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

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Abstract

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

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

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Summary

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

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

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

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

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

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

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

| Code(a) | Commodity | Existing MRL (b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|-----------------|-------------|--------------------------|
| 0152000 | Strawberries | 4 (ft 1) | 4 | The data gap identified by EFSA during the MRL review for additional residue trials was addressed. The MRL derived for the adjusted indoor GAP with a longer PHI of 3 days corresponds to the current MRL. Thus, no modification of the MRL is necessary. Risk for consumer is unlikely. The adjusted NEU GAP, which is sufficiently supported by data, would require a lower MRL. The original GAPs assessed in the framework of the MRL review with a shorter PHI of 1 day and the adjusted SEU GAP are not sufficiently supported by data. |

**Enforcement residue definition for plant products:** Fludioxonil

**Enforcement residue definition for animal products:** Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (F).

**N.B.** EFSA noted an inaccuracy regarding the residue definition for animal products currently implemented in Regulation (EC) No 396/2005 (the last part of the residue definitions 'expressed as fludioxonil' is missing). Thus, when implementing the current MRL recommendations, the residue definition should be updated as reported above.
| Code<sup>(a)</sup> | Commodity           | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|------------------|---------------------|---------------------------|--------------|---------------------------|
| 1011010          | Swine, muscle       | 0.01*<sup>(c)</sup>       | 0.01*        | Based on the updated dietary burden calculation and the new feeding study, the MRL required for swine products were recalculated. The new assessment confirmed the existing MRLs for swine muscle; a lower MRL would be sufficient for fat, liver and kidney. The option to lower existing EU MRL should be further discussed by risk managers. A risk for consumer is unlikely. |
| 1011020          | Swine, fat          | 0.05*<sup>(c)</sup>       | 0.01*        | Further risk management consideration required. |
| 1011030          | Swine, liver        | 0.05*<sup>(c)</sup>       | 0.02         | Further risk management consideration required. |
| 1011040          | Swine, kidney       | 0.05*<sup>(c)</sup>       | 0.03         | Further risk management consideration required. |
| 1011050          | Swine edible offal  | 0.05*<sup>(c)</sup>       | Further risk management consideration required. | The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues. |
| 1011990          | Swine, other products | 0.05*<sup>(c)</sup> | Further risk management consideration required. |
| 1012010          | Bovine, muscle      | 0.04<sup>(ft 2)</sup>     | 0.01*        | The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for bovine tissues (muscle, fat, liver and kidney). The option to lower existing EU MRL should be further discussed by risk managers. Risk for consumer is unlikely. |
| 1012020          | Bovine, fat         | 0.2<sup>(ft 2)</sup>      | 0.01*        | Further risk management consideration required. |
| 1012030          | Bovine, liver       | 0.2<sup>(ft 2)</sup>      | 0.06         | Further risk management consideration required. |
| 1012040          | Bovine, kidney      | 0.2<sup>(ft 2)</sup>      | 0.07         | Further risk management consideration required. |
| 1012050          | Bovine, edible offal | 0.05*<sup>(ft 2)</sup>    | Further risk management consideration required. | The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues. |
| 1012990          | Bovine, other products | 0.05*<sup>(ft 2)</sup> | Further risk management consideration required. |
| 1013010          | Sheep, muscle       | 0.04<sup>(ft 2)</sup>     | 0.01*        | The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient for sheep tissues (muscle, fat, liver and kidney). The option to lower existing EU MRL should be further discussed by risk managers. Risk for consumer is unlikely. |
| 1013020          | Sheep, fat          | 0.2<sup>(ft 2)</sup>      | 0.01*        | Further risk management consideration required. |
| 1013030          | Sheep, liver        | 0.2<sup>(ft 2)</sup>      | 0.02         | Further risk management consideration required. |
| 1013040          | Sheep, kidney       | 0.2<sup>(ft 2)</sup>      | 0.03         | Further risk management consideration required. |
| 1013050          | Sheep, edible offal  | 0.05*<sup>(ft 2)</sup>    | Further risk management consideration required. | The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues. |
| 1013990          | Sheep, other products | 0.05*<sup>(ft 2)</sup> | Further risk management consideration required. |

<sup>(a)</sup> Code is a unique identifier for each commodity.

