REASONED OPINION

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Setting of import tolerances for fludioxonil in sugar beet roots and bananas

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

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Crop Protection AG submitted a request to the competent national authority in France to set import tolerances for the active substance fludioxonil in sugar beet roots and bananas. The data submitted in support of the request were found to be sufficient to derive maximum residue level (MRL) proposals for sugar beet roots and bananas. Adequate analytical methods for enforcement are available to control the residues of fludioxonil in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg and in animal matrices at the validated LOQ of 0.01 mg/kg in milk and muscle and 0.05 mg/kg in liver, kidney, fat tissues and eggs. 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 practices is unlikely to present a risk to consumer health.

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Keywords: fludioxonil, sugar beets, bananas, fungicide, MRL, import tolerance, consumer risk assessment

Requestor: European Commission
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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in France (evaluating Member State, EMS) to set import tolerances for the active substance fludioxonil in sugar beet roots and bananas. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 19 July 2020. The EMS proposed to establish maximum residue levels (MRLs) for sugar beet roots imported from the USA at the level of 4 mg/kg and for bananas imported from Guatemala, Honduras and Colombia at the level of 2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements, which were requested from the EMS. On 04 August 2021 the EMS submitted a revised evaluation report, which replaced the previously submitted report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil, the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005, as well as the conclusions from previous EFSA opinions on fludioxonil and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fludioxonil was investigated in crops belonging to the groups of fruit crops (foliar treatment), root crops (foliar and seed treatments), leafy crops (foliar treatment), cereals (seed treatment), pulses/oilseeds (seed treatment).

As the proposed uses of fludioxonil are for post-harvest application of imported crops, investigations of residues in rotational crops are not required.

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

Based on the metabolic pattern identified in metabolism studies and hydrolysis studies, the residue definitions for plant products were proposed as ‘fludioxonil’ for enforcement and ‘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. These residue definitions are applicable to primary crops, rotational crops and processed products and all types of application, including post-harvest.

EFSA concluded that for the commodities assessed in this application, the metabolism of fludioxonil and the possible degradation in processed products have 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 the limit of quantification (LOQ) of 0.01 mg/kg in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 4 and 2 mg/kg for sugar beet roots and bananas respectively.

Specific studies investigating the magnitude of fludioxonil residues in processed commodities are not required, considering the low individual contribution of residues in the commodities under assessment to the total chronic consumer exposure.

As the crops under consideration and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal groups. Therefore, the possible occurrence of fludioxonil residues in commodities of animal origin was investigated. The nature of fludioxonil residues in livestock has been investigated during the EU pesticides peer review of fludioxonil and the MRL review and the residue definitions both for enforcement and risk assessment were proposed as ‘sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic moiety, expressed as fludioxonil’. These are also the residue definitions used by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to set Codex MRLs (CXLs) on commodities of animal origin. Updated calculations of the MRLs for all animal tissues and products confirmed that modifications of the current MRLs in animal commodities which are set on the basis of the CXLs are not triggered.

The toxicological profile of fludioxonil was assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.37 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.
The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The highest estimated long-term dietary intake accounted for 22% of the ADI (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure were 2.53% of the ADI (NL child diet) for sugar beet roots and 0.03% of the ADI (NL toddler diet) for bananas. An acute exposure calculation was not required since for the active substance no ARfD has been derived.

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

As the procedure for the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendix B.

| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------|------------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 163020      | Bananas          | 0.01*                   | 2                       | The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely. |
| 900010      | Sugar beet roots | 0.01*                   | 4                       | The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely. |

MRL: maximum residue level.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{(F)}\): Fat soluble.
Table of contents

Abstract ................................................................................................................................................... 1
Summary ................................................................................................................................................. 3
Assessment ........................................................................................................................................... 6
1. Residues in plants .......................................................................................................................... 7
  1.1. Nature of residues and methods of analysis in plants ................................................................. 7
  1.1.1. Nature of residues in primary crops .......................................................................................... 7
  1.1.2. Nature of residues in rotational crops ...................................................................................... 8
  1.1.3. Nature of residues in processed commodities ........................................................................... 8
  1.1.4. Methods of analysis in plants ................................................................................................... 8
  1.1.5. Storage stability of residues in plants ....................................................................................... 8
  1.1.6. Proposed residue definitions .................................................................................................... 8
  1.2. Magnitude of residues in plants .................................................................................................. 9
  1.2.1. Magnitude of residues in primary crops .................................................................................... 9
  1.2.2. Magnitude of residues in rotational crops ................................................................................ 9
  1.2.3. Magnitude of residues in processed commodities ................................................................... 9
  1.2.4. Proposed MRLs ....................................................................................................................... 10
2. Residues in livestock ....................................................................................................................... 10
  2.1. Nature of residues and methods of analysis in livestock ............................................................ 10
  2.2. Magnitude of residues in livestock ............................................................................................. 11
3. Consumer risk assessment .............................................................................................................. 11
4. Conclusion and Recommendations ............................................................................................... 12
References ............................................................................................................................................... 12
Abbreviations ........................................................................................................................................... 14
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs .................... 16
Appendix B – List of end points ............................................................................................................ 20
Appendix C – Pesticide Residue Intake Model (PRIMo) ..................................................................... 30
Appendix D – Input values for the exposure calculations ................................................................... 32
Appendix E – Used compound codes ............................................................................................... 38
**Assessment**

The European Food Safety Authority (EFSA) received an application to set import tolerances for fludioxonil in sugar beet roots and bananas. The detailed description of the existing uses of fludioxonil authorised in the USA in sugar beet roots and in Guatemala, Honduras and Colombia in bananas, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

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

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

The EU MRLs for fludioxonil are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011a) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA issued several reasoned opinions on the modification of MRLs for fludioxonil. The proposals from these reasoned opinions have been considered in recent MRL regulations.4 The evaluation of the confirmatory data following the MRL review under Article 12 of Regulation (EC) No 396/2005 has been recently completed (EFSA, 2019d) and the MRL proposals were implemented in the Commission Regulation (EU) 2020/16335; it is noted that for various commodities of animal origin the implemented MRLs were different than EFSA proposals and were based on the risk management decision. In addition, EFSA recently assessed the MRL application on the modification of fludioxonil MRL in blueberries, cranberries, gooseberries and currants (EFSA, 2021). MRL proposals have been taken over by a draft Regulation (SANTE/10518/2021) but are not yet applicable.

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in France (evaluating Member State, EMS) to set import tolerances for the active substance fludioxonil in sugar beet roots and bananas. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 19 July 2020. The EMS proposed to establish MRLs for sugar beet roots imported from the USA at the level of 4 mg/kg and for bananas imported from Guatemala, Honduras and Colombia at the level of 2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements, which were requested from the EMS. On 04 August 2021 the EMS submitted a revised evaluation report (France, 2020), which replaced the previously submitted report.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2020), the DAR and its addendum (Denmark, 2005, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on fludioxonil (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil (EFSA, 2007), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011a), as

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2007/76/EC of 20 December 2007 amending Council Directive 91/414/EEC to include fludioxonil, clomazone and prosulfocarb as active substances OJ L 337, 21.12.2007, p. 100–104.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
5 Commission Regulation (EU) 2020/1633 of 27 October 2020 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and tebufenozide in or on certain products. OJ L 367/1, 5.11.2020, p. 1–38.
well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2011b, 2012, 2013a, 2016a,b, 2019b,d,e, 2020a,b, 2021) and scientific reports (EFSA, 2013b, 2014, 2019c).

For this application, the data requirements established in Regulation (EU) No 544/20116 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, 2017a,b; 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 546/20117.

As the procedure for the renewal of the approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

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

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fludioxonil in primary crops was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2007, 2011a).

Metabolism of fludioxonil was investigated for foliar application on fruits and fruiting vegetables (grapes, peaches, tomatoes), on leafy vegetables (lettuces) and on root and tuber vegetables (spring onions) and was considered as qualitatively similar in all of them. However, compared to other crop groups, the metabolism was more extensive in root vegetables (spring onions), where fludioxonil was detected for a maximum of 31% total radioactive residue (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.

Metabolism studies following seed treatment were performed in root and tuber vegetables (potatoes), pulses and oilseeds (cotton and soybeans) and cereals (wheat, rice). In these studies, the uptake and translocation of fludioxonil was low (EFSA, 2007, 2011a).

For cereals (seed treatment), fruits and leafy vegetables, a conversion factor (CF) of 1 was derived, which gave an indication that no significant concentrations of metabolites containing the 2,2–difluorobenzo[1,3]dioxole-4 carboxylic moiety are expected (EFSA, 2011a). For root crops following foliar treatment, a CF of 2.8 from enforcement to risk assessment was proposed by the MRL review (EFSA, 2011a), based on the metabolism study in spring onions. The application of the CF of 2.8 was also proposed for some oilseeds in the context of a recent MRL application on certain oilseeds (EFSA, 2020a).

No studies investigating the metabolism of fludioxonil following post-harvest treatment are available. However, as a more extensive metabolism of the active substance is not expected in the post-harvest use, EFSA concluded that for all plant commodities and all types of application, the same residue definitions as established by the peer review apply (EFSA, 2011a).

