Modification of the existing maximum residue levels for fludioxonil in elderberries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta Agro GmbH submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance fludioxonil in elderberries in support of the intended NEU use. The data submitted in support of the request were found to be sufficient to derive an MRL proposal of 4 mg/kg for elderberries, as an extrapolation from red and black currants and blueberries. Adequate analytical methods for enforcement are available to control the residues of fludioxonil in the plant matrix under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the intended use of fludioxonil according to the reported agricultural practice and from the existing authorised uses is unlikely to present a risk to consumer health.

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

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**Summary**

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Agro GmbH submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance fludioxonil in elderberries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 October 2019. To accommodate for the intended NEU uses of fludioxonil, the EMS proposed to raise the existing MRL from 0.8 to 4.0 mg/kg.

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

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments, including the review of the existing fludioxonil MRLs according to Article 12 of Regulation (EC) 396/2005, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of fludioxonil following foliar application was investigated in crops belonging to the groups of fruit crops, leafy crops and root crops; in addition, metabolism studies for seed treatment in root crops, cereals/grasses and pulses/oilseeds are available.

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

In rotational crops, the metabolic pathway of fludioxonil is similar to that in primary crops. For the current application, as the proposed use of fludioxonil is on a permanent crop, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed as ‘fludioxonil’ for enforcement and as ‘sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil’ for risk assessment. For fruit crops, relevant for the current assessment, the conversion factor of 1 from enforcement to risk assessment was derived in the MRL review. EFSA concluded that for elderberries, metabolism of fludioxonil in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are appropriate.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition at or above the limit of quantification (LOQ) of 0.01 mg/kg.

The data submitted in support of this MRL application were found sufficient to derive an MRL proposal of 4.0 mg/kg in elderberries, which was derived by extrapolation from residue trials on red and black currants and blueberries. Residue trial samples were not analysed according to risk assessment residue definition, but this was not considered as a data gap since the metabolism of fludioxonil in fruit crops indicates insignificant concentrations of metabolites containing 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid moiety.

Specific studies investigating the magnitude of fludioxonil residues in processed commodities are not required due to the low contribution of residues in elderberries to the total consumer exposure.

Residues of fludioxonil in commodities of animal origin were not assessed since elderberries are not fed to livestock.

The toxicological profile of fludioxonil was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.37 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure to fludioxonil in elderberries, EFSA used the supervised trials median residue (STMR) value as derived from the trials in red and black currants and blueberries.

For the remaining crops, the STMR values as reported by the MRL review and in succeeding reasoned opinions were used; for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by the JMPR were taken into account in the risk assessment.

The crops on which no EU uses were reported in the framework of the MRL review or in subsequent EFSA reasoned opinions have not been taken into account in the exposure calculation,
assuming that these crops are not treated with fludioxonil. The long-term exposure accounted for a maximum of 20% of the ADI (NL toddler diet); the contribution of residues in elderberries to the total consumer exposure was low (< 0.1% of the ADI).

An acute exposure calculation was not required since for the active substance, no ARfD has been derived.

EFSA concluded that the long-term intake of residues of fludioxonil resulting from the existing and the intended uses is unlikely to present a risk to consumer health. As the procedure for the renewal of the approval of fludioxonil in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

EFSA proposes to amend the existing MRL as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|------------------------|------------------------|-----------------------|
| 0154080 | Elderberries | 0.8                   | 4                      | The submitted data are sufficient to derive an MRL proposal for the intended NEU use of fludioxonil on elderberries (extrapolation from residue trials on red and black currants and blueberries). Risk for consumers unlikely |

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

Abstract ................................................................................................................................................... 1  
Summary ................................................................................................................................................. 4  
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 .................................................................................. 7  
      1.1.3. Nature of residues in processed commodities ..................................................................... 7  
      1.1.4. Methods of analysis in plants .............................................................................................. 7  
      1.1.5. Storage stability of residues in plants ................................................................................... 7  
      1.1.6. Proposed residue definitions ................................................................................................ 7  
   1.2. Magnitude of residues in plants ............................................................................................... 8  
      1.2.1. Magnitude of residues in primary crops .............................................................................. 8  
      1.2.2. Magnitude of residues in rotational crops ........................................................................... 8  
      1.2.3. Magnitude of residues in processed commodities ............................................................... 8  
      1.2.4. Proposed MRLs .................................................................................................................... 8  
2. Residues in livestock ....................................................................................................................... 8  
3. Consumer risk assessment .............................................................................................................. 9  
4. Conclusion and Recommendations ............................................................................................... 9  
References ............................................................................................................................................... 9  
Abbreviations ........................................................................................................................................... 11  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ............ 13  
Appendix B – List of end points ........................................................................................................... 14  
Appendix C – Pesticide Residue Intake Model (PRIMo) ..................................................................... 20  
Appendix D – Input values for the exposure calculations ................................................................. 22  
Appendix E – Used compound codes ............................................................................................... 26
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for fludioxonil in elderberries. The detailed description of the intended NEU use of fludioxonil in elderberries, which is the basis for the current MRL application, is reported in Appendix A.