<sup>(b)</sup> MRL: Maximum Residue Limit.

<sup>(c)</sup> * Indicates a new MRL value.

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

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; NEU: northern Europe; SEU: southern Europe.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): Although formally, no data gap was identified for swine products, EFSA re-assessed the MRLs, since the new feeding study in ruminants allowed to update the MRLs.
(d): Although formally, no data gap was identified for milk, EFSA re-assessed the MRLs, since the new feeding study allowed to update the MRLs for milk.
(F): Fat soluble.

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 1).

ft 2: The European Food Safety Authority identified some information on a livestock feeding study as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it (footnote related to data gap No 4).
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Assessment

The review of existing maximum residue levels (MRLs) for fludioxonil according to Article 12 of Regulation (EC) No 396/20051 (MRL review) has been performed in 2011. The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified (EFSA, 2011). The Good Agricultural Practices (GAPs) for cucurbits with inedible peel and celery were assessed by EFSA in previous reasoned opinions (EFSA, 2011, 2012, 2013). A new feeding study in ruminants was provided. The data gaps identified by EFSA, the applicant amended the GAPs for strawberries by proposing a longer preharvest interval (PHI) of 3 days compared to the GAP assessed in the MRL review (hereafter referred to as adjusted GAPs); in addition, a new feeding study in ruminants was provided. The data gaps identified for cucurbits with inedible peel and celery were assessed by EFSA in previous reasoned opinions (EFSA, 2012, 2013).

The RMS assessed the new information provided by the applicant in the Renewal Assessment Report (RAR), prepared under the framework of the peer review on fludioxonil for renewal of approval according to Article 13 of Regulation (EU) No 844/2012.2

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

For this application, the data requirements established in Regulation (EU) No 544/20114 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 79/2014 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20115. An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

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

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

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

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

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

4 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

5 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1. **Residues in plants**

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

1.1.1. **Nature of residues in primary crops**

Not relevant for the current assessment.

1.1.2. **Nature of residues in rotational crops**

Not relevant for the current assessment.

1.1.3. **Nature of residues in processed commodities**

Not relevant for the current assessment.

1.1.4. **Methods of analysis in plants**

Not relevant for the current assessment.

1.1.5. **Stability of residues in plants**

Not relevant for the current assessment.

1.1.6. **Proposed residue definitions**

The previously derived residue definitions are still applicable.

1.2. **Magnitude of residues in plants**

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

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

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

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

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

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6 Data gap number 1: six additional residue trials supporting the northern outdoor GAP, four additional residue trials supporting the southern outdoor GAP and six residue trials supporting the indoor GAP on strawberries.
Indoor: To support the adjusted indoor use, 10 residue trials conducted in several EU Member States in different years were submitted. Some of the trials were already assessed by EFSA in the framework of the MRL review. The trials are compliant with the adjusted GAP and were found acceptable for MRL setting and risk assessment.

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

1.2.1. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.2. Magnitude of residues in processed commodities

Not relevant for the current assessment.

1.2.3. Proposed MRLs

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

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

2. Residues in livestock

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

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

2.1. Nature of residues

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

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

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

2.2. Methods of analysis in livestock

Not relevant for the current assessment.
2.3. Magnitude of residues in livestock

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

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

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

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

2.4. Proposed MRLs

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

3. Consumer risk assessment

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

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

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

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

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

4. Conclusion and Recommendations

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

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

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7 Livestock feeding study for meat ruminants at higher dose levels, taking into account the calculated dietary burdens where levels of fludioxonil and metabolites containing the 2,2-difluorobenzo [1,3]dioxole-4 carboxylic moiety are preferably reported separately.
The peer review of the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised and therefore the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the EU pesticides peer review.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. fludioxonil