In addition, for post-harvest uses, it was concluded that residues of CGA 192155, included in the residue definition for risk assessment, are not expected to be present in significant concentrations, and that a conversion factor is therefore unnecessary (CF = 1) (EFSA, 2011a).

For the uses under assessment, the metabolic behaviour is sufficiently addressed.

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6 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.

7 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.
1.1.2. Nature of residues in rotational crops

As the proposed uses of fludioxonil are for post-harvest application, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

In the framework of the EU pesticides peer review and the MRL review (EFSA, 2007, 2011a), the effect of processing on the nature of fludioxonil residues was investigated under standard hydrolysis conditions, indicating that fludioxonil is hydrolytically stable under the representative processing conditions of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fludioxonil residues were assessed during the EU pesticides peer review and further discussed in the MRL review (EFSA, 2007, 2011a). The multiresidue DFG S19 method using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is sufficiently validated for the determination of fludioxonil with an limit of quantification (LOQ) of 0.01 mg/kg in high oil (avocados), high acid (kiwis, citrus fruits) and dry/high starch content (wheat grain) commodities (EFSA, 2011a).

The multi-residue QuEChERS method using HPLC-MS/MS was also validated for the determination of residues of fludioxonil in high water and high acid content commodities with an LOQ of 0.01 mg/kg (EFSA, 2011a).

Sugar beet root and banana belong to high water content commodity group; therefore, sufficiently validated analytical methods are available for the determination of residues of fludioxonil in the plant commodities under consideration.

EFSA notes that the extraction efficiency of the analytical methods proposed for enforcement was not proven as indicated according to the requirements of the extraction efficiency Technical Guideline (European Commission, 2017b). EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

The storage stability of fludioxonil in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and MRL review (EFSA, 2007, 2011a). It was demonstrated that fludioxonil is stable for up to 24 months in commodities of high water, high acid and high oil content, as well as in dry/high starch content commodities and other matrices (straw, corn meal, sorghum hay) when stored frozen at or below –16°C.

1.1.6. Proposed residue definitions

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

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

These residue definitions are applicable to primary crops, rotational crops and processed products and all types of application, including post-harvest. The current residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the EU pesticides peer review and the MRL review.

Taking into account the uses assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application for import tolerance, the applicant submitted residue trials performed in sugar beet roots and bananas.

A total of six residue trials were conducted on sugar beet roots during 2015 in the USA. Each trial consisted of one post-harvest treatment, in which spray was applied directly to the sugar beet roots at an application rate of 4.66 g fludioxonil/1,000 kg roots, according to the authorised US Good Agricultural Practice (GAP).

A total of six residue trials were conducted on bananas during 2017 in Ecuador. Each trial consisted of two post-harvest treatment regimes, either a spray or a dip application. Spray applications were performed using a knapsack sprayer calibrated to apply a nominal rate of 13.2 mL of test solution per kilogram of fruit, equivalent to an application rate of 2.64 mg a.s./kg fruit. Dip applications were performed by dipping the fruit into a water mixture containing 20 g a.s./100 L of water for a period of 30 seconds. A complete data set was available for each treatment regime (spray and dip application) and indicated that both treatment regimens give similar results. The trials were compliant with the GAPs authorised in Guatemala, Honduras and Columbia.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. The method used in the analysis of samples in the context of the residue trials is based on liquid chromatography with tandem mass spectrometry (LC-MS/MS). According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (France, 2020). It is acknowledged that the efficiency of the extraction of the analytical method used in the residue trials was not investigated according to the Technical Guideline (European Commission, 2017b), therefore uncertainties on the validity of measurements cannot be excluded.

The samples were analysed for the parent compound included in the residue definitions for enforcement (fludioxonil only). Information on residues of CGA 192155, included in the residue definition for risk assessment, was not provided. This data gap is considered a minor deficiency, as it was concluded that residues of this metabolite are not expected to be present in significant concentrations following post-harvest use and that a conversion factor is therefore unnecessary (CF = 1) (EFSA, 2011a).

Residues in sugar beet tops have not been investigated in the present application, as these commodities are not relevant for post-harvest use and not relevant for import.

The number of trials is sufficient to derive import tolerance MRLs for fludioxonil in sugar beet roots and bananas. The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current application, as the proposed uses of fludioxonil are for post-harvest application.

1.2.3. Magnitude of residues in processed commodities

Only one processing study on sugar beet roots was submitted in the framework of the present MRL application. The study was not considered valid, as the analytical method used is not validated due to an insufficient number of replicates per fortification level (France, 2020).

As a sufficient number of processing studies is not available, it was not possible to derive reliable processing factors (PFs). Default PF for sugar beet by-products have been considered for dietary burden calculation (see Section 2).

No processing studies on bananas were submitted in the framework of the present MRL application. However, the residue data submitted by the applicant (data on whole fruit and pulp) were sufficient to derive peeling factors (see Section B.1.2.3). These data indicate that after the post-harvest treatment

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8 Application rate originally expressed as 0.0093 lb fludioxonil per 2,000 lb sugar beet roots, corresponding to 4.22 g fludioxonil per 907.19 kg sugar beet roots and 4.66 g fludioxonil per 1000 kg sugar beet roots.

9 The test solution was prepared adding 84 mL of GRADUATE® (239 g fludioxonil/L product) in 100 L of water. This results in a concentration of 20 g fludioxonil/L. Spray applications of 13.2 mL of test solution per kilogram of fruit correspond to 2.64 mg fludioxonil per kilogram of fruit.
under assessment, most of the residues remain on the peel part of the fruits. Therefore, a significant reduction of the residue concentration is expected by peeling.

Further processing studies on sugar beet roots and bananas are not required, since, considering the low individual contribution of residues in the commodities under assessment to the total chronic consumer exposure (2.53% and 0.03% of the acceptable daily intake (ADI), respectively), such results would not be expected to affect the outcome of the risk assessment (see Section 3).

It is noted that, for sugar beet root processed commodities (e.g. refined sugar) it was not possible to derive robust processing factors and therefore they are not available for inclusion in Annex VI of Regulation (EC) No 396/2005. If risk managers wish to derive robust processing factors, which allow enforcement of fludioxonil residues in imported processed commodities of sugar beet root, further processing trials would be required.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 3 EFSA assessed whether residues on these crops resulting from the uses authorised in the USA, Guatemala, Honduras and Columbia are likely to pose a consumer health risk.

2. Residues in livestock

By-products of sugar beets may be used for feed purposes. Hence, it was necessary to update the previous dietary burden calculations for livestock (EFSA, 2020a), including sugar beet and its by-products under assessment, in order to evaluate whether the new uses would trigger a modification of the MRLs for food of animal origin.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The default PFs were used to estimate the residue concentration in sugar beet dried pulp, ensiled pulp and molasses. The results of the dietary burden calculation are presented in Appendix B.2.

The exposure exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all animal groups considered. Compared to the calculations performed in the previous assessment (EFSA, 2020a), a significant increase of the dietary burden is only observed in sheep (5.60–11.62 mg/kg DM). This increase can be attributed to the inclusion of sugar beet dried pulp as new feed item which was not considered in the previous assessment.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in livestock, conducted in lactating goats and laying hens, have been assessed previously in the framework of the EU pesticides peer review and MRL review (EFSA, 2007, 2011a). The following residue definition was derived: 'sum of fludioxonil and all metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic moiety, expressed as fludioxonil' both for enforcement and risk assessment. This is also the residue definition used by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to set Codex MRLs (CXLs) on commodities of animal origin. The active substance is considered fat-soluble.

Methods of analysis for products of animal origin have been assessed by EFSA during the EU pesticides peer review and were considered as sufficiently validated for the determination of the sum of fludioxonil and its metabolites that can be oxidised to metabolite CGA 192155 (2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid), expressed as fludioxonil, with an LOQ of 0.01 mg/kg in milk and muscle and a LOQ of 0.05 mg/kg in liver, kidney, fat and eggs (EFSA, 2007, 2011a).

The storage stability of fludioxonil in commodities of animal origin was investigated in the framework of the EU pesticides peer review (EFSA, 2007). Studies demonstrated storage stability of fludioxonil in milk, eggs, beef muscle and liver for up to 12 months when stored at −16°C. Storage stability of metabolites determined as 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155) was not demonstrated but considering that the residue definition is based on a common moiety obtained after oxidation of the extracts, it is unlikely that the residue will hydrolyse even further (EFSA, 2011a).
2.2. Magnitude of residues in livestock

No feeding studies are available for poultry. However, these are not relevant in the context of this import tolerance as neither sugar beet roots nor bananas are fed to poultry according to the current feedstuff tables (OECD, 2013).

The impact of sugar beet by-products (dried pulp, ensiled pulp, molasses) as potential feed items was assessed in an updated calculation of the animal dietary burden, which resulted in a significant increase of exposure only for sheep, compared to the exposure calculated in the previous assessment (EFSA, 2020a). A feeding study with lactating cows was assessed during the EU peer review and considered during the MRL review (EFSA, 2007, 2011a).

