1.2. Magnitude of residues in plants

In order to address data gaps number 1,[6] the applicant amended the GAP (hereafter referred to as adjusted GAP) and submitted residue trials conducted in the northern and the southern Europe and under indoor conditions representative for the adjusted GAP for strawberries; the details of the adjusted GAP are reported in Appendix A. The adjusted GAP foresees the same application rate and number of applications, but a longer PHI of 3 days instead of the PHI of 1 day originally evaluated in the framework of the MRL review (EFSA, 2011).

None of the trials was analysed for the metabolite CGA 192155, which is included in the residue definition for risk assessment. Based on the metabolism of fludioxonil in fruit crops, the EU pesticides peer review concluded that this metabolite is not expected to occur in fruits. Thus, a default conversion factor for risk assessment of 1 (EFSA, 2007) is appropriate.

According to the RMS, the analytical methods used to analyse the samples from the residue trials have been sufficiently validated and were proven to be fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (France, 2018).

NEU: To support the adjusted GAP in the NEU, the applicant re-submitted the same eight residue trials assessed by EFSA in the framework of the MRL review. These trials are compliant with the adjusted GAP, except one of them, where samples were taken 1 and 4 days after the last application. Evaluating Member State (EMS) proposed to consider this trial as acceptable and derived the residue level at PHI 3 days by interpolation (0.40 mg/kg) between the residues found at 1 and 4 days. EFSA agreed that the trial can be used to complete the data set. However, in contrast to the RMS, EFSA selected the residue concentration of 0.54 mg/kg measured at the PHI of 1 day for MRL setting and risk assessment.

SEU: To support the adjusted use in the SEU, the applicant re-submitted the seven residue trials conducted in different Member States that were already assessed by EFSA in the framework of the MRL review. The trials are compliant with the adjusted GAP. According to current data requirements, at least eight trials are required to support the reported use in strawberries, since strawberries is a major crop in the SEU (European Commission, 2017). EFSA concludes that the adjusted GAP is not fully supported by data.

[6] Data gap number 1: six additional residue trials supporting the northern outdoor GAP, four additional residue trials supporting the southern outdoor GAP and six residue trials supporting the indoor GAP on strawberries.

Indoor: To support the adjusted indoor use, 10 residue trials conducted in several EU Member States in different years were submitted. Some of the trials were already assessed by EFSA in the framework of the MRL review. The trials are compliant with the adjusted GAP and were found acceptable for MRL setting and risk assessment.

The results of the trials used are detailed in the Table B.1.2.1.

1.2.1. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.2. Magnitude of residues in processed commodities

Not relevant for the current assessment.

1.2.3. Proposed MRLs

The available data were considered sufficient to derive an MRL proposal as well as risk assessment values for the adjusted GAP for the indoor use and the northern EU use on strawberries (see Appendix B.4). The southern use (adjusted GAP) is not sufficiently supported by data. The MRL proposal for the indoor use corresponds to the current value. Thus, no modification is necessary.

The more critical uses with the PHI of 1 day originally evaluated in the framework of the MRL review are not sufficiently supported by data. In Section 3, EFSA assessed whether residues on this crop resulting from the adjusted use are likely to pose a consumer health risk.

2. Residues in livestock

In the framework of the MRL review, the livestock dietary burdens were calculated using PROFile version 2.1. Thus, in accordance with the Commission working document SANTE/10235/2016, the dietary burden was recalculated according to the more recent calculation methodology (OECD, 2013). The input values included in the calculations are reported in Appendix D.1.

Comparing the results of the revised dietary burden calculation with the calculation performed in the framework of the MRL review (EFSA, 2011), it becomes evident that the new calculation methodology lead to a lower result for beef cattle, while for dairy cattle, swine and poultry the calculated exposure increased. It is noted that for poultry, the dietary burden calculation performed in the MRL review (EFSA, 2011) did not exceed the trigger value, although with the new dietary burden calculation method the trigger value is exceeded. The assessment of MRLs for poultry is not subject of the current reasoned opinion. However, EFSA highlights that in case new uses relevant for feed will be requested, the MRLs for poultry will be reconsidered. Thus, a feeding study for poultry will be required.