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

Fludioxonil was evaluated in the framework of Directive 91/414/EEC 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 (EFSA, 2007). Fludioxonil was approved for the use as a 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 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2007a) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for fludioxonil as well as on the evaluation of confirmatory data following the Article 12 MRL review for fludioxonil. The proposals from these reasoned opinions have been considered in recent MRL regulations.4

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2019), the draft assessment report (DAR) and its addendum (Denmark, 2005, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on fludioxonil (European Commission, 2007), the conclusion on the peer review of the pesticide risk assessment of the active substance fludioxonil (EFSA, 2007), as well as the conclusions from previous EFSA opinions on fludioxonil (EFSA, 2011b, 2012, 2013, 2016a,b, 2019b,c,d) and the EFSA scientific report (EFSA, 2019c).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–h, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

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

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

The evaluation report submitted by the EMS (Germany, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo version 3.1) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fludioxonil in primary crops (fruit crops, root crops, leafy crops, cereals/grass and pulses/oilseeds) was evaluated in the framework of the EU peer review and in the MRL review (EFSA, 2007, 2011a). Following foliar application, the major component of residues was parent fludioxonil, accounting for up to 73% of the total radioactive residue (TRR) in tomatoes. Besides the parent compound, a large number of metabolites are formed, individually occurring at low levels (each < 10% of TRR). Compared to other crop groups, however, the metabolism was more extensive in root vegetables (spring onions) where fludioxonil was detected for a maximum of 31% TRR and the remaining radioactive residues composed of several metabolites (each < 7% of the TRR) containing the 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic moiety. Based on the metabolism study in spring onions, for root crop group a conversion factor of 2.8 from enforcement to risk assessment was proposed by the MRL review. Following seed application, uptake and translocation of fludioxonil was low. The metabolism was qualitatively similar in all crops (EFSA, 2007, 2011a). For cereals (seed treatment), fruits and leafy crops, a conversion factor (CF) of 1 was derived which gave an indication that no significant concentrations of metabolites containing the 2,2-difluorobenzo[1,3]dioxole-4 carboxylic moiety are expected (EFSA, 2011a).

1.1.2. Nature of residues in rotational crops

Not relevant for the current application since elderberries are not considered to be a rotational crop (OECD, 2007).

1.1.3. Nature of residues in processed commodities

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

1.1.4. Methods of analysis in plants

Various analytical methods for enforcement purposes were assessed by the peer review and further discussed in the MRL review (EFSA, 2007, 2011a).

Fully validated multiresidue DFG S19 and QuEChERS methods applying high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available for the analysis of fludioxonil in high water-, high acid-, high oil content commodities and in dry commodities at the LOQ of 0.01 mg/kg (EFSA, 2007, 2011a).

It is concluded that for elderberries (high acid content commodity), adequate analytical methods for monitoring of residues are available.

1.1.5. Storage stability of residues in plants

Fludioxonil was demonstrated to be stable upon storage at ≤ 20°C for at least 24 months in commodities of high water (tomato, apple, fresh peas, maize forage), high acid (grapes) and high oil (rapeseed, corn oil) content as well as in dry/high starch content (cereal grains, maize grains, potato tubers) commodities and other matrices (straw, corn meal, sorghum hay) (EFSA, 2007, 2011a).

1.1.6. Proposed residue definitions

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

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

The same residue definitions are applicable to rotational crops and processed products.

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

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

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended northern European (NEU) outdoor use of fludioxonil on elderberries, the applicant referred to residue trials performed on red currants (one trial), black currants (four trials) and blueberries (four trials) which were evaluated previously by EFSA during the MRL review (EFSA, 2011a). These trials were performed in Germany over growing seasons of 1999 and 2000. Additionally, the applicant submitted four GAP compliant trials on red currants which were performed in Poland, Germany and Hungary in 2018. All the residue trials were compliant with the intended GAP.

The residue trial samples were analysed for fludioxonil and no information was provided on metabolites containing 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid moiety. Since metabolism of fludioxonil in fruit crops indicates insignificant concentrations of metabolites containing 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid moiety (see Section 1.1.1), the lack of this information is not considered a data gap and the default conversion factor of 1 from enforcement to risk assessment is applicable according to the proposal of the MRL review.

The applicant proposes to combine available residue data on red currant, black currant and blueberries and to extrapolate to elderberries. According to EU guidance document (European Commission, 2017), such an extrapolation is acceptable and is sufficiently supported by residue data.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Germany, 2019).

Based on the submitted trials, EFSA concludes that an MRL of 4 mg/kg for fludioxonil in elderberries is required to support the intended GAP.