EFSA assessed whether the current MRL values for animal commodities (taken from Codex MRLs) are still applicable when considering the updated calculations. The results of the calculations are presented in Section B.2.2. Based on the updated calculations, higher residues compared to the estimates from the previous assessment (EFSA, 2020a) are expected in sheep liver, kidney and milk (up to a potential MRL of 0.05 mg/kg for sheep liver and kidney and 0.04 mg/kg for sheep milk). However, this is covered by the MRLs that are currently in place for liver, kidney, edible offals and milk of all ruminants (0.1 mg/kg for liver, kidney and edible offals of all animal groups and 0.04 mg/kg for milk), which reflect the CXLs derived by the JMPR (FAO, 2019) on the basis of higher livestock dietary burdens. Consequently, the current assessment does not trigger any modifications of the current MRLs in sheep or any other ruminant commodities.

It is therefore concluded that modifications of the current MRLs in animal commodities are not triggered by the current assessment.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference value (TRV) for fludioxonil used in the risk assessment (i.e. ADI of 0.37 mg/kg body weight (bw) per day) was derived in the framework of the EU pesticides peer review (European Commission, 2007).

Short-term (acute) dietary risk assessment

Considering the toxicological profile of the active substance, a short-term dietary risk assessment was not required (EFSA, 2007; European Commission, 2007).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2011a). EFSA updated the calculations with the relevant STMR values derived from the residue trials submitted in support of this MRL application for sugar beet roots and bananas. For bananas, the highest STMR value between the two GAPs under assessment was selected for the exposure assessment. The selected value is the STMR-pulp, derived from residues measured in edible portion (pulp) of samples treated with dip post-harvest application.

In addition, STMRs derived in EFSA opinions published after the MRL review (EFSA, 2011b, 2012, 2013a, 2014, 2016a,b, 2019b,d,e, 2020a,b, 2021) and, where relevant, in the evaluations by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) were selected as input values (FAO, 2013, 2014, 2019).

For the assessed commodities (post-harvest treatment), cereals (seed treatment), fruits, fruitsing and leafy vegetables and pulses, the conversion factor of 1 between residue definitions for enforcement and risk assessment was applied to reflect the fact that no significant concentrations of metabolites containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety are expected (EFSA, 2011a).

For root and bulb crops (foliar treatment) and some oilseeds (linseeds, sesame seeds, rapeseeds, mustard seeds, borage seeds, gold of pleasure seeds and hemp seeds), the conversion factor of 2.8 (derived from the metabolism study on spring onions) was applied to recalculate residues according to the residue definition for risk assessment (EFSA, 2011a, EFSA, 2020a).

This approach was also applied to the risk assessment values derived from the JMPR.

The input values used in the exposure calculations are summarised in Appendix D.2.

The highest estimated long-term dietary intake accounted for a maximum of 22% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in this application to
the overall long-term exposure are 0.03% of ADI (NL toddler diet) for bananas and 2.53% of ADI (NL child diet) for sugar beet roots (see Appendix B.3).

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

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive MRL proposals for bananas and sugar beet roots. A modification of the previously proposed MRLs for commodities of animal origin was not triggered. Hence, the MRL proposals derived in previous EFSA outputs are still valid.

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

EFSA noted that the MRL derived for this import tolerance is on raw commodities. However, the import of sugar beet commodities might also include processed commodities such as refined sugar. In the absence of a robust PF for inclusion in Annex VI in view of monitoring of residues in these commodities, the enforcement of fludioxonil residues in the imported processed commodities is uncertain. Therefore, although an MRL proposal can be derived in the present opinion, risk managers may require additional data on the effect of processing on the magnitude of residues in refined sugar and sugar beet root by-products (e.g. molasses, dried pulp, ensiled pulp) in order to derive a robust PF for Annex VI in view of monitoring of residues in imported commodities.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

- a.s.: active substance
- ADI: acceptable daily intake
- AR: applied radioactivity
- ARF: acute reference dose
- BBCH: growth stages of mono- and dicotyledonous plants
- bw: body weight
- CAC: Codex Alimentarius Commission
- CAS: Chemical Abstract Service
- CCPR: Codex Committee on Pesticide Residues
- CF: conversion factor for enforcement to risk assessment residue definition
- CXL: Codex maximum residue limit
- DAR: draft assessment report
- DAT: days after treatment
- DM: dry matter
- EMS: evaluating Member State
- EURL: EU Reference Laboratory (former Community Reference Laboratory (CRL))
- FAO: Food and Agriculture Organization of the United Nations
- GAP: Good Agricultural Practice
- HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry
- HPLC-UVD: high performance liquid chromatography with ultra-violet detector
- HR: highest residue
- IEDI: international estimated daily intake
- ILV: independent laboratory validation
- ISO: International Organisation for Standardisation
- IUPAC: International Union of Pure and Applied Chemistry
- JMPR: Joint FAO/WHO Meeting on Pesticide Residues
- LC: liquid chromatography
- LOQ: limit of quantification
- MRL: maximum residue level
- MS: Member States
- NEU: northern Europe
OECD  Organisation for Economic Co-operation and Development  
PBI    plant-back interval  
PF    processing factor  
PHI    preharvest interval  
P<sub>ow</sub>    partition coefficient between n-octanol and water  
PRIMO    (EFSA) Pesticide Residues Intake Model  
QuEChERS    Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)  
RA    risk assessment  
RAC    raw agricultural commodity  
RD    residue definition  
RMS    rapporteur Member State  
RPF    relative potency factor  
SANCO    Directorate-General for Health and Consumers  
SC    suspension concentrate  
SEU    southern Europe  
STMR    supervised trials median residue  
TRR    total radioactive residue  
UV    ultraviolet (detector)  
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 | FG or I(2) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|-------------------------|-----------|-----------------------------------|-------------|------------|-------------------------------|--------------|---------|
| Sugar beet roots     | USA                     | I         | Fusarium spp., Botrytis spp., Penicillium spp., Rhizoctonia spp. | SC 239.4 (equivalent to 1.99 lb/gallon) | Post-harvest spray | n.r. 1 n.a. n.a. | 4.66 g a.s./1,000 kg roots | Direct spray to roots. 0.0093 lb fludioxonil per 2,000 lb sugar beet roots, corresponding to 4.22 g fludioxonil per 907.19 kg sugar beet roots and 4.66 g fludioxonil per 1,000 kg sugar beet roots |
| Crop and/or situation | NEU, SEU, MS or country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-----------|-----------------------------------|-------------|------------|-----------------------------|-------------|---------|
| Bananas               | Guatemala, Honduras I   | SC        | Colletotrichum musae, Fusarium semitectum, Fusarium roseum, Botryodiplodia theobromae | Type(b)     | Conc. a.s. (g/L) | Method kind | Range of growth stages and season(e) | Number min-max | Interval between application (days) min-max | g a.s./L min-max | Water (L/ha) min-max | Rate min-max | Unit | |
|                       |                         |           |                                    | SC 239.4 (equivalent to 1.99 lb/gallon) | Post-harvest spray (fruits are sprayed for 3–5 s) | n.r. | 1 | n.a. | Max: 20 | n.a. | 2.64 | mg a.s./kg fruits | 0 | 63–84 mL of product per L of water, where 84 mL of product (239 g/L of fludioxonil) is equivalent to 20 g fludioxonil per L of water. Spray applications of 13.2 mL of test solution per kg of fruit, corresponding to 2.64 mg fludioxonil per kg of fruit.
| Crop and/or situation | NEU, SEU, MS or country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------------------|-----------|-----------------------------------|-------------|-------------|-----------------------------|---------------|---------|
| Bananas               | Guatemala, Honduras       | I         | Colletotrichum musae, Fusarium semitectum, Fusarium roseum, Botryodiplodia theobromae | SC          | 239.4 (equivalent to 1.99 lb/gallon) | Post-harvest drench/dip | n.r.           | 1       | n.a.    | Max: 20 | 2.64 | mg a.s./kg fruits | 0       | 63–84 mL of product per hL of water, where 84 mL of product (239 g/L of fludioxonil) is equivalent to 20 g fludioxonil per hL of water. Applied at a rate of 2.64 mg fludioxonil per kilogram of fruit. |
| Crop and/or situation | NEU, SEU, MS or country | FG or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|---------|-----------------------------------|-------------|------------|-------------------------------|------------|
| Bananas               | Colombia (South America)| I       | Colletotrichum musae, Fusarium semitectum, Fusarium roseum, Botryodiplodia theobromae Verticillium sp., Gloeosporium musarum, Thielaviopsis paradoxa, Ceratocystis paradoxa sp, Botryodiplodia theobromae | SC          | 239.4 (equivalent to 1.99 lb/gallon) | Post-harvest spray (fruits are sprayed for 3-5 s) | n.r. | 1 | n.a. | Max: 20 | n.a. | 2.64 mg a.s./kg fruits | 0 | 63-84 mL of product per L of water, where 84 mL of product (239 g/L of fludioxonil) is equivalent to 20 g fludioxonil per L of water. Spray applications of 13.2 mL of test solution per kilogram of fruit, corresponding to 2.64 mg fludioxonil per kilogram of fruit. |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; n.r.: not relevant; n.a.: not applicable; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s)       | Application(s)                          | Sampling (DAT) | Comment/Source                                                                 |
|----------------------------------|-------------|---------------|----------------------------------------|----------------|--------------------------------------------------------------------------------|
| Fruit crops                      | Grapes      | Foliar, 3 × 0.5 kg a.s./ha | 0, 14, 35 (maturity)                  | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007, 2011a) |
|                                  | Tomatoes    | Foliar, 3 × 0.75 kg a.s./ha | 0, 40                                  | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007)      |
|                                  | Peaches     | Foliar, 3 × 0.28 kg a.s./ha | 28                                     | Radiolabelling: [phenyl-U-14C] (EFSA, 2007)      |
|                                  |             | 3 × 2.8 kg a.s./ha | 28                                     |                                                     |
|                                  |             | 2.1 + 6.3 kg a.s./ha | 30, 114                                |                                                     |
| Root crops                       | Spring onions | Foliar, 0.6 + 0.9 kg a.s./ha | 0, 7, 14, 28                           | Radiolabelling: [phenyl-U-14C] (EFSA, 2011a)     |
|                                  | Potatoes    | Seed, 2.5 g a.s./100 kg seed | 0, 40, 71, 95                         | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |
| Leafy crops                      | Lettuces    | Foliar, 3 × 0.2 kg a.s./ha | 0, 6, 13                               | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |
|                                  |             | 3 × 0.6 kg a.s./ha         |                                        |                                                     |
| Cereals/grass                    | Rice        | Seed, 6.5 g a.s./100 kg seed | 0, 38, 76, 152                      | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |
|                                  | Wheat       | Seed, 3.9 – 7.4 g a.s./100 kg seed | 48, 83, 106                         | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |
| Pulses/oilseeds                  | Cotton      | Seed, 2.5 or 5 g a.s./100 kg seed | 186                               | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |
|                                  | Soybean     | Seed, 5 g a.s./100 kg seed  | 28, 38, 133                           | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a)    |