2.1. Nature of residues

In the framework of the MRL review, a possible simplification of the enforcement residue definition for certain animal products (muscle, fat and liver) was discussed. EFSA noted that a livestock feeding study would be required where fludioxonil and metabolites containing the 2,2-difluorobenzo [1,3]dioxole-4 carboxylic moiety are reported separately (EFSA, 2011). Since the new feeding study used the common moiety method (see Section 2.3), the residue definitions for enforcement and risk assessment set during the MRL review are still valid.

Comparing the residue definition recommended by EFSA in the MRL review with the residue definition for enforcement established in Regulation (EC) No 396/2005, EFSA noted an inaccuracy, which should be corrected when the MRL regulation is updated, following the current assessment:

- Current residue definition established in Regulation (EC) No 396/2005 (applicable to animal products, except honey): sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid
- Residue definition recommended by EFSA (2011): sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil.

2.2. Methods of analysis in livestock

Not relevant for the current assessment.

2.3. Magnitude of residues in livestock

In order to address data gaps number 4,[7] the applicant submitted a new feeding study in ruminants. Lactating cows were dosed with fludioxonil at nominal doses of 0.8 and 4.3 mg/kg body weight (bw) per day (equivalent to 20 mg/kg and 100 mg/kg dry matter (DM) feed) over a period of 28 days. Milk and tissue samples were analysed for the active substance and metabolites that can be oxidized to 2,2-difluorobenzo [1,3]dioxole-4 carboxylic (CGA 192155). Results were expressed as fludioxonil equivalents. The analytical method used did not allow to report separately the residue concentration of parent fludioxonil and of individual metabolites.

According to the RMS, the analytical method used in the new feeding study was sufficiently validated. The samples from the study were analysed (up to 4 months) within the demonstrated storage stability.

The feeding study was performed with parent fludioxonil only; relevant metabolites that were identified in plant metabolism and that were included in the risk assessment residue definition for plants have not been fed to livestock. EFSA considers the study is acceptable, since the main contributor in the dietary burden calculation were fruit by-products. From metabolism studies in fruit, it is known that the parent fludioxonil is the main residue in fruit crops. Thus, the study is valid and it is used to estimate the residues in ruminant products and by extrapolation in pigs (supervised trials median residue (STMR), highest residue (HR) and MRL for animal commodities).

EFSA concluded that the data gap identified in the framework of the MRL review was satisfactorily addressed. Details of the calculations are presented in Appendix B.1.2.1.

2.4. Proposed MRLs

Taking into account the calculated dietary burden values and the results of the new feeding study, a lowering of the existing MRLs for ruminant tissues may be considered by risk managers. Although formally no data gap was identified for milk, the revised dietary burden calculation and the new feeding study suggest a higher MRL for milk.

3. Consumer risk assessment

EFSA updated the most recent chronic consumer risk assessment for fludioxonil (EFSA, 2019) with the relevant median residue (STMR) values for strawberries and for tissues and milk of ruminants as derived in this assessment of confirmatory data.

The estimated long-term dietary intake of fludioxonil was in the range of 2–20% of the acceptable daily intake (ADI). The contribution of residues in strawberries accounted for a maximum 0.04% of the ADI; for ruminant milk, the exposure accounted for a maximum of 0.32% of the ADI (bovine milk).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

A short-term consumer risk assessment was not performed as an acute reference dose (ARfD) was not deemed necessary for fludioxonil (European Commission, 2007). If in the framework of the renewal of the active substance the setting of an ARfD is deemed necessary, the existing MRLs, including the MRLs for the commodities assessed in this reasoned opinion, need to be reconsidered.

For further details on the exposure calculations, a screenshot of the Report sheet of the EFSA PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

To address the data gaps identified in the framework of the MRL review (EFSA, 2011), the applicant provided the residue trials on strawberries conducted according to an adjusted GAP with a longer preharvest interval and the results of a new feeding study in ruminants. The data gaps were considered satisfactorily addressed, except for the southern outdoor use on strawberries.