ADI acceptable daily intake

ARfD acute reference dose

BBCH growth stages of mono- and dicotyledonous plants

bw body weight

CF conversion factor for enforcement to risk assessment residue definition

DAT days after treatment

DM dry matter

EMS evaluating Member State

GAP Good Agricultural Practice

HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry

HR highest residue
| Acronym | Description |
|---------|-------------|
| IEDI    | international estimated daily intake |
| IESTI   | international estimated short-term intake |
| ILV     | independent laboratory validation |
| InChiKey| International Chemical Identifier Key |
| ISO     | International Organisation for Standardisation |
| IUPAC   | International Union of Pure and Applied Chemistry |
| LOQ     | limit of quantification |
| MRL     | maximum residue level |
| NEU     | northern Europe |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant-back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| PRIMO   | (EFSA) Pesticide Residues Intake Model |
| PROFile | (EFSA) Pesticide Residues Overview File |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RAR     | Renewal Assessment Report |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SEU     | southern Europe |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue |
| UV      | ultraviolet (detector) |
| WG      | water-dispersible granule |
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

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

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|
|                       |                         |              |                                   | Type(b)     | Conc. a.s.  | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate Unit | PHI (days) (d) | Remarks |
| Strawberry NEU        | F                       | W G          | 250 g/kg                          | Foliar – spraying | 3 10 | 250 g a.s/ha |
| Strawberry SEU        | F                       | W G          | 250 g/kg                          | Foliar – spraying | 3 10 | 250 g a.s/ha |
| Strawberry EU         | G                       | W G          | 250 g/kg                          | Foliar – spraying | 3 10 | 250 g a.s/ha |

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

| Crop and/or situation | NEU, SEU, MS or country | F, G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|--------------|-----------------------------------|-------------|-------------|-------------------------------|
|                       |                         |              |                                   | Type(b)     | Conc. a.s.  | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate Unit | PHI (days) (d) | Remarks |
| Strawberry NEU        | F                       | W G          | Aspergillus spp. Botrytis cinerea Colletotrichum spp. | Foliar spray BBCH 55-89 | 3 10 | 0.25-1.666 300-2000 | 250 g a.s/ha |
| Strawberry SEU        | F                       | W G          | Aspergillus spp. Botrytis cinerea Colletotrichum spp. | Foliar spray BBCH 55-89 | 3 10 | 0.25-1.666 300-2000 | 250 g a.s/ha |
| Strawberry EU         | G                       | W G          | Aspergillus spp. Botrytis cinerea Colletotrichum spp. | Foliar spray BBCH 55-89 | 3 10 | 0.25-1.666 300-2000 | 250 g a.s/ha |

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

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

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## Appendix B – List of end points

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      | Grape       | Foliar 3 x 0.5 kg a.s./ha | 0, 14, 35 (maturity) | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007, 2011) |
|                                  | Tomato      | Foliar 3 x 0.75 kg a.s./ha | 0, 40 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2007) |
|                                  | Peach       | Foliar, 3 x 0.28 kg a.s./ha, 3 x 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, 2011) |
|                                  | Potato      | Seed, 2.5 g a.s./100 kg seed | 0, 40, 71, 95 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Leafy crops                      | Lettuce     | Foliar, 3 x 0.2 kg a.s./ha, 3x0.6 kg a.s./ha | 0, 6, 13 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Cereals/ grass                   | Rice        | Seed, 6.5 g a.s./100 kg seed | 0, 38, 76, 152 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
|                                  | Wheat       | Seed, 3.9 - 7.4 g a.s./100 kg seed | 48, 83, 106 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Pulses/oilseeds                 | Cotton      | Seed, 2.5 or 5 g a.s./100 kg seed | 186 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
|                                  | Soybean     | Seed, 5 g a.s./100 kg seed | 28, 38, 133 | Radiolabelling: [pyrrole-4-14C] (EFSA, 2011) |
| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
| Root/tuber crops                 | Sugar beets | 0.75 kg a.s./ha | 140, 320, 345 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                  | Turnips     | 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                  | Radishes    | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                  |             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [phenyl-14C] (EFSA, 2007, 2011) |
| Leafy crops                      | Lettuce     | 0.75 kg a.s./ha | 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
| Pulses and oilseeds             | Mustard     | 0.124 kg a.s./ha | 33, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                  |             | 0.062 kg a.s./ha | 32, 90 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
|                                  |             | 1.117 kg a.s./ha | 30, 90, 210 | Radiolabelling: [pyrrole-14C] (EFSA, 2007, 2011) |
## Cereal (small grain)