| Rotational crops (available studies) | Crop groups | Crop(s)       | Application(s)                          | PBI (DAT) | Comment/Source                                                                 |
|-------------------------------------|-------------|---------------|----------------------------------------|-----------|--------------------------------------------------------------------------------|
| Root/tuber crops                    | Sugar beets | 0.75 kg a.s./ha | 140, 320, 345                          | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|                                    | Turnips     | 0.124 kg a.s./ha | 33, 90                                | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|                                    | Radishes    | 0.062 kg a.s./ha | 32, 90                                | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|                                    |             | 1.117 kg a.s./ha | 30, 90, 210                           | Radiolabelling: [phenyl-14C] (EFSA, 2007, 2011a)  |
| Leafy crops                        | Lettuces    | 0.75 kg a.s./ha | 90                                    | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
| Pulses and oilseeds                | Mustards    | 0.124 kg a.s./ha | 33, 90                                | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|                                    |             | 0.062 kg a.s./ha | 32, 90                                |                                                     |
|                                    |             | 1.117 kg a.s./ha | 30, 90, 210                           |                                                     |
| Cereals (small grain)              | Winter wheat | 0.75 kg a.s./ha | 140, 320, 345                          | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|                                    | Spring wheat| 0.124 kg a.s./ha | 33, 90                                | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a)  |
|                                    |             | 0.062 kg a.s./ha | 32, 90                                |                                                     |
Rotational crops (available studies)

| Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------|---------|----------------|-----------|----------------|
|             |         |                | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|             | Corn    |                | 0.75 kg a.s./ha | 140, 320, 345 | Radiolabelling: [phenyl-14C] (EFSA, 2007, 2011a) |

Processed commodities (hydrolysis study)

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

Can a general residue definition be proposed for primary crops? Yes EFSA (2011a)
Rotational crop and primary crop metabolism similar? Yes EFSA (2011a)
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes EFSA (2011a)
Plant residue definition for monitoring (RD-Mo) 
Plant residue definition for risk assessment (RD-RA) 
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  
Matrices with high oil content, high acid content and dry matrices: DFG S19 using HPLC–MS/MS, LOQ 0.01 mg/kg. Confirmatory method available. ILV available.  
Matrices with high water and high acid content: QuEChERS method using HPLC–MS/MS, LOQ of 0.01 mg/kg. (EFSA, 2011a, 2012)  

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

No studies investigating the metabolism of fludioxonil following post-harvest treatment are available. However, as a more extensive metabolism of the active substance is not expected in the post-harvest use, the same residue definitions apply (EFSA, 2011a)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------|-------------------|----------------|
|                                   | High water content | Tomato, apples, peas | -18 | 24 Months | Fludioxonil | EFSA (2007) |
|                                   |          | Maize forage | -20 | 24 Months | Fludioxonil | EFSA (2007) |
|                                   |          | Potato tubers | -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) |
|                                   | High acid content | Grapes | < -20 | 24 Months | Fludioxonil | EFSA (2011a) |
|                                   | Others | Cereal straw | -16 | 24 Months | Fludioxonil | EFSA (2007) |
|                                   |          | Corn meal | -20 | 24 Months | Fludioxonil | EFSA (2007) |
|                                   |          | Sorghum hay | -20 | 24 Months | Fludioxonil | EFSA (2007) |
### B.1.2. Magnitude of residues in plants

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

| Commodity       | Region(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) |
|-----------------|----------------------------|---------------------------------------------------------------|--------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Sugar beet roots| USA; Post-harvest (spray)  | 0.64; 0.90; 0.96; 1.25; 1.65; 1.90                              | Residue trials on sugar beet roots compliant with GAP.       | 4                      | 1.90          | 1.11            | 1     |
|                 | Ecuador; Post-harvest (spray) | Whole fruit: 0.58; 0.77; 0.82; 0.93; 1.15; 1.18 Pulp: < 0.01; 3 × 0.01; 0.015; 0.02 | Residue trials on bananas compliant with GAP.               |                        |               |                 |       |
|                 | Ecuador; Post-harvest (dip)  | Whole fruit: 0.65; 0.68; 0.70; 0.84; 1.06; 1.16 Pulp: 0.01; 2 × 0.015; 2 × 0.02; 0.025 | Residue trials on bananas compliant with GAP.               |                        |               |                 |       |

**Monitoring residue definition:** fludioxonil

**Risk assessment residue definition:** sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluorobenzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil

MRL: maximum residue level; GAP: Good Agricultural Practice.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue.

(c): Supervised trials median residue.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. The conversion factor was considered unnecessary (CF = 1) as residues of the metabolite CGA 192155, included in the residue definition for risk assessment, are not expected to be present in significant concentrations following post-harvest use (EFSA, 2011a).
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

| Residues expected | Occurrence | Nature and magnitude of residues in succeeding crops |
|-------------------|------------|-----------------------------------------------------|
| No                | Based on the available information, significant residue levels are unlikely to occur. |

For the current assessment residues in rotational crops are not relevant since the GAPs under consideration are post-harvest applications.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies | Processing Factor (PF) | CF<sub>r</sub> | Comment/Source |
|---------------------|-------------------------|------------------------|---------------|----------------|
|                     | a)                      | Individual values | Median PF |              |
| Banana, peeling factor (banana pulp/whole fruit) | 6 | 4 × 0.01; 0.02; 0.03 | 0.01 | n.a. | Samples treated with spray application (France, 2020). |
| Banana, peeling factor (banana pulp/whole fruit) | 6 | 0.01; 4 × 0.02; 0.03 | 0.02 | n.a. | Samples treated with dip application (France, 2020). |

PF: processing factor; n.a: not applicable.
(a): Studies with residues in the raw agricultural commodities (RAC) at or close to the limit of quantification (LOQ) were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

No valid processing studies on sugar beet root were submitted in the framework of the present MRL application (France, 2020).