EFSA updated the most recent chronic consumer risk assessment for fludioxonil and concluded that the long-term dietary intake is unlikely to present a risk to consumer health.

[7] Livestock feeding study for meat ruminants at higher dose levels, taking into account the calculated dietary burdens where levels of fludioxonil and metabolites containing the 2,2-difluorobenzo [1,3]dioxole-4 carboxylic moiety are preferably reported separately.

The peer review of the renewal of approval 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 may need to be reconsidered in the light of the outcome of the EU pesticides peer review.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	fludioxonil
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
DAT	days after treatment
DM	dry matter
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
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
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
PROFile	(EFSA) Pesticide Residues Overview File
RA	risk assessment
RAC	raw agricultural commodity
RAR	Renewal Assessment Report
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
UV	ultraviolet (detector)
WG	water-dispersible granule

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

Original GAPs assessed in the framework of the MRL review assessment (EFSA, 2011)

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		
Strawberry	NEU	F		WG	250 g/kg	Foliar – Spraying		3	10			250	g a.s/ha	1	
Strawberry	SEU	F		WG	250 g/kg	Foliar – Spraying		3	10			250	g a.s/ha	1	
Strawberry	EU	G		WG	250 g/kg	Foliar – Spraying		3	10			250	g a.s/ha	1	

Adjusted GAPs proposed in the framework of the MRL review confirmatory data (France, 2018)

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		
Strawberry	NEU	F	*Aspergillus* spp. *Botrytis cinerea* *Colletotrichum* spp.	WG	250 g/kg	Foliar spray	BBCH 55–89	3	10	0.25–1.666	300–2000	250	g a.s./ha	3	
Strawberry	SEU	F		WG	250 g/kg	Foliar spray	BBCH 55–89	3	10	0.25–1.666	300–2000	250	g a.s./ha	3	
Strawberry	EU	G		WG	250 g/kg	Foliar spray	BBCH 55–89	3	10	0.25–1.666	300–2000	250	g a.s./ha	3	

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): 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 3x0.6 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 oxidized 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 (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 (2011)
	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]
Strawberry	NEU	**GAP with PHI 1 day** **Mo:** EFSA, 2011: 0.24; 0.54 France, 2018: – **RA:** –	No new information provided. The GAP assessed in the MRL review with PHI 1 day is not sufficiently supported by data	---	---	---	---
		GAP with PHI 3 days **Mo:** France, 2018: 0.07; 0.09; 0.10; 0.16; 0.21; 0.21; 0.23; 0.54 **RA:** –	Seven trials fully compliant with the adjusted GAP. Data set completed with one trial compliant with the sample collected at PHI 1 day instead of 3 days (underlined)	0.8	0.54	0.19	1
Strawberry	SEU	**GAP with PHI 1 day** **Mo:** EFSA, 2011: 0.31; 0.77; 0.87; 0.7 **RA**: –	No new information provided. The GAP assessed in the MRL review with PHI 1 day is not sufficiently supported by data	---	---	---	---

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)]
		GAP with PHI 3 days **Mo:** France, 2018: 0.2; 0.27; 0.64; 0.71; 0.73; 0.89; 1.02 **RA:** –	Seven trials compliant with the adjusted GAP. Underlined values, higher residues observed at a longer PHI of 7 days. Data set not sufficient to derive proposal	–	1.02	0.71	1
Strawberry	Indoor	**GAP with PHI 1 day** **Mo:** EFSA, 2011: 0.78; 0.26 **RA:** –	No new information provided. The GAP assessed in the MRL review with PHI 1 day is not supported by data	–	–	–	–
		GAP with PHI 3 days **Mo:** France, 2018: 0.19; 0.20; 0.21; 0.24; 0.29; 0.33; 0.45; 0.66; 1.04; 2.24. **RA:** –	Residue trials compliant with the adjusted GAP	**4**	**2.24**	**0.31**	1

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval.
(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): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. Metabolism in fruit crops after foliar application does not result in the formation of the metabolite CGA 192155, therefore the EU pesticide peer review concluded to use the conversion from enforcement to risk assessment of 1 (EFSA, 2007).