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

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current application since elderberries are not considered to be a rotational crop (OECD, 2007).

1.2.3. Magnitude of residues in processed commodities

Studies to assess the magnitude of fludioxonil residues on elderberries during processing were not provided for the current application and are not considered necessary as the consumer exposure to fludioxonil residues resulting from elderberries consumption is negligible.

1.2.4. Proposed MRLs

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

2. Residues in livestock

Not relevant for the current application since elderberries are not used as livestock feed item.
3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA et al., 2018, 2019a). The toxicological profile of fludioxonil was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.37 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary (European Commission, 2007).

Short-term (acute) dietary risk assessment

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

Long-term (chronic) dietary risk assessment

For the calculation of the chronic exposure resulting from the residues of fludioxonil in elderberries, EFSA used the supervised trials median residue (STMR) value derived from the residue trials on red and black currants and blueberries (see Section B.1.2.1). For the remaining crops, the STMR values as reported by the MRL review and in succeeding reasoned opinions were used (EFSA, 2011a, 2012, 2013, 2016a,b, 2019b,c,d, 2020) and the EFSA scientific report (EFSA, 2019c); for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by the JMPR were taken into account in the risk assessment (FAO, 2012, 2013).

The exposure calculation was performed only for those crops for which authorised uses were reported in the MRL review and for the accepted Codex MRLs taken over in the EU legislation. The exposure calculation was performed only for those crops for which authorised uses were reported in the MRL review and for the accepted Codex MRLs taken over in the EU legislation.

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

The calculated long-term exposure accounted for a maximum of 20% of the ADI (NL toddler diet); the contribution of residues in elderberries to the total consumer exposure was low (< 0.1% of the ADI) (See Appendix B.3).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo 3.1 is presented in Appendix C.

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.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 4 mg/kg for fludioxonil in elderberries, as extrapolated from residue trials on red and black currants and blueberries, in support of the intended NEU GAP.

EFSA concluded that the proposed use of fludioxonil on elderberries will not result in a long-term consumer exposure exceeding the ADI value for fludioxonil and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
DS powder for dry seed treatment
EC emulsifiable concentrate
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
Modification of the existing maximum residue levels for fludioxonil in elderberries

GC gas chromatography
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
HPLC high performance liquid chromatography
HPLC-MS high performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SL soluble concentrate
SP water-soluble powder
STMR supervised trials median residue
TAR total applied radioactivity
TRR total radioactive residue
UV ultraviolet (detector)
WG water-dispersible granule
WHO World Health Organization
WP wettable powder
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)^(d) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|--------------------------------|----------------|---------|
| Elderberries          | NEU F                   | Colletotrichum                    | WG          | Foliar treatment – broadcast spraying | 60 3 10 1,000 250.00 g a.i./ha | 7               |         |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule.

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

(b): CropLife International Technical Monograph no 2, 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

| Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-------------|---------|----------------|----------------|----------------|
| Fruit crops | Grape   | Foliar, 3 × 0.5 kg a.s./ha | 0, 14, 35 (maturity) | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007, 2011a) |
|             | Tomato  | Foliar, 3 × 0.75 kg a.s./ha | 0, 40 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007) |
|             | Peach   | Foliar, 3 × 0.28 kg a.s./ha 2 × 2.8 kg a.s./ha 2.1 + 6.3 kg a.s./ha | 28 28 30, 114 | Radiolabelling: [phenyl-U-14C] (EFSA, 2007) |
| Root crops | Spring onion | Foliar, 0.6 + 0.9 kg a.s./ha 2.8 + 3.4 kg a.s./ha | 0, 7, 14, 28 | Radiolabelling: [phenyl-U-14C] (EFSA, 2011a) |
|             | Potato   | Seed, 2.5 g a.s./100 kg seed | 0, 40, 71, 95 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a) |
| Leafy crops | Lettuce  | Foliar, 3 × 0.2 kg a.s./ha 3 × 0.6 kg a.s./ha | 0, 6, 13 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011a) |
|             | 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) |

| 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 | Lettuce | 0.75 kg a.s./ha | 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
| Pulses and oilseeds | Mustard | 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|             | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
|             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011a) |
### Cereal (small grain)

| Crop          | Active Substance | Radiolabelling          | Conditions | Stable? | Comment/Source |
|---------------|------------------|-------------------------|------------|---------|----------------|
| Winter wheat  | 0.75 kg a.s./ha  | [pyrrole-14C] (EFSA, 2007, 2011a) |            |         |                |
| Spring wheat  | 0.124 kg a.s./ha | [pyrrole-14C] (EFSA, 2007, 2011a) |            |         |                |
|               | 0.062 kg a.s./ha | [pyrrole-14C] (EFSA, 2007, 2011a) |            |         |                |
|               | 1.117 kg a.s./ha | [phenyl-14C] (EFSA, 2007, 2011a) |            |         |                |
| Corn          | 0.75 kg a.s./ha  | [pyrrole-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) Fludioxonil
Plant residue definition for risk assessment (RD-RA)

Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil
Conversion factors (CF) for risk assessment (EFSA, 2011a):
- Root crops: 2.8
- Fruit crops, leafy crops and cereals (soil treatment): 1

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg
Confirmatory method available
ILV available
QuEChERS method also available for high acid and high water content commodities: HPLC–MS/MS, LOQ of 0.01 mg/kg (EFSA, 2011a)

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

www.efsa.europa.eu/efsajournal 15 EFSA Journal 2020;18(7):6175
### B.1.1.2. Stability of residues in plants

| 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)    |
| High oil content         | Rapeseed, corn oil         | –18    | 24 Months        | Fludioxonil       | EFSA (2007)    |
| Dry/High starch          | Cereal grains, maize grains, | –18    | 24 Months        | Fludioxonil       | EFSA (2007)    |
|                          | Potato tubers              | –20    | 24 Months        | Fludioxonil       | EFSA (2007)    |
| High acid content        | Grapes                     | < –20  | 24 Months        | Fludioxonil       | EFSA (2011a)   |
| Others                   | Cereal straw               | –16    | 24 Months        | Fludioxonil       | EFSA (2007)    |
|                          | Corn meal                  | –20    | 24 Months        | Fludioxonil       | EFSA (2007)    |
|                          | Sorghum hay                | –20    | 24 Months        | Fludioxonil       | EFSA (2007)    |
B.1.2. Magnitude of residues in plants

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

| Commodity   | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-------------|-----------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|----------------|
| Elderberries| NEU                         | 0.15; 0.26<sup>(e)</sup>; 0.31; 0.31; 0.37; 0.60; 0.62; 0.63<sup>(e)</sup>; 1.30; 1.40<sup>(f)</sup>; 1.60; 2.00 | Residue trials on red and black currants and blueberries compliant with NEU GAP. Extrapolation to elderberries possible | 4                      | 2                        | 0.62                      | 1              |

MRL: maximum residue level; GAP: Good Agricultural Practice.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
(e): Residues higher at a longer PHI interval of 10 days.
(f): Residues higher at a longer PHI interval of 14 days.
B.1.2.2. Residues in rotational crops

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

| No | Fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP (EFSA, 2007) |
| No | Not relevant since elderberries are not considered to be a rotational crop |

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

| No | Not relevant since elderberries are not considered to be a rotational crop |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

**ARfD**

| No | Not relevant since no ARfD has been considered necessary (European Commission, 2007) |

**Highest IESTI, according to EFSA PRIMO**

| Not applicable |

**Assumptions made for the calculations**

| Not applicable |

**ADI**

| 0.37 mg/kg bw per day (European Commission, 2007) |

**Highest IEDI, according to EFSA PRIMO**

| 20% ADI (NL toddler) |

| Contribution of crops assessed: Elderberries: < 0.1 % of ADI |

**Assumptions made for the calculations**

| Calculations were performed with PRIMO rev. 3.1. For elderberries, the median residue value (STMR) as derived from the residue trials on red and black currants and blueberries was used as an input value. Additionally, the median residue levels for the crops assessed in the MRL review and in reasoned opinions issued after the MRL review and safe CXLs implemented in the EU legislation were included in the calculation. Although not yet implemented in the EU legislation, for currants, the STMR value as derived by the JMPR and evaluated by EFSA (EFSA, 2019c) was used as an input value. For mangoes and cucurbits with inedible peel, the STMR for pulp (peeled commodity) was used as an input value. The median residue for root crops and certain oilseeds was multiplied by the conversion factor for risk assessment of 2.8 derived from metabolism study on spring onions during the EU pesticides peer review. The contributions of commodities where no GAP was reported in the framework of the MRL review or in the following EFSA evaluations were not included in the calculation. |

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

| Code<sup>(a)</sup> | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------------|------------|-------------------------|-------------------------|-----------------------|
| 0154080          | Elderberries | 0.8                     | 4                       | The submitted data are sufficient to derive an MRL proposal for the intended NEU use of fludioxonil on elderberries (extrapolation from residue trials on red and black currants and blueberries). Risk for consumers unlikely |

MRL: maximum residue level; NEU: northern Europe.