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

| Relevant groups (sub groups) | Dietary burden expressed in mg/kg bw per day | mg/kg DM | Most critical subgroup | Most critical commodity | Trigger exceeded (Y/N) 0.10 mg/kg DM | Previous assessment (EFSA, 2020a) Maximum burden mg/kg DM |
|-----------------------------|---------------------------------------------|----------|------------------------|-------------------------|---------------------------------------|-----------------------------------------------------------|
| Cattle (all diets)          | Median 0.397 Maximum 0.415                  | Median 10.33 Maximum 10.79 | Dairy cattle | Beet, sugar (ensiled pulp) | Y | 10.69 |
| Cattle (dairy only)         | Median 0.397 Maximum 0.415                  | Median 10.33 Maximum 10.79 | Dairy cattle | Beet, sugar (ensiled pulp) | Y | 10.69 |
| Sheep (all)                 | Median 0.468 Maximum 0.494                 | Median 11.01 Maximum 11.62 | Lamb | Beet, sugar (dried pulp) | Y | 5.60 |
| Sheep (ewe only)            | Median 0.166 Maximum 0.387                 | Median 4.99 Maximum 11.62 | Ram/Ewe | Beet, sugar (dried pulp) | Y | 5.60 |
### Relevant groups (subgroups)

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) | Previous assessment (EFSA, 2020a) Maximum burden mg/kg DM |
|-----------------------------|-----------------------------|---------------------------|---------------------------|------------------------|----------------------------------------------------------|
|                             | mg/kg bw per day            | mg/kg DM                  |                           |                        |                                                          |
|                             | Median | Maximum | Median | Maximum |                           |                                                          |
| Swine (all diets)           | 0.208  | 0.231   | 8.99   | 9.74     | Swine (finishing)        | Beet, sugar (dried pulp)   | Y                              | 9.74                     |
| Poultry (all diets)         | 0.080  | 0.102   | 1.14   | 1.44     | Poultry broiler         | Carrot (culls)             | Y                              | 1.44                     |
| Poultry (layer only)        | 0.075  | 0.096   | 1.10   | 1.40     | Poultry layer           | Carrot (culls)             | Y                              | 1.40                     |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry “all” including broiler, layer and turkey), the result of the most critical subgroup 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-4-14C]-Fludioxonil, 5 hens (EFSA, 2011a)                               |
|                               | Lactating ruminants | 3.5                  | 4               | [pyrrole-4-14C]-Fludioxonil, 2 Goats (EFSA, 2011a)                              |
|                               | Pig            |                         |                 |                                                                                  |
|                               | Fish           |                         |                 |                                                                                  |

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, 2011a)

Animal residue definition for monitoring (RD-Mo)
- Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil (EFSA, 2011a)
- Reg. (EU) 396/2005: Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (N.B. EFSA recommends aligning the wording of the residue definition in the MRL legislation with the recommendation of EFSA, 2011a)

Animal 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 (EFSA, 2011a)

Fat soluble residues
- Yes (EFSA, 2011a)

Methods of analysis for monitoring of residues
- Milk and muscle:
(analytical technique, matrix, LOQs) HPLC-UV, LOQ 0.01 mg/kg for the sum of fludioxonil and its metabolites that can be oxidised to metabolite CGA 192155\(^\text{11}\), expressed as fludioxonil. Confirmatory method available (analytical method confirmed by the use of an alternative column in the HPLC system). ILV available. (EFSA, 2011a)

Liver, kidney, fat and eggs:
HPLC-UV, LOQ 0.05 mg/kg for the sum of fludioxonil and its metabolites that can be oxidised to metabolite CGA 192155\(^\text{11}\), expressed as fludioxonil. Confirmatory method available. ILV available. (EFSA, 2011a)

bw: body weight; HPLC-UV: high-performance liquid chromatography with ultra-violet detector; LOQ: limit of quantification; ILV: independent laboratory validation.

### B.2.1.2. Stability of residues in livestock

#### Table: Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period Value Unit | Compounds covered\(^{\text{(a)}}\) | Comment/Source |
|-------------------------------------|--------|-----------|--------|---------------------------|--------------------------------|----------------|
|                                      | 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): Storage stability was performed with samples fortified with fludioxonil and analysed with a method which convert fludioxonil and its oxidisable metabolites into CGA 192155. The stability of metabolites determined as 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155) was not demonstrated but considering that the residue definition is based on a common moiety obtained after oxidation of the extracts, it is unlikely that the residue will hydrolyse even further (EFSA, 2011a).

### B.2.2. Magnitude of residues in livestock

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

Calculations performed with Animal model 2017\(^\text{12}\)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|-----------------------|----------------------|
|                  | Mean              | Highest                      | STMR\(^{\text{(a)}}\) (mg/kg) | HR\(^{\text{(b)}}\) (mg/kg) |                      |
| Cattle (all)     |                  |                                |                      |                      |                      |
| Closest feeding level (0.8 mg/kg bw; 1.9 N Dairy cattle (highest diet))\(^c\) |                  |                                |                      |                      |                      |
| Muscle           | 0.01             | 0.01                           | 0.01                 | 0.01                 | 0.01*                |
| Fat              | 0.01             | 0.01                           | 0.01                 | 0.01                 | 0.01*                |
| Liver            | 0.05             | 0.07                           | 0.04                 | 0.06                 | 0.06                 |
| Kidney           | 0.06             | 0.08                           | 0.05                 | 0.07                 | 0.07                 |
| Cattle (dairy only) |                  |                                |                      |                      |                      |
| Closest feeding level (0.8 mg/kg bw; 1.9 N Dairy cattle)\(^c\) |                  |                                |                      |                      |                      |
| Milk\(^d\)       | 0.08             | 0.29                           | 0.02                 | 0.02                 | 0.02                 |
| Sheep (all)\(^e\) |                  |                                |                      |                      |                      |
| Closest feeding level (0.8 mg/kg bw; 1.6 N Lamb (highest diet))\(^c\) |                  |                                |                      |                      |                      |

\(^{11}\) CGA 192155: 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid. See Appendix E.

\(^{12}\) [https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en](https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en)
### Animal commodity

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|----------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |           |
| Muscle           | 0.01 | 0.01    | 0.01                       | 0.01                     | 0.01*     |
| Fat              | 0.01 | 0.01    | 0.01                       | 0.01                     | 0.01*     |
| Liver            | 0.05 | 0.07    | 0.03                       | 0.04                     | 0.05      |
| Kidney           | 0.06 | 0.08    | 0.04                       | 0.05                     |           |

### Sheep (ewe only)<sup>(c)</sup>

Closest feeding level (0.8 mg/kg bw; 2.1 N Ewe)<sup>(c)</sup>

| Milk<sup>(d)</sup> | 0.08 | 0.15 | 0.02 | 0.04 | 0.04 |

### Swine (all)<sup>(e)</sup>

Closest feeding level (0.8 mg/kg bw; 3.5 N Finishing (highest diet))<sup>(c)</sup>

| Muscle           | 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
| Fat              | 0.01 | 0.01 | 0.00 | 0.00 | 0.01* |
| Liver            | 0.05 | 0.07 | 0.01 | 0.02 | 0.02  |
| Kidney           | 0.06 | 0.08 | 0.02 | 0.02 | 0.03  |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; bw: body weight.

*: Indicates that the MRL is proposed at the limit of quantification.

(a): The mean residue level for milk tissues were recalculated at the 1N rate for the median dietary burden.

(b): The high residue level in milk tissues, were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): Highest residue level from day 14 to day 28 (daily mean of 3 cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine commodities.
B.3. Consumer risk assessment

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

| Scenario | Value |
|----------|-------|
| ADI      | 0.37 mg/kg bw per day (European Commission, 2007) |
| Highest IEDI, according to EFSA PRIMO | 22% ADI (NL toddler diet) |

Contribution of crops assessed:
- Sugar beet roots: 2.53% of ADI (NL child diet)
- Bananas: 0.03% of ADI (NL toddler diet)

Assumptions made for the calculations
- Calculations were performed with PRIMo rev. 3.1.
- The calculation is based on the median residue levels (STMR values) of fludioxonil as derived from residue trials in bananas and sugar beet roots. For bananas, the highest STMR value between the two GAPs under assessment was selected for the exposure assessment. The selected value is the STMR-RACpulp, derived from residues measured in edible portion (pulp) of samples treated with dip post-harvest application.
- As residues of the metabolites included in the risk assessment residue definition are not expected to be present in significant concentrations following post-harvest use, a conversion factor (CF) to recalculate residues according to the residue definition for risk assessment is not necessary (CF= 1) (EFSA, 2011a).
- For the crops assessed in the MRL review and in reasoned opinions issued after the MRL review as well as for CXLs implemented in the EU legislation, the respective STMR values were used.
- For mangoes and cucurbits with inedible peel, the median residue refers to the edible part.
- For those commodities for which the existing EU MRLs is set on the basis of CXLs, the residue data according to the EU risk assessment residue definition are not available. However, this will not lead to an underestimation of residue levels, considering that, for those commodities, a CF of 1 was proposed to recalculate residues according to the residue definition for enforcement (same as JMPR residue definition for risk assessment) to EU residue definition for risk assessment.
- A CF of 2.8 (derived from metabolism study in spring onions) was used to recalculate residues according to the residue definition for risk assessment in root and bulb crops (EFSA, 2011a). The same CF was used for some oilseeds (linseeds, sesame seeds, rapeseeds, mustard seeds, borage seeds, gold of pleasure seeds and hemp seeds) in a recent application (EFSA, 2020a) and now applied for soybeans for reason of consistency.
- The contributions of commodities, where no GAP was reported in the framework of the MRL review (EFSA, 2011a), were not included in the calculation.