| Crop       | Active Substance (kg a.s./ha) | Matrix | Radiolabelling          | Conditions          | Stable? | Comment/Source |
|------------|-------------------------------|--------|-------------------------|---------------------|---------|----------------|
| Winter wheat | 0.75                          | 140, 320, 345 | [pyrrole-14C] (EFSA, 2007, 2011) |                     |         |                |
|            | 0.124                         | 33, 90 | [pyrrole-14C] (EFSA, 2007, 2011) |                     |         |                |
|            | 0.062                         | 32, 90 | [pyrrole-14C] (EFSA, 2007, 2011) |                     |         |                |
|            | 1.117                         | 30, 90, 210 | [phenyl-14C] (EFSA, 2007, 2011) |                     |         |                |
| Spring wheat | 0.124                         | 33, 90 | [pyrrole-14C] (EFSA, 2007, 2011) |                     |         |                |
| Corn        | 0.75                          | 140, 320, 345 | [pyrrole-14C] (EFSA, 2007, 2011) |                     |         |                |

## Processed commodities (hydrolysis study)

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

## Can a general residue definition be proposed for primary crops?
- Yes (EFSA, 2011)

## Rotational crop and primary crop metabolism similar?
- Yes (EFSA, 2011)

## Residue pattern in processed commodities similar to residue pattern in raw commodities?
- Yes (EFSA, 2011)

## Plant residue definition for monitoring (RD-Mo)

## Plant residue definition for risk assessment (RD-RA)

## Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
- Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3] dioxole-4 carboxylic acid (CGA 192155), expressed as fludioxonil
- Matrices with high water content, high oil content, high acid content and dry matrices: HPLC/MS-MS, LOQ 0.01 mg/kg
- Confirmatory method available
- ILV available (EFSA, 2011)

**DAT:** days after treatment; **a.s.:** active substance; **PBI:** plant-back interval; **HPLC–MS/MS:** high-performance liquid chromatography with tandem mass spectrometry; **LOQ:** limit of quantification; **ILV:** independent laboratory validation.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity                          | T °C  | Stability period Value | 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  | Rapseed, corn oil                   | –18   | 24 Months              | Fludioxonil       | EFSA (2007)   |
|                                  | Dry/High starch   | Cereal grains, maize grains,         | –18   | 24 Months              | Fludioxonil       | EFSA (2007)   |
|                                  |                   | potato tubers                       | –20   | 24 Months              | Fludioxonil       | EFSA (2007)   |
|                                  | High acid content | Grapes                             | < –20 | 24 Months              | Fludioxonil       | EFSA (2011)   |
|                                  | Others            | Cereal straw, Corn meal, Sorghum hay| –16   | 24 Months              | Fludioxonil       | EFSA (2007)   |

### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/ Indoor\(a\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(b\) (mg/kg) | STMR\(c\) (mg/kg) | CF\(d\)   |
|-----------|---------------------|-----------------------------------------------------------------|-----------------|------------------------|-----------------|-----------------|----------------|
| Strawberry| NEU                 | GAP with PHI 1 day                                               | No new information provided. The GAP assessed in the MRL review with PHI 1 day is not sufficiently supported by data | ---         | ---            | ---            | ---             |
|           |                     | Mo: EFSA, 2011: 0.24; 0.54; France, 2018: –                     |                 |                        |                 |                 |                 |
|           |                     | RA: –                                                            |                 |                        |                 |                 |                 |
|           |                     | GAP with PHI 3 days                                              | Seven trials fully compliant with the adjusted GAP. Data set completed with one trial compliant with the sample collected at PHI 1 day instead of 3 days (underlined) | 0.8         | 0.54          | 0.19          | 1               |
|           |                     | Mo: France, 2018: 0.07; 0.09; 0.10; 0.16; 0.21; 0.23; 0.54 RA: – |                 |                        |                 |                 |                 |
| Strawberry| SEU                 | GAP with PHI 1 day                                               | No new information provided. The GAP assessed in the MRL review with PHI 1 day is not sufficiently supported by data | ---         | ---            | ---            | ---             |
|           |                     | Mo: EFSA, 2011: 0.31; 0.77; 0.87; 0.7 RA: –                      |                 |                        |                 |                 |                 |
| Commodity      | Region/ Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|---------------|------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| GAP with PHI 3 days Mo: France, 2018: 0.2; 0.27; 0.64; 0.71; 0.73; 0.89; 1.02 RA: – | Seven trials compliant with the adjusted GAP. Underlined values, higher residues observed at a longer PHI of 7 days. Data set not sufficient to derive proposal | – | 1.02 | 0.71 | 1 |
| Strawberry Indoor GAP with PHI 1 day Mo: EFSA, 2011: 0.78; 0.26 RA: – | Residue trials compliant with the adjusted GAP                  | 4 | 2.24 | 0.31 | 1 |
|               | GAP with PHI 3 days Mo: France, 2018: 0.19; 0.20; 0.21; 0.24; 0.29; 0.33; 0.45; 0.66; 1.04; 2.24. RA: – | No new information provided. The GAP assessed in the MRL review with PHI 1 day is not supported by data | – | – | – | – |

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. Metabolism in fruit crops after foliar application does not result in the formation of the metabolite CGA 192155, therefore the EU pesticide peer review concluded to use the conversion from enforcement to risk assessment of 1 (EFSA, 2007).

**B.1.2.2. Residues in rotational crops**

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No | Fludioxonil residues are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP (EFSA, 2007) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No | Based on the rotational crop study (bare soil: 1.5N to rate of the adjusted GAP) fludioxonil residues above the LOQ of 0.01 mg/kg are not expected to occur in rotational crops when fludioxonil is applied according to the proposed GAP |

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

**B.1.2.3. Processing factors**

No new processing studies were submitted in the framework of the present MRL application.
B.2. Residues in livestock

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

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

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

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

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

| Livestock (available studies) | Animal     | Dose (mg/kg bw per day) | Duration (days) | Comment/Source                                      |
|-------------------------------|------------|-------------------------|----------------|-----------------------------------------------------|
| Laying hen                    | 6.3        | 8                       | [pyrrole-4-\(^{14}\)C]-Fludioxonil, 5 hens (EFSA, 2011) |
| Lactating ruminants           | 3.5        | 4                       | [pyrrole-4-\(^{14}\)C]-Fludioxonil, 2 Goats (EFSA, 2011) |
| Pig                           | –          | –                       | N/A             |
| Fish                          | –          | –                       | N/A             |
### Time needed to reach a plateau concentration in milk and eggs (days)

| Animal       | Commodity | Time (days) |
|--------------|-----------|-------------|
| Milk         |           | 14          |
| Eggs         |           | 5           |

EFSA (2007)

### Metabolism in rat and ruminant similar

Yes

EFSA (2007)

### Can a general residue definition be proposed for animals?

Yes

EFSA (2011)

### Animal residue definition for monitoring (RD-Mo)

**Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil** (EFSA, 2011)

Reg. 396/2005: Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid

(N.B. EFSA recommends to align the residue definition in the MRL legislation with the recommendation of EFSA, 2011)

### Animal residue definition for risk assessment (RD-RA)

**Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4-carboxylic acid (CGA 192155), expressed as fludioxonil** (EFSA, 2011)

### Fat soluble residues

Yes

EFSA (2011)

bw: body weight; MRL: maximum residue level.

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

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

(a): Samples analysed with a method which convert fludioxonil and its oxidisable metabolites into CGA 192155.
### B.2.2. Magnitude of residues in livestock

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

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

bw: body weight; MRL: maximum residue level; STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; HR: highest residue; Mo: monitoring.