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	Based on the rotational crop study (bare soil: 1.5N to rate of the adjusted GAP) fludioxonil residues above the LOQ of 0.01 mg/kg are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP

GAP: Good Agricultural Practice; LOQ: limit of quantification.

B.1.2.3. Processing factors

No new processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Animal dietary burden calculated according to OECD methodology (OECD, 2013) from existing uses of fludioxonil (residue definition: Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil)

Relevant groups	Dietary burden expressed in				Most critical diet[(a)]	Most critical commodity[(b)]		Trigger exceeded (Yes/No)	Previous assessment (EFSA, 2011)
	mg/kg bw per day		mg/kg DM					0.10	Max burden
	Median	Maximum	Median	Maximum				mg/kg DM	mg/kg DM
Cattle (all diets)	0.394	0.411	10.24	10.69	Dairy cattle	Citrus	Dried pulp	Yes	15.32
Cattle (dairy only)	0.394	0.411	10.24	10.69	Dairy cattle	Citrus	Dried pulp	Yes	5.22
Sheep (all diets)	0.212	0.238	4.99	5.60	Lamb	Apple	Pomace, wet	Yes	–
Sheep (ewe only)	0.166	0.187	4.99	5.60	Ram/ Ewe	Apple	Pomace, wet	Yes	–
Swine (all diets)	0.207	0.225	8.99	9.74	Swine (breeding)	Citrus	Dried pulp	Yes	0.18
Poultry (all diets)	0.080	0.102	1.14	1.44	Poultry broiler	Carrot	Culls	Yes	0.07
Poultry (layer only)	0.075	0.096	1.10	1.40	Poultry layer	Carrot	Culls	Yes	–

OECD: Organisation for Economic Co-operation and Development; bw: body weight; DM: dry matter.
(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment/Source
	Laying hen	6.3	8	[pyrrole-4-^{14}C]-Fludioxonil, 5 hens (EFSA, 2011)
	Lactating ruminants	3.5	4	[pyrrole-4-^{14}C]-Fludioxonil, 2 Goats (EFSA, 2011)
	Pig	–	–	N/A
	Fish	–	–	N/A

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 14 days	EFSA (2007)
	Eggs: 5 days	EFSA (2007)
Metabolism in rat and ruminant similar	Yes	EFSA (2007)
Can a general residue definition be proposed for animals?	Yes	EFSA (2011)
Animal residue definition for monitoring (RD-Mo)	Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil (EFSA, 2011) Reg. 396/2005: Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (**N.B.** EFSA recommends to align the residue definition in the MRL legislation with the recommendation of EFSA, 2011)	
Animal residue definition for risk assessment (RD-RA)	Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil (EFSA, 2011)	
Fat soluble residues	Yes	EFSA (2011)

bw: body weight; MRL: maximum residue level.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability period		Compounds covered[(a)]	Comment/ Source
				Value	Unit		
	Beef	Muscle	−16	12	Months	Fludioxonil	EFSA (2007)
	Beef	Liver	−16	12	Months	Fludioxonil	EFSA (2007)
	Beef	Milk	−16	12	Months	Fludioxonil	EFSA (2007)
	Poultry	Eggs	−16	12	Months	Fludioxonil	EFSA (2007)

(a): Samples analysed with a method which convert fludioxonil and its oxidisable metabolites into CGA 192155.