ARfD: acute reference dose; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; STMR-RAC: supervised trials median residue in raw agricultural commodity; CXL: codex maximum residue limit; MRL: maximum residue level.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity            | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|-------------------|----------------------|------------------------|-------------------------|------------------------------------------------------------|
| 163020            | Bananas              | 0.01*                  | 2                       | The submitted data are sufficient to derive an MRL proposal for Import Tolerance (Guatemala, Honduras, Columbia GAP). Risk for consumers unlikely. |
| 900010            | Sugar beet roots     | 0.01*                  | 4                       | The submitted data are sufficient to derive an MRL proposal for Import Tolerance (US GAP). Risk for consumers unlikely. |

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

MRIL: maximum residue level.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Fludioxonil (F)

#### Toxicological reference values

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD |
|------------------------|----------------|---------------|----------------|
| 0.37                   | not necessary  | EC            | EFSA PRIMo revision 3.1; 2019/03/19 |

#### Exposure resulting from Fludioxonil (F)

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

### Details – chronic risk assessment/children

#### Input values

- **Toxicological reference values**
  - ADI (mg/kg bw per day): 0.37
  - ARfD (mg/kg bw): not necessary

#### Details – acute risk assessment/children

#### Details – acute risk assessment/adults

#### Details – chronic risk assessment

#### Supplementary results – chronic risk assessment

#### Details – acute risk assessment

### Table: Calculated exposure (% of ADI)

| Commodity/group of commodities | % of ADI | Exposure (% of ADI) | Highest contributor (in % of ADI) | 2nd contributor (in % of ADI) | 3rd contributor (in % of ADI) |
|--------------------------------|----------|--------------------|-----------------------------------|------------------------------|------------------------------|
| Pears                          | 0.0%     | 22% (80.04 µg/kg)  | 6%                                | 3%                           | 2%                           |
| Potatoes                       | 0.0%     | 18% (68.35 µg/kg)  | 7%                                | 6%                           | 1%                           |
| Oranges                        | 0.0%     | 14% (50.75 µg/kg)  | 3%                                | 3%                           | 2%                           |
| Grapefruits                    | 0.0%     | 11% (39.83 µg/kg)  | 4%                                | 1%                           | 1.0%                         |
| Apples                         | 0.0%     | 10% (35.85 µg/kg)  | 5%                                | 1%                           | 1%                           |
| Mandarins                      | 0.0%     | 9% (31.86 µg/kg)   | 2%                                | 2%                           | 1%                           |
| Sugar beet roots               | 0.0%     | 8% (29.80 µg/kg)   | 3%                                | 1%                           | 1%                           |
| Lettuces                       | 0.0%     | 7% (26.72 µg/kg)   | 2%                                | 1%                           | 1%                           |
| Tomato                         | 0.0%     | 6% (23.65 µg/kg)   | 2%                                | 1%                           | 0.7%                         |
| Spinaches                      | 0.0%     | 5% (20.15 µg/kg)   | 2%                                | 1%                           | 0.4%                         |
| Apples                         | 0.0%     | 5% (20.02 µg/kg)   | 2%                                | 0.9%                         | 0.6%                         |
| Apples                         | 0.0%     | 5% (19.18 µg/kg)   | 1%                                | 1.0%                         | 0.6%                         |
| Carrots                        | 0.0%     | 5% (17.21 µg/kg)   | 2%                                | 0.8%                         | 0.5%                         |
| Apples                         | 0.0%     | 5% (17.10 µg/kg)   | 2%                                | 0.8%                         | 0.4%                         |
| Apples                         | 0.0%     | 5% (16.86 µg/kg)   | 2%                                | 0.6%                         | 0.5%                         |
| Apples                         | 0.0%     | 4% (15.54 µg/kg)   | 0.7%                              | 0.7%                         | 0.5%                         |
| Spinaches                      | 0.0%     | 4% (15.27 µg/kg)   | 1%                                | 0.9%                         | 0.4%                         |
| Spinaches                      | 0.0%     | 4% (15.04 µg/kg)   | 0.8%                              | 0.5%                         | 0.3%                         |
| Spinaches                      | 0.0%     | 4% (14.03 µg/kg)   | 2%                                | 0.5%                         | 0.3%                         |
| Apples                         | 0.0%     | 4% (13.10 µg/kg)   | 1%                                | 1%                           | 0.2%                         |
| Pears                          | 0.0%     | 3% (12.94 µg/kg)   | 1%                                | 0.6%                         | 0.3%                         |
| Potatoes                       | 0.0%     | 3% (12.10 µg/kg)   | 0.8%                              | 0.4%                         | 0.3%                         |
| Lettuces                       | 0.0%     | 3% (11.30 µg/kg)   | 1%                                | 1%                           | 0.1%                         |
| Potatoes                       | 0.0%     | 3% (10.12 µg/kg)   | 0.8%                              | 0.6%                         | 0.3%                         |
| Oranges                        | 0.0%     | 3% (9.34 µg/kg)    | 0.5%                              | 0.5%                         | 0.2%                         |
| Apples                         | 0.0%     | 2% (8.94 µg/kg)    | 0.6%                              | 0.5%                         | 0.3%                         |
| Apples                         | 0.0%     | 0.8% (2.98 µg/kg)  | 2%                                | 0%                           | 0.2%                         |

### Details – acute risk assessment

- **Fludioxonil (F)**
  - Toxicological reference values
    - ADI (mg/kg bw per day): 0.37
    - ARfD (mg/kg bw): not necessary

- **No of diets exceeding the ADI**: ---

- **Calculated exposure (% of ADI)**
  - **MS Diet**:
    - Exposure (% of ADI): 22% (80.04 µg/kg)
    - Calculated exposure (% of ADI): 22% (80.04 µg/kg)

- **Highest contributor (in % of ADI)**
  - Pears: 6%

- **2nd contributor (in % of ADI)**
  - Apples: 3%

- **3rd contributor (in % of ADI)**
  - Oranges: 2%

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

**Table: Acute risk assessment**

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

**Results for all crops**

|                                      |                                |                                |
|--------------------------------------|--------------------------------|--------------------------------|
|                                      | 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) |
|                                      |                                |                                |                        |                                |                                |                        |
|                                      |                                |                                |                        |                                |                                |                        |

**Conclusion:**

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

|                                      |                                |                                |
|--------------------------------------|--------------------------------|--------------------------------|
|                                      | Results for children            | Results for adults              |
|                                      | No of commodities for which ARfD/ADI is exceeded (IESTI): | No of commodities for which ARfD/ADI is exceeded (IESTI): |
|                                      |                                |                                |
|                                      |                                |                                |                        |                                |                                |                        |
|                                      |                                |                                |                        |                                |                                |                        |

**Processed commodities**

|                                      |                                |                                |
|--------------------------------------|--------------------------------|--------------------------------|
|                                      | 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) |
|                                      |                                |                                |                        |                                |                                |                        |
|                                      |                                |                                |                        |                                |                                |                        |

**Conclusion:**

No. of commodities for which ARfD/ADI is exceeded (IESTI):
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                    | Input value (mg/kg) | Comment                  | Input value (mg/kg) | Comment                  |
|-----------------------------------|---------------------|--------------------------|---------------------|--------------------------|
| **Modified commodities**          |                     |                          |                     |                          |
| Sugar beet, dried pulp            | 19.98               | Median residue (1.11 mg/kg) × CF (1) × default PF (18)<sup>a</sup> | 19.98               | Median residue (1.11 mg/kg) × CF (1) × default PF (18)<sup>a</sup> |
| Sugar beet, ensiled pulp          | 3.33                | Median residue (1.11 mg/kg) × CF (1) × default PF (3)<sup>a</sup> | 3.33                | Median residue (1.11 mg/kg) × CF (1) × default PF (3)<sup>a</sup> |
| Sugar beet, molasses              | 31.08               | Median residue (1.11 mg/kg) × CF (1) × default PF (28)<sup>a</sup> | 31.08               | Median residue (1.11 mg/kg) × CF (1) × default PF (28)<sup>a</sup> |
| **Unmodified commodities**        |                     |                          |                     |                          |
| Citrus, dried pulp                | 39.96               | Median residue (5.3 mg/kg) × PF (7.5) (EFSA, 2019d) | 39.96               | Median residue (5.3 mg/kg) × PF (7.5) (EFSA, 2019d) |
| Apple, wet pomace                 | 12.19               | Median residue (2.3 mg/kg) × PF (5.3) (EFSA, 2019d) | 12.19               | Median residue (2.3 mg/kg) × PF (5.3) (EFSA, 2019d) |
| Carrots, culls                    | 1.15                | Median residue (0.41 mg/kg) × CF (2.8) (EFSA, 2019d) | 1.51                | Highest residue (0.54 mg/kg) × CF (2.8) (EFSA, 2019d) |
| Wheat, rye grain                  | 0.01                | Median residue (EFSA, 2011a) | 0.1                 | Median residue (EFSA, 2011a) |
| Barley, oat grain                 | 0.01                | Median residue (EFSA, 2011a) | 0.01                | Median residue (EFSA, 2011a) |
| Maize, grain                      | 0.01                | Median residue (EFSA, 2011a) | 0.01                | Median residue (EFSA, 2011a) |
| Wheat, rye straw                  | 0.04                | Median residue (EFSA, 2011a) | 0.05                | Highest residue (EFSA, 2011a) |
| Barley, oat straw                 | 0.04                | Median residue (EFSA, 2011a) | 0.05                | Highest residue (EFSA, 2011a) |
| Peas, beans, lupins, cowpeas (dry)| 0.02                | Median residue (EFSA, 2011a) | 0.02                | Median residue (EFSA, 2011a) |
| Brewer’s grain                    | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Corn, milled by-products          | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Corn, hominy meal                 | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Corn, gluten feed                 | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Corn, gluten meal                 | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Distiller’s grain (dried)         | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.1                 | Median residue (EFSA, 2011a)<sup>b</sup> |
| Lupin seed, meal                  | 0.02                | Median residue (0.02 mg/kg) × default PF (1.1) (EFSA, 2011a)<sup>a</sup> | 0.02                | Median residue (0.02 mg/kg) × default PF (1.1) (EFSA, 2011a)<sup>a</sup> |
| Soybean, hulls                    | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Wheat gluten, meal                | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Wheat, milled by-products         | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> | 0.01                | Median residue (EFSA, 2011a)<sup>b</sup> |
| Potatoes, culls                   | 0.02                | Median residue (EFSA, 2011a) | 0.04                | Highest residue (EFSA, 2011a) |
| Potatoes, process waste           | 0.40                | Median residue (0.02 mg/kg) × default PF (20) (EFSA, 2011a)<sup>a</sup> | 0.40                | Median residue (0.02 mg/kg) × default PF (20) (EFSA, 2011a)<sup>a</sup> |