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

(F): Fat soluble.
### Fludioxonil (R) (F)

#### Toxicological reference values

- **LOQs (mg/kg):** range from 0.01 to 0.05
- **ADI (mg/kg bw per day):** 0.37
- **ARfD (mg/kg bw):** not necessary

Source of ADI: EFSA PRIMo revision 3.1; 2019/03/19

#### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | Highest contributor to MS diet (% of ADI) | 2nd contributor to MS diet (% of ADI) | 3rd contributor to MS diet (% of ADI) |
|--------------------------------|-------------------------|------------------------------------------|--------------------------------------|--------------------------------------|
|                                |                         | Source                                    | Source                                | Source                                |
|                                |                         | % of ADI                                  | % of ADI                               | % of ADI                               |
|                                |                         | (µg/kg bw per day)                        |                                       |                                       |
| MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
| [
| 20% 75.82 7% 3% 3% Pears 20%  |
| 19% 70.60 8% 6% 1% Potatoes 19%  |
| 11% 42.22 4% 2% 1% Potatoes 11%  |
| 11% 40.00 4% 1% 1.0% Grapefruits 11%  |
| 9% 31.71 5% 1% 0.6% Potatoes 9%  |
| 8% 28.80 2% 2% 1% Mandarins 8%  |
| 7% 26.25 2% 1% 0.9% Apples 7%  |
| 7% 26.25 2% 1% 0.9% Apples 7%  |
| 7% 26.13 3% 0.9% 0.7% Potatoes 7%  |
| 6% 23.55 2% 1% 0.7% Lettuces 6%  |
| 6% 22.29 2% 2% 0.5% Potatoes 6%  |
| 6% 22.20 2% 0.8% 0.7% Oranges 6%  |
| 5% 20.27 2% 0.9% 0.7% Apples 5%  |
| 5% 20.11 2% 1% 0.5% Apples 5%  |
| 5% 20.08 2% 1% 1.0% Apples 5%  |
| 5% 19.19 1% 1.0% 0.7% Apples 5%  |
| 5% 18.74 1% 1.0% 0.9% Apples 5%  |
| 5% 17.50 1% 1.0% 0.4% Carrots 5%  |
| 5% 17.01 2% 0.6% 0.6% Mandarins 5%  |
| 4% 15.76 0.7% 0.7% Potatoes 4%  |
| 4% 15.69 2% 0.4% Potatoes 4%  |
| 4% 15.23 0.8% Lettuces 4%  |
| 3% 14.15 2% 0.4% Apples 3%  |
| 3% 13.62 1% Apple 3%  |
| 3% 13.53 1% 1% Apples 3%  |
| 3% 12.45 1% Lettuce 3%  |
| 3% 11.62 1% 0.1% Lettuce 3%  |
| 3% 10.60 0.6% Potatoes 3%  |
| 3% 9.02 0.6% Potatoes 3%  |
| 3% 8.40 0.6% Potatoes 3%  |
| 3% 7.82 0.6% Potatoes 3%  |
| 3% 7.24 0.6% Potatoes 3%  |
| 3% 6.66 0.6% Potatoes 3%  |

**Comments:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Fludioxonil (R) (F) is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Unprocessed commodities

| IESTI | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-------------|--------------------------|---------------------|
|       |                       |             |                          |                     |

Expand/collapse list

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

### Processed commodities

| IESTI | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-----------------------|--------------------------|---------------------|
|       |                       |                       |                          |                     |

Expand/collapse list

Conclusion:

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

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

Details - acute risk assessment/children

Details - acute risk assessment/adults/general population

Modification of the existing maximum residue levels for fludioxonil in elderberries