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Cattle (all diets)								
Closest feeding level[(a)]:	0.8	mg/kg bw	1.9	N Dairy cattle (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***	1.0	0.01	0.01
Fat	0.01	0.01	0.01	0.01	**0.01***	1.0	0.01	0.01
Liver	0.05	0.07	0.04	0.06	**0.06**	1.0	0.04	0.06
Kidney	0.06	0.08	0.05	0.07	**0.07**	1.0	0.05	0.07
Cattle (dairy only)								
Closest feeding level[(a)]:	0.8	mg/kg bw	1.9	N Dairy cattle				
Milk[(b)]	0.08	0.29	0.02	0.02	**0.02**	1.0	0.02	0.02
Sheep (all diets)								
Closest feeding level[(a)]:	0.8	mg/kg bw	3.4	N Lamb (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***	1.0	0.01	0.01
Fat	0.01	0.01	0.00	0.00	**0.01***	1.0	0.00	0.00
Liver	0.05	0.07	0.01	0.02	**0.02**	1.0	0.01	0.02
Kidney	0.06	0.08	0.02	0.02	**0.03**	1.0	0.02	0.02
Sheep (dairy only)								
Closest feeding level[(a)]:	0.8	mg/kg bw	4.3	N Ewe				
Milk[(b)]	0.08	0.15	0.02	0.02	**0.02**	1.0	0.02	0.02
Swine								
Closest feeding level[(a)]:	0.8	mg/kg bw	3.6	N Breeding (highest diet)				
Muscle	0.01	0.01	0.01	0.01	**0.01***	1.0	0.01	0.01
Fat	0.01	0.01	0.00	0.00	**0.01***	1.0	0.00	0.00
Liver	0.05	0.07	0.01	0.02	**0.02**	1.0	0.01	0.02
Kidney	0.06	0.08	0.02	0.02	**0.03**	1.0	0.02	0.02

bw: body weight; MRL: maximum residue level; STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; HR: highest residue; Mo: monitoring.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): The mean residue level for milk was recalculated at the 1N rate for the median dietary burden.

B.3. Consumer risk assessment

ARfD	Not 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 2	20% ADI (NL toddler) Contribution of crops assessed: Strawberries: 0.04% of ADI Bovine milk: 0.32% of ADI
Assumptions made for the calculations	The most recent risk assessment performed by EFSA using PRIMo revision 3 (EFSA, 2019) was updated, including the median residue level derived from the indoor use on strawberries and the risk assessment values derived from the new feeding study for ruminants and swine. 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; bw: body weight; IESTI: international estimated short-term intake; ADI: acceptable daily intake; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Enforcement residue definition for plant products: Fludioxonil **Enforcement residue definition for animal products:** Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (F) **N.B.** EFSA noted an inaccuracy regarding the residue definition for animal products currently implemented in Regulation (EC) No 396/2005 (the last part of the residue definitions 'expressed as fludioxonil' is missing). Thus, when implementing the current MRL recommendations, the residue definition should be updated as reported above				
0152000	Strawberries	4 (ft 1)	4	The data gap identified by EFSA during the MRL review for additional residue trials was addressed The MRL derived for the adjusted indoor GAP with a longer PHI of 3 days corresponds to the current MRL. Thus, no modification of the MRL is necessary. Risk for consumer is unlikely The adjusted NEU GAP, which is sufficiently supported by data, would require a lower MRL. The original GAPs assessed in the framework of the MRL review with a shorter PHI of 1 day and the adjusted SEU GAP are not sufficiently supported by data
1011010	Swine, muscle	0.01* (c)	0.01*	Based on the updated dietary burden calculation and the new feeding study, the MRL required for swine products were re-calculated The new assessment confirmed the existing MRLs for swine muscle; a lower MRL would be sufficient for fat, liver and kidney The option to lower existing EU MRL should be further discussed by risk managers A risk for consumer is unlikely
1011020	Swine, fat	0.05* (c)	0.01* Further risk management consideration required	
1011030	Swine, liver	0.05* (c)	0.02 Further risk management consideration required	