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**Risk assessment residue definition:** Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil.
### D.2. Consumer risk assessment

| Commodity                  | Existing/proposed MRL (mg/kg) | Source                          | Input value (mg/kg) | Chronic risk assessment | Comment                                      |
|----------------------------|-------------------------------|--------------------------------|---------------------|-------------------------|-----------------------------------------------|
| Banana                     | 2 Proposed MRL                | EFSA (2011a)                   | 0.02                | STMR-RACpulp (edible portion)                      |
| Sugar beet roots           | 4 Proposed MRL                | EFSA (2011a)                   | 1.11                | STMR-RAC                        |
| Citrus fruits              | 10 EFSA (2011a)               | 5.3 STMR-RAC                   |
| Pistachios                 | 0.2 EFSA (2011a)              | 0.06 STMR-RAC                   |
| Pome fruits                | 5 EFSA (2011a)                | 2.1 STMR-RAC                   |
| Apricots                   | 5 EFSA (2011a)                | 1.06 STMR-RAC                   |
| Cherries (sweet)           | 5 EFSA (2011a)                | 0.8 STMR-RAC                   |
| Peaches                    | 10 EFSA (2011a)               | 3.65 STMR-RAC                   |
| Plums                      | 5 EFSA (2011a)                | 1.06 STMR-RAC                   |
| Table grapes               | 5 EFSA (2011a)                | 0.38 STMR-RAC                   |
| Wine grapes                | 4 EFSA (2011a)                | 0.33 STMR-RAC                   |
| Strawberries               | 4 EFSA (2019d)                | 0.31 STMR-RAC                   |
| Cane fruits                | 5 EFSA (2011a)                | 1 STMR-RAC                      |
| Blueberries                | 4 EFSA (2021)                 | 0.93 STMR-RAC                   |
| Cranberries                | 4 EFSA (2021)                 | 0.93 STMR-RAC                   |
| Currants (red, black and white) | 4 EFSA (2021)                 | 0.93 STMR-RAC                   |
| Gooseberries (green, red and yellow) | 4 EFSA (2021)                 | 0.93 STMR-RAC                   |
| Elderberries               | 4 EFSA (2020b)                | 0.62 STMR-RAC                   |
| Kiwi fruits (green, red, yellow) | 15 EFSA (2011a)               | 7.3 STMR-RAC                    |
| Commodity                        | Existing/proposed MRL (mg/kg) | Source                  | Input value (mg/kg) | Comment                                      |
|---------------------------------|-------------------------------|-------------------------|---------------------|----------------------------------------------|
| Avocados                        | 1.5                           | FAO (2019)              | 0.50                | STMR-RAC (whole fruit)$^{b,d}$               |
| Mangoes                         | 2                             | FAO (2013)              | 0.02                | STMR-RAC$_{pulp}$ (edible portion)$^{b}$     |
| Granate apples/pomegranates     | 3                             | EFSA (2011a)            | 0.95                | STMR-RAC                                     |
| Guavas                          | 0.5                           | FAO (2019)              | 0.125               | STMR-RAC                                     |
| Pineapples                      | 7                             | EFSA (2016a)            | 2.14                | STMR-RAC                                     |
| Potatoes                        | 5                             | FAO (2014)              | 1.5                 | STMR-RAC$^{(b)}$                             |
| Sweet potatoes                  | 10                            | EFSA (2011a)            | 3.76                | STMR-RAC                                     |
| Yams                            | 10                            | EFSA (2011a)            | 3.76                | STMR-RAC                                     |
| Beetrootsin                     | 1                             | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Carrots                         | 1                             | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Celeriacs/turnip rooted celeries| 0.2                           | EFSA (2011a)            | 0.20                | STMR-RAC (0.07 mg/kg) × CF (2.8)$^{(e)}$     |
| Horseradishes                   | 1                             | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Parsnips                        | 1                             | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Parsley roots/Hamburg roots parsley | 1                           | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Radishes                        | 0.3                           | FAO (2014)              | 0.17                | STMR-RAC (0.06 mg/kg) × CF (2.8)$^{(e)}$     |
| Salsifies                       | 1                             | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)$^{(e)}$     |
| Garlic                          | 0.5                           | FAO (2019)              | 0.11                | STMR-RAC (0.04 mg/kg) × CF (2.8)$^{(e)}$     |
| Onions                          | 0.5                           | FAO (2019)              | 0.11                | STMR-RAC (0.04 mg/kg) × CF (2.8)$^{(e)}$     |
| Shallots                        | 0.5                           | FAO (2019)              | 0.11                | STMR-RAC (0.04 mg/kg) × CF (2.8)$^{(e)}$     |
| Spring onions/green onions and Welsh onions | 5                             | EFSA (2011a)            | 1.65                | STMR-RAC (0.59 mg/kg) × CF (2.8)$^{(e)}$     |
| Other bulb vegetables           | 0.5                           | FAO (2019)              | 0.11                | STMR-RAC (0.04 mg/kg) × CF (2.8)$^{(e)}$     |
| Tomatoes                        | 3                             | FAO (2014)              | 0.66                | STMR-RAC                                     |
| Sweet peppers/bell peppers      | 1                             | EFSA (2011a)            | 0.21                | STMR-RAC                                     |
| Aubergines/egg plants           | 0.4                           | EFSA (2011a)            | 0.12                | STMR-RAC                                     |
| Cucurbits with edible peel      | 0.4                           | EFSA (2011a)            | 0.1                 | STMR-RAC                                     |
| Cucurbits with inedible peel    | 0.3                           | EFSA (2013a)            | 0.01                | STMR-RAC$_{pulp}$ (edible portion)           |
| Sweet corn                      | 0.01*                         | EFSA (2011a)            | 0.01                | STMR-RAC                                     |
| Broccoli                       | 0.7                           | EFSA (2011a)            | 0.23                | STMR-RAC                                     |
| Head cabbages                   | 2                             | EFSA (2011a)            | 0.24                | STMR-RAC                                     |
| Chinese cabbages/pe-tsai        | 10                            | EFSA (2011a)            | 1.2                 | STMR-RAC                                     |
| Lamb's lettuce/corn salads      | 20                            | EFSA (2016b)            | 6.13                | STMR-RAC                                     |
| Lettuces                        | 40                            | FAO (2014)              | 8.3                 | STMR-RAC$^{(b)}$                             |
| Escaroles/broad-leaved endives  | 20                            | EFSA (2016b)            | 6.13                | STMR-RAC                                     |
| Cress and other sprouts and shoots | 20                           | EFSA (2016b)            | 6.13                | STMR-RAC                                     |
| Land cress                      | 20                            | EFSA (2016b)            | 6.13                | STMR-RAC                                     |
| Commodity                                      | Existing/proposed MRL (mg/kg) | Source            | Chronic risk assessment | Input value (mg/kg) | Comment                  |
|------------------------------------------------|------------------------------|-------------------|-------------------------|---------------------|--------------------------|
| Roman rocket/rucola                           | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Red mustards                                  | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Baby leaf crops (including brassica species)  | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Other lettuce and other salad plants          | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Spinaches                                     | 30                           | FAO (2014)        |                         | 5.8                 | STMR-RAC\(^{(b)}\)       |
| Purslanes                                     | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Chard/beet leaves                             | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Other spinach and similar                     | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Watercress                                    | 10                           | EFSA (2011a)      |                         | 1.2                 | STMR-RAC                 |
| Witloofs/Belgian endives                      | 0.02                         | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Herbs and edible flowers                      | 20                           | EFSA (2016b)      |                         | 6.13                | STMR-RAC                 |
| Beans (with pods)                             | 1                            | EFSA (2011a)      |                         | 0.48                | STMR-RAC                 |
| Beans (without pods)                          | 0.4                          | FAO (2014)        |                         | 0.02                | STMR-RAC\(^{(b)}\)       |
| Peas (with pods)                              | 1                            | EFSA (2011a)      |                         | 0.48                | STMR-RAC                 |
| Peas (without pods)                           | 0.3                          | EFSA (2016b)      |                         | 0.04                | STMR-RAC                 |
| Lentils (fresh)                               | 0.05                         | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Asparagus                                     | 0.01*                        | EFSA (2011a)      |                         | 0.01                | STMR-RAC                 |
| Celeries                                      | 1.5                          | EFSA (2012)       |                         | 0.32                | STMR-RAC                 |
| Florence fennels                              | 1.5                          | EFSA (2019b, 2019d, 2020a, 2020b, 2021) | | 0.32                | STMR-RAC                 |
| Rhubarbs                                      | 0.7                          | EFSA (2019e)      |                         | 0.23                | STMR-RAC                 |
| Beans (dry)                                   | 0.5                          | FAO (2014)        |                         | 0.04                | STMR-RAC\(^{(b)}\)       |
| Lentils (dry)                                 | 0.4                          | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Peas (dry)                                    | 0.4                          | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Lupins/lipini beans (dry)                     | 0.4                          | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Other pulses (dry)                            | 0.4                          | EFSA (2011a)      |                         | 0.02                | STMR-RAC                 |
| Linseeds                                      | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Poppy seeds                                  | 0.01*                        | EFSA (2011a)      |                         | 0.01                | STMR-RAC                 |
| Sesame seeds                                  | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Sunflower seeds                               | 0.01*                        | EFSA (2011a)      |                         | 0.01                | STMR-RAC                 |
| Rapeseeds/canola seeds                        | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Soyabeans                                     | 0.2                          | EFSA (2019c)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Mustard seeds                                 | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Cotton seeds                                  | 0.01*                        | EFSA (2011a)      |                         | 0.01                | STMR-RAC                 |
| Borage seeds                                  | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Gold of pleasure seeds                        | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Hemp seeds                                    | 0.3                          | EFSA (2020a)      |                         | 0.028               | STMR-RAC (0.01 mg/kg) × CF (2.8)\(^{(e)}\) |
| Cereals                                       | 0.01*                        | EFSA (2011a)      |                         | 0.01                | STMR-RAC                 |
| Commodity                              | Existing/ proposed MRL (mg/kg) | Source                  | Input value (mg/kg) | Comment               |
|----------------------------------------|--------------------------------|-------------------------|---------------------|-----------------------|
| Valerian root                          | 1                              | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)
| Ginseng root                           | 4                              | FAO (2014)              | 0.80                | STMR-RAC (0.29 mg/kg) × CF (2.8)
| Other herbal infusions (dried roots)   | 1                              | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)
| Liquorice                              | 1                              | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)
| Turmeric/curcuma                       | 1                              | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)
| Other spices (roots)                   | 1                              | EFSA (2011a)            | 1.15                | STMR-RAC (0.41 mg/kg) × CF (2.8)