www.efsa.europa.eu/efsajournal 21 EFSA Journal 2020;18(7):6175
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               |                       |
|                            | Comment                 |                       | Input value (mg/kg)   | Comment               |
| **Risk assessment residue definition:** Sum of fludioxonil and its metabolites oxidised to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil |                       |                       |
| Elderberries               | 0.62 STMR               |                       | 0.62 STMR (EFSA, 2011a) |                       |
| Grapefruits                | 5.3 STMR (EFSA, 2011a)  | Acute risk assessments not relevant |
| Oranges                    | 5.3 STMR (EFSA, 2011a)  |                       |
| Lemons                     | 5.3 STMR (EFSA, 2011a)  |                       |
| Limes                      | 5.3 STMR (EFSA, 2011a)  |                       |
| Mandarins                  | 5.3 STMR (EFSA, 2011a)  |                       |
| Other citrus fruit         | 5.3 STMR (EFSA, 2011a)  |                       |
| Pistachios                 | 0.06 STMR (EFSA, 2011a) |                       |
| Apples                     | 2.3 STMR (EFSA, 2011a)  |                       |
| Pears                      | 2.3 STMR (EFSA, 2011a)  |                       |
| Quinces                    | 2.3 STMR (EFSA, 2011a)  |                       |
| Medlar                     | 2.3 STMR (EFSA, 2011a)  |                       |
| Loquats/Japanese medlars    | 2.3 STMR (EFSA, 2011a)  |                       |
| Other pome fruit           | 2.3 STMR (EFSA, 2011a)  |                       |
| Apricots                   | 1.06 STMR (EFSA, 2011a) |                       |
| Cherries (sweet)           | 0.8 STMR (EFSA, 2011a)  |                       |
| Peaches                    | 3.65 STMR (EFSA, 2011a) |                       |
| Plums                      | 1.06 STMR (EFSA, 2011a) |                       |
| Table grapes               | 0.38 STMR (EFSA, 2011a) |                       |
| Wine grapes                | 0.33 STMR (EFSA, 2011a) |                       |
| Strawberries               | 0.31 STMR (EFSA, 2019d) |                       |
| Blackberries               | 1 STMR (EFSA, 2011a)    |                       |
| Dewberries                 | 1 STMR (EFSA, 2011a)    |                       |
| Raspberries (red and yellow)| 1 STMR (EFSA, 2011a)    |                       |
| Other cane fruit           | 1 STMR (EFSA, 2011a)    |                       |
| Blueberries                | 0.37 STMR (EFSA, 2011a) |                       |
| Cranberries                | 0.37 STMR (EFSA, 2011a) |                       |
| Currants (red, black and white) | 0.62 STMR (EFSA, 2019c) |                       |
| Gooseberries (green, red and yellow) | 0.37 STMR (EFSA, 2011a) |                       |
| Kiwi fruits (green, red, yellow) | 7.3 STMR (EFSA, 2011a)  |                       |
| Avocados                   | 0.05 STMR (FAO, 2013)   |                       |
| Mangoes                    | 0.02 STMR (FAO, 2012)   |                       |
| Granate apples/pomegranates| 0.95 STMR (EFSA, 2011a) |                       |
| Pineapples                 | 2.14 STMR (EFSA, 2016a) |                       |
| Potatoes                   | 1.5 STMR (FAO, 2013)    |                       |
| Sweet potatoes             | 3.76 STMR (EFSA, 2011a) |                       |
| Yams                       | 3.76 STMR (EFSA, 2011a) |                       |
| Beetroots                  | 1.148 STMR (0.410 \times CF (2.8) (EFSA, 2011a) |                       |
| Commodity                              | Input value (mg/kg) | Chronic risk assessment | Acute risk assessment |
|---------------------------------------|---------------------|-------------------------|-----------------------|
| Commodity                              | Comment             |                         |                        |
| Carrots                               | 1.148               | STMR (0.410) × CF (2.8) (EFSA, 2011a) |                         |
| Celeriacs/turnip-rooted celeries       | 0.196               | STMR (0.07) × CF (2.8) (EFSA, 2011a) |                         |
| Horseradishes                         | 1.148               | STMR (0.410) × CF (2.8) (EFSA, 2011a) |                         |
| Parsnips                              | 1.148               | STMR (0.410) × CF (2.8) (EFSA, 2011a) |                         |
| Parsley roots/Hamburg roots parsley    | 1.148               | STMR (0.410) × CF (2.8) (EFSA, 2011a) |                         |
| Radishes                              | 0.098               | STMR (0.035) × CF (2.8) (EFSA, 2013) |                         |
| Salsifies                             | 1.148               | STMR (0.410) × CF (2.8) (EFSA, 2011a) |                         |
| Garlic                                | 0.056               | STMR (0.02) × CF (2.8) (EFSA, 2011a) |                         |
| Onions                                | 0.056               | STMR (0.02) × CF (2.8) (EFSA, 2011a) |                         |
| Shallots                              | 0.056               | STMR (0.02) × CF (2.8) (EFSA, 2011a) |                         |
| Radishes                              | 0.532               | STMR (0.19) × CF (2.8) (EFSA, 2011a) |                         |
| Tomatoes                              | 0.66                | STMR (EFSA, 2013)        |                         |
| Sweet peppers/bell peppers            | 0.21                | STMR (EFSA, 2011a)       |                         |
| Aubergines/egg plants                 | 0.12                | STMR (EFSA, 2011a)       |                         |
| Cucumbers                             | 0.1                 | STMR (EFSA, 2011a)       |                         |
| Gherkins                              | 0.1                 | STMR (EFSA, 2011a)       |                         |
| Courgettes                            | 0.1                 | STMR (EFSA, 2011a)       |                         |
| Other cucurbits - edible peel         | 0.1                 | STMR (EFSA, 2011a)       |                         |
| Melons                                | 0.01                | STMR edible portion (EFSA, 2013) |                         |
| Pumpkins                              | 0.01                | STMR edible portion (EFSA, 2013) |                         |