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Conclusion/recommendation
1011040	Swine, kidney	0.05* [c]	0.03 Further risk management consideration required	
1011050	Swine edible offal	0.05* [c]	Further risk management consideration required	The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1011990	Swine, other products	0.05* [c]	Further risk management consideration required	
1012010	Bovine, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient bovine tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers Risk for consumer is unlikely
1012020	Bovine, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1012030	Bovine, liver	0.2 (ft 2)	0.06 Further risk management consideration required	
1012040	Bovine, kidney	0.2 (ft 2)	0.07 Further risk management consideration required	
1012050	Bovine, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactory addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1012990	Bovine, other products	0.05* (ft 2)	Further risk management consideration required	
1013010	Sheep, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for sheep tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers. Risk for consumer is unlikely
1013020	Sheep, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1013030	Sheep, liver	0.2 (ft 2)	0.02 Further risk management consideration required	
1013040	Sheep, kidney	0.2 (ft 2)	0.03 Further risk management consideration required	
1013050	Sheep, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactory addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1013990	Sheep, other products	0.05* (ft 2)	Further risk management consideration required	
1014010	Goat, muscle	0.04 (ft 2)	0.01* Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for goat tissues (muscle, fat, liver and kidney) The option to lower existing EU MRL should be further discussed by risk managers Risk for consumer is unlikely
1014020	Goat, fat	0.2 (ft 2)	0.01* Further risk management consideration required	
1014030	Goat, liver	0.2 (ft 2)	0.02 Further risk management consideration required	
1014040	Goat, kidney	0.2 (ft 2)	0.03 Further risk management consideration required	

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
1014050	Goat, edible offal	0.05* (ft 2)	Further risk management consideration required	The data gap identified in the MRL review for a new feeding study in ruminants has been addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues
1014990	Goat, other products	0.05* (ft 2)	Further risk management consideration required	
1020010	Cattle milk	0.01* (d)	Further risk management considerations required 0.02	The new feeding study suggests a higher MRL for milk. A risk for consumer is unlikely
1020020	Sheep milk	0.01* (d)		
1020030	Goat milk	0.01* (d)		

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; NEU: northern Europe; SEU: southern 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
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): Although formally, no data gap was identified for swine products, EFSA re-assessed the MRLs, since the new feeding study in ruminants allowed to update the MRLs.
(d): Although formally, no data gap was identified for milk, EFSA re-assessed the MRLs, since the new feeding study allowed to update the MRLs for milk.
(F): Fat-soluble
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1)
ft 2: The European Food Safety Authority identified some information on a livestock feeding study as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).

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 – acuterisk 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	39.69	4%	Sweet potatoes	1%	Oranges	1.0%	Grapefruits		
	9%	FR child 3–15 year	31.69	5%	Oranges	1%	Apples	0.6%	Potatoes		
	8%	FR toddler 2–3 year	28.79	2%	Oranges	2%	Apples	1%	Mandarins		
	7%	GEMS/Food G11	26.21	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	25.55	2%	Oranges	2%	Potatoes	0.6%	Apples		
	7%	UK toddler	25.10	3%	Oranges	1%	Potatoes	1%	Apples		
	7%	DE women 14–50 year	24.97	3%	Oranges	2%	Apples	0.4%	Potatoes		
	6%	GEMS/Food G10	23.53	2%	Oranges	1%	Potatoes	0.7%	Lettuces		
	6%	DE general	22.27	2%	Oranges	2%	Apples	0.5%	Potatoes		
	6%	GEMS/Food G08	21.64	2%	Potatoes	0.8%	Apples	0.7%	Oranges		
	6%	GEMS/Food G06	21.53	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	20.06	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 year	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 year	14.12	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 – acuterisk 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. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil				
Citrus, pomace	39.96	Median residue (5.3) × PF (7.5)	39.96	Median residue (5.3) × PF (7.5)
Apple, pomace	12.19	Median residue (2.3) × PF (5.3)	12.19	Median residue (2.3) × PF (5.3)
Carrots	1.13	Highest residue (0.41) × CF (2.8)	1.51	Highest residue (0.54) × CF (2.8)
Wheat, rye grain	0.01	Median residue	0.01	Median residue
Barley, oat grain	0.01	Median residue	0.01	Median residue
Maize grain	0.01	Median residue	0.01	Median residue
Wheat, rye bran	0.01	Median residue	0.01	Median residue
Wheat, rye straw	0.04	Median residue	0.05	Highest residue
Barley, oat straw	0.04	Median residue	0.05	Highest residue
Peas, beans, lupins (dry)	0.02	Median residue	0.02	Median residue
Potatoes	0.02	Median residue	0.04	Highest residue
Rape seed Cotton seed Sunflower seed Soya bean	0.01	Median residue	0.01	Median residue
Rape seed meal Cotton seed meal Sunflower seed meal Soya bean meal	0.01	Median residue	0.01	Median residue

PF: processing factor; CF: conversion factor for risk assessment residue definition (EFSA, 2011).