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

| Swine: Muscle/meat                     | 0.02 (fat)                     | FAO (2019)              | 0.02                | CXL                   |
| Swine: Fat tissue                      | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Swine: Liver                           | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Swine: Kidney                          | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Swine: Edible offals (other than liver and kidney) | 0.1 | FAO (2019) | 0.1 | CXL |
| Swine: other products                  | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Bovine: Muscle/meat                    | 0.02 (fat)                     | FAO (2019)              | 0.02                | CXL                   |
| Bovine: Fat tissue                     | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Bovine: Liver                          | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Bovine: Kidney                         | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Bovine: Edible offals (other than liver and kidney) | 0.1 | FAO (2019) | 0.1 | CXL |
| Bovine: other products                 | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Sheep: Muscle/meat                     | 0.02 (fat)                     | FAO (2019)              | 0.02                | CXL                   |
| Sheep: Fat tissue                      | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Sheep: Liver                           | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Sheep: Kidney                          | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Sheep: Edible offals (other than liver and kidney) | 0.1 | FAO (2019) | 0.1 | CXL |
| Sheep: other products                  | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Goat: Muscle/meat                      | 0.02 (fat)                     | FAO (2019)              | 0.02                | CXL                   |
| Goat: Fat tissue                       | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Goat: Liver                            | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Goat: Kidney                           | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Goat: Edible offals (other than liver and kidney) | 0.1 | FAO (2019) | 0.1 | CXL |
| Goat: other products                   | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Equine: Muscle/meat                    | 0.02 (fat)                     | FAO (2019)              | 0.02                | CXL                   |
| Equine: Fat tissue                     | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Equine: Liver                          | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Equine: Kidney                         | 0.1                            | FAO (2019)              | 0.1                 | CXL                   |
| Equine: Edible offals (other than liver and kidney) | 0.1 | FAO (2019) | 0.1 | CXL |
| Equine: other products                 | 0.02                           | FAO (2019)              | 0.02                | CXL                   |
| Commodity                                      | Existing/proposed MRL (mg/kg) | Source          | Chronic risk assessment | Comment |
|-----------------------------------------------|-------------------------------|-----------------|-------------------------|---------|
| Poultry: Muscle/meat                          | 0.01*                         | FAO (2019)      | 0.01                    | CXL     |
| Poultry: Fat tissue                           | 0.01*                         | FAO (2019)      | 0.01                    | CXL     |
| Poultry: Liver                                | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Poultry: Kidney                               | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Poultry: Edible offals (other than liver and kidney) | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Poultry: other products                       | 0.01*                         | FAO (2019)      | 0.01                    | CXL     |
| Other farmed animals: Muscle/meat             | 0.02 (fat)                    | FAO (2019)      | 0.02                    | CXL     |
| Other farmed animals: Fat tissue              | 0.02                          | FAO (2019)      | 0.02                    | CXL     |
| Other farmed animals: Liver                   | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Other farmed animals: Kidney                  | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Other farmed animals: Edible offals (other than liver and kidney) | 0.1                           | FAO (2019)      | 0.1                     | CXL     |
| Other farmed animals: other products          | 0.02                          | FAO (2019)      | 0.02                    | CXL     |
| Milk: Cattle, sheep, goat, horse, others      | 0.04                          | FAO (2019)      | 0.04                    | CXL     |
| Eggs: Chicken, duck, goose, quail, others     | 0.02                          | FAO (2019)      | 0.02                    | CXL     |

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; CF: conversion factor; CXL: Codex maximum residue limit.

(a): The highest STMR-RAC_{pulp} between the two derived from two sets of GAP-compliant residue trials (dip and spray treatments) was selected for the exposure assessment. The selected STMR-RAC_{pulp} is derived from residues measured in edible portion (pulp) of samples treated with dip post-harvest application.

(b): Input values derived according to the JMPR risk assessment residue definition (‘fludioxonil’). A conversion factor of 1 was proposed to convert the residue levels measured according to the EU enforcement residue definition (same as JMPR risk assessment residue definition) to residue levels according to the EU risk assessment residue definition in root and bulb crops (seed and post-harvest treatments), cereals (seed treatment), fruits and leafy vegetables. No difference in the estimation of the residue levels is therefore expected for these commodities.

(c): MRL on blueberries, cranberries, currants and gooseberries voted at the Standing Committee on Plants, Animals, Food and Feed Section Phytopharmaceuticals – Pesticide Residues on 14–15 June 2021 and included in a draft MRL Regulation (SANTE/10518/2021), not yet implemented.

(d): JMPR agreed to use the STMR of 0.01 mg/kg derived from the combined residues in the flesh. However, as information on the time of sampling (whether samples were analysed after a realistic storage period, allowing for penetration of residues in edible part of the fruit, as fludioxonil is fat soluble) is not available, the STMR relevant for the whole fruit was used in the exposure calculation (EFSA, 2019c).

(e): Conversion factor (CF) of 2.8 (derived from metabolism study in spring onions) applied to recalculate residues according to the residue definition for risk assessment in root and bulb crops following foliar application (EFSA, 2011a) and oilseeds (except where the MRLs were set to the LOQ) (EFSA, 2020a). The same CF is now applied to soyabeans for reasons of consistency.

(f): Consumption figures in the EFSA PRIMo are expressed as meat. Since the active substance is a fat-soluble pesticide, risk assessment values were calculated considering a 90% muscle and 10% fat content for poultry meat (FAO, 2016).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| **Fludioxonil**  
CGA 173506 | 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile  
N#Cc1c[NH]cc1ccc2OC(F)(F)Oc12  
MUJOIMFVNIBMKC-UHFFFAOYSA-N | ![Structural formula of Fludioxonil](image) |
| **CGA 192155** | 2,2-difluoro-2H-1,3-benzodioxole-4-carboxylic acid  
O=C(O)c1cccc2OC(F)(F)Oc12  
ZGAQVJDFVVTWJK-WXRBYKJCNA-N | ![Structural formula of CGA 192155](image) |

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

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

<sup>(c)</sup> ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).