| Watermelons                           | 0.01                | STMR edible portion (EFSA, 2013) |                         |
| Other cucurbits - inedible peel       | 0.01                | STMR edible portion (EFSA, 2013) |                         |
| Sweet corn                            | 0.01                | STMR (EFSA, 2011a)       |                         |
| Broccoli                              | 0.23                | STMR (EFSA, 2011a)       |                         |
| Head cabbages                         | 0.24                | STMR (EFSA, 2011a)       |                         |
| Chinese cabbages/pe-tsai              | 1.2                 | STMR (EFSA, 2011a)       |                         |
| Lamb’s lettuce/corn salads            | 6.13                | STMR (EFSA, 2016b)       |                         |
| Lettuces                              | 8.3                 | STMR (FAO, 2013)         |                         |
| Escaroles/broadleaved endives         | 6.13                | STMR (EFSA, 2016b)       |                         |
| Cress and other sprouts and shoots    | 6.13                | STMR (EFSA, 2016b)       |                         |
| Land cress                            | 6.13                | STMR (EFSA, 2016b)       |                         |
| Roman rocket/rucola                   | 6.13                | STMR (EFSA, 2016b)       |                         |
| Red mustards                          | 6.13                | STMR (EFSA, 2016b)       |                         |
| Baby leaf crops (including brassica species) | 6.13 | STMR (EFSA, 2016b)       |                         |
| Other lettuce and other salad plants  | 6.13                | STMR (EFSA, 2016b)       |                         |
| Spinaches                             | 5.8                 | STMR (FAO, 2013)         |                         |
| Commodity                      | Input value (mg/kg) | Chronic risk assessment            | Acute risk assessment         |
|-------------------------------|---------------------|------------------------------------|-------------------------------|
| Purslanes                     | 6.13                | STMR (EFSA, 2016b)                |                               |
| Chards/beet leaves            | 6.13                | STMR (EFSA, 2016b)                |                               |
| Other spinach and similar     | 6.13                | STMR (EFSA, 2016b)                |                               |
| Chervil                       | 6.13                | STMR (EFSA, 2016b)                |                               |
| Chives                        | 6.13                | STMR (EFSA, 2016b)                |                               |
| Celery leaves                 | 6.13                | STMR (EFSA, 2016b)                |                               |
| Parsley                       | 6.13                | STMR (EFSA, 2016b)                |                               |
| Sage                          | 6.13                | STMR (EFSA, 2016b)                |                               |
| Rosemary                      | 6.13                | STMR (EFSA, 2016b)                |                               |
| Thyme                         | 6.13                | STMR (EFSA, 2016b)                |                               |
| Basil and edible flowers      | 6.13                | STMR (EFSA, 2016b)                |                               |
| Laurel/bay leaves             | 6.13                | STMR (EFSA, 2016b)                |                               |
| Tarragon                      | 6.13                | STMR (EFSA, 2016b)                |                               |
| Other herbs                   | 6.13                | STMR (EFSA, 2016b)                |                               |
| Beans (with pods)             | 0.48                | STMR (EFSA, 2011a)                |                               |
| Beans (without pods)          | 0.02                | STMR (EFSA, 2016b)                |                               |
| Peas (with pods)              | 0.48                | STMR (EFSA, 2011a)                |                               |
| Peas (without pods)           | 0.04                | STMR (EFSA, 2016b)                |                               |
| Lentils (fresh)               | 0.02                | STMR (EFSA, 2011a)                |                               |
| Asparagus                     | 0.01                | STMR (EFSA, 2011a)                |                               |
| Celeries                      | 0.32                | STMR (EFSA, 2012)                 |                               |
| Florence fennels              | 0.32                | STMR (EFSA, 2019b,c,d, 2020)      |                               |
| Rhubarbs                      | 0.23                | STMR (EFSA, 2019e)                |                               |
| Beans                         | 0.04                | STMR (FAO, 2013)                  |                               |
| Lentils                       | 0.02                | STMR (EFSA, 2011a)                |                               |
| Peas                          | 0.02                | STMR (EFSA, 2011a)                |                               |
| Lupins/lupini beans           | 0.02                | STMR (EFSA, 2011a)                |                               |
| Other pulses                  | 0.02                | STMR (EFSA, 2011a)                |                               |
| Linseeds                      | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Peanuts/groundnuts            | 0.01                | STMR (EFSA, 2011a)                |                               |
| Poppy seeds                   | 0.01                | STMR (EFSA, 2011a)                |                               |
| Sesame seeds                  | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Sunflower seeds               | 0.01                | STMR (EFSA, 2011a)                |                               |
| Rapeseeds/canola seeds        | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Soyabeanse                    | 0.01                | STMR (EFSA, 2011a)                |                               |