D.2. Consumer risk assessment

Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[a]	
				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

Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[a]	
				Input value (mg/kg)	Comment
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	Proposed MRL	0.31	STMR-RAC
153010	Blackberries	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
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

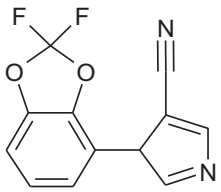
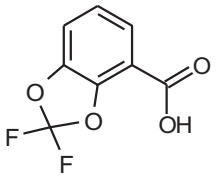
Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[a]	
				Input value (mg/kg)	Comment
232990	Other cucurbits - edible peel	0.4	Existing EU MRL	0.1	STMR-RAC
233010	Melons	0.3	Existing EU MRL	0.01	STMR-RAC
233020	Pumpkins	0.3	Existing EU MRL	0.01	STMR-RAC
233030	Watermelons	0.3	Existing EU MRL	0.01	STMR-RAC
233990	Other cucurbits - inedible peel	0.3	Existing EU MRL	0.01	STMR-RAC
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
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
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

Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[a]	
				Input value (mg/kg)	Comment
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
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
1011010	Swine: Muscle/meat	0.01	Existing EU MRL	0.01	STMR-RAC
1011030	Swine: Liver	0.02	Proposed new MRL	0.01	STMR-RAC
1011040	Swine: Kidney	0.03	Proposed new MRL	0.02	STMR-RAC
1012010	Bovine: Muscle/meat	0.01	Proposed new MRL	0.01	STMR-RAC
1012020	Bovine: Fat tissue	0.01	Proposed new MRL	0.01	STMR-RAC
1012030	Bovine: Liver	0.06	Proposed new MRL	0.04	STMR-RAC
1012040	Bovine: Kidney	0.07	Proposed new MRL	0.05	STMR-RAC
1013010	Sheep: Muscle/meat	0.01	Proposed new MRL	0.01	STMR-RAC
1013030	Sheep: Liver	0.02	Proposed new MRL	0.01	STMR-RAC
1013040	Sheep: Kidney	0.03	Proposed new MRL	0.02	STMR-RAC
1014010	Goat: Muscle/meat	0.01	Proposed new MRL	0.01	STMR-RAC
1014030	Goat: Liver	0.02	Proposed new MRL	0.01	STMR-RAC
1014040	Goat: Kidney	0.03	Proposed new MRL	0.02	STMR-RAC
1016010	Poultry: Muscle/meat	0.01	Existing EU MRL	0.01	STMR-RAC
1016020	Poultry: Fat tissue	0.05	Existing EU MRL	0.05	STMR-RAC
1016030	Poultry: Liver	0.05	Existing EU MRL	0.05	STMR-RAC
1016040	Poultry: Kidney	0.05	Existing EU MRL	0.05	STMR-RAC
1020010	Milk: Cattle	0.02	Proposed new MRL	0.02	STMR-RAC
1020020	Milk: Sheep	0.02	Proposed new MRL	0.02	STMR-RAC
1020030	Milk: Goat	0.02	Proposed new MRL	0.02	STMR-RAC
1020040	Milk: Horse	0.02	Proposed new MRL	0.02	STMR-RAC
1020990	Milk: Others	0.02	Proposed new MRL	0.02	STMR-RAC
1030010	Eggs: Chicken	0.05	Existing EU MRL	0.05	STMR-RAC
1030020	Eggs: Duck	0.05	Existing EU MRL	0.05	STMR-RAC
1030030	Eggs: Goose	0.05	Existing EU MRL	0.05	STMR-RAC

Code	Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment[a]	
				Input value (mg/kg)	Comment
1030040	Eggs: Quail	0.05	Existing EU MRL	0.05	STMR-RAC
1030990	Eggs: Others	0.05	Existing EU MRL	0.05	STMR-RAC
...	Other crops/ commodities		–		

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, 2007).

Appendix E – Used compound codes

Code/trivial name[a]	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-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): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(b): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).