| Mustard seeds                 | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Cotton seeds                  | 0.02                | STMR (EFSA, 2011a)                |                               |
| Pumpkin seeds                 | 0.01                | STMR (EFSA, 2011a)                |                               |
| Safflower seeds               | 0.01                | STMR (EFSA, 2011a)                |                               |
| Borage seeds                  | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Gold of pleasure seeds        | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Hemp seeds                    | 0.028               | STMR (0.01) \times CF (2.8) (EFSA, 2019d) |                               |
| Castor beans                  | 0.01                | STMR (EFSA, 2011a)                |                               |
| Other oilseeds                | 0.01                | STMR (EFSA, 2011a)                |                               |
| Barley                        | 0.01                | STMR (EFSA, 2011a)                |                               |
| Buckwheat and other           | 0.01                | STMR (EFSA, 2011a)                |                               |
| pseudo-cereals                |                     |                                   |                               |
| Commodity                         | Input value (mg/kg) | Chronic risk assessment | Acute risk assessment |
|----------------------------------|---------------------|-------------------------|-----------------------|
| Maize/corn                       | 0.01                | STMR (EFSA, 2011a)     |                       |
| Common millet/proso millet       | 0.01                | STMR (EFSA, 2011a)     |                       |
| Oat                              | 0.01                | STMR (EFSA, 2011a)     |                       |
| Rice                             | 0.01                | STMR (EFSA, 2011a)     |                       |
| Rye                              | 0.01                | STMR (EFSA, 2011a)     |                       |
| Sorghum                          | 0.01                | STMR (EFSA, 2011a)     |                       |
| Wheat                            | 0.01                | STMR (EFSA, 2011a)     |                       |
| Other cereals                    | 0.01                | STMR (EFSA, 2011a)     |                       |
| Ginseng root                     | 0.8                 | STMR (0.286) × CF (2.8) (FAO, 2013) |           |
| Sugar beet roots                 | 0.01                | STMR (EFSA, 2011a)     |                       |
| Swine: Muscle/meat               | 0.01                | STMR (EFSA, 2019d)     |                       |
| Swine: Fat tissue                | 0.003               | STMR (EFSA, 2019d)     |                       |
| Swine: Liver                     | 0.01                | STMR (EFSA, 2019d)     |                       |
| Swine: Kidney                    | 0.02                | STMR (EFSA, 2019d)     |                       |
| Bovine: Muscle/meat              | 0.01                | STMR (EFSA, 2019d)     |                       |
| Bovine: Fat tissue               | 0.01                | STMR (EFSA, 2019d)     |                       |
| Bovine: Liver                    | 0.04                | STMR (EFSA, 2019d)     |                       |
| Bovine: Kidney                   | 0.05                | STMR (EFSA, 2019d)     |                       |
| Sheep: Muscle/meat               | 0.01                | STMR (EFSA, 2019d)     |                       |
| Sheep: Fat tissue                | 0.003               | STMR (EFSA, 2019d)     |                       |
| Sheep: Liver                     | 0.01                | STMR (EFSA, 2019d)     |                       |
| Sheep: Kidney                    | 0.02                | STMR (EFSA, 2019d)     |                       |
| Goat: Muscle/meat                | 0.01                | STMR (EFSA, 2019d)     |                       |
| Goat: Fat tissue                 | 0.003               | STMR (EFSA, 2019d)     |                       |
| Goat: Liver                      | 0.01                | STMR (EFSA, 2019d)     |                       |
| Goat: Kidney                     | 0.02                | STMR (EFSA, 2019d)     |                       |
| Poultry: Muscle/meat             | 0.01                | STMR (EFSA, 2019d)     |                       |
| Poultry: Fat tissue              | 0.05                | STMR (EFSA, 2019d)     |                       |
| Poultry: Liver                   | 0.05                | STMR (EFSA, 2019d)     |                       |
| Poultry: Kidney                  | 0.05                | STMR (EFSA, 2019d)     |                       |
| Milk: Cattle                     | 0.02                | STMR (EFSA, 2019d)     |                       |
| Milk: Sheep                      | 0.02                | STMR (EFSA, 2019d)     |                       |
| Milk: Goat                       | 0.02                | STMR (EFSA, 2019d)     |                       |
| Milk: Horse                      | 0.02                | STMR (EFSA, 2019d)     |                       |
| Milk: Others                     | 0.02                | STMR (EFSA, 2019d)     |                       |
| Eggs: Chicken                    | 0.05                | STMR (EFSA, 2019d)     |                       |
| Eggs: Duck                       | 0.05                | STMR (EFSA, 2019d)     |                       |
| Eggs: Goose                      | 0.05                | STMR (EFSA, 2019d)     |                       |
| Eggs: Quail                      | 0.05                | STMR (EFSA, 2019d)     |                       |
| Eggs: Others                     | 0.05                | STMR (EFSA, 2019d)     |                       |

STMR: supervised trials median residue; CF: conversion factor.
# 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]cc1cccc2OC(F)(F)Oc12  
MUJOIMFVNIBMKC-UHFFFAOYSA-N | ![Structural formula](image) |
| CGA 192155                      | 2,2-difluoro-2H-1,3-benzodioxole-4-carboxylic acid  
O=C(O)c1cccc2OC(F)(F)Oc12  
ZGAQVJDFFVTWJK-WXRBYKJCNA-N     | ![Structural formula](image) |

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

<sup>(b)</sup>: ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).

<sup>(c)</sup>: ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 December 2018).