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

<sup>a</sup>: Closest feeding level and N dose rate related to the maximum dietary burden.

<sup>b</sup>: The mean residue level for milk was recalculated at the 1N rate for the median dietary burden.

### B.3. Consumer risk assessment

| ARfD | Not necessary (European Commission, 2007) |
|------|------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Not applicable |
| Assumptions made for the calculations | Not applicable |
ADI 0.37 mg/kg bw per day (European Commission, 2007)

Highest IEDI, according to EFSA PRIMo 2

20% ADI (NL toddler)
Contribution of crops assessed:
Strawberries: 0.04% of ADI
Bovine milk: 0.32% of ADI

Assumptions made for the calculations

The most recent risk assessment performed by EFSA using PRIMo revision 3 (EFSA, 2019) was updated, including the median residue level derived from the indoor use on strawberries and the risk assessment values derived from the new feeding study for ruminants and swine. The median residue refers to the edible part of mangoes and cucurbits with inedible peel. The median residue for root crops was multiplied by the conversion factor for risk assessment of 2.8 derived from metabolism study during the EU pesticides peer review

The contributions of commodities where no GAP was reported in the framework of the MRL review or in the following EFSA evaluations were not included in the calculation

B.4. Recommended MRLs

| Code(a) | Commodity     | Existing MRL(h) | Proposed MRL | Conclusion/recommendation |
|---------|---------------|-----------------|--------------|---------------------------|
| 01S2000 | Strawberries  | 4 (f.o. 1)      | 4            | The data gap identified by EFSA during the MRL review for additional residue trials was addressed. The MRL derived for the adjusted indoor GAP with a longer PHI of 3 days corresponds to the current MRL. Thus, no modification of the MRL is necessary. Risk for consumer is unlikely. The adjusted NEU GAP, which is sufficiently supported by data, would require a lower MRL. The original GAPs assessed in the framework of the MRL review with a shorter PHI of 1 day and the adjusted SEU GAP are not sufficiently supported by data. |
| 1011010 | Swine, muscle | 0.01* (c)       | 0.01*        | Based on the updated dietary burden calculation and the new feeding study, the MRL required for swine products were re-calculated. The new assessment confirmed the existing MRLs for swine muscle; a lower MRL would be sufficient for fat, liver and kidney. The option to lower existing EU MRL should be further discussed by risk managers. A risk for consumer is unlikely. |
| 1011020 | Swine, fat    | 0.05* (c)       | 0.01*        | Further risk management consideration required. |
| 1011030 | Swine, liver  | 0.05* (c)       | 0.02         | Further risk management consideration required. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; ADI: acceptable daily intake; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; MRL: maximum residue level.

Enforcement residue definition for plant products: Fludioxonil
Enforcement residue definition for animal products: Sum of fludioxonil and its metabolites oxidized to metabolite 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid, expressed as fludioxonil (F)

N.B. EFSA noted an inaccuracy regarding the residue definition for animal products currently implemented in Regulation (EC) No 396/2005 (the last part of the residue definitions 'expressed as fludioxonil' is missing). Thus, when implementing the current MRL recommendations, the residue definition should be updated as reported above.
| Code<sup>(a)</sup> | Commodity              | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|-----------------|------------------------|----------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011040         | Swine, kidney          | 0.05*<sup>(c)</sup>         | 0.03         | Further risk management consideration required                                                                                                                                                                    |
| 1011050         | Swine edible offal     | 0.05*<sup>(c)</sup>         | Further risk management consideration required                                                                                                                |
| 1011990         | Swine, other products  | 0.05*<sup>(c)</sup>         | Further risk management consideration required                                                                                                                |
| 1012010         | Bovine, muscle         | 0.04<sup>(ft 2)</sup>       | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1012020         | Bovine, fat            | 0.2<sup>(ft 2)</sup>        | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1012030         | Bovine, liver          | 0.2<sup>(ft 2)</sup>        | 0.06         | Further risk management consideration required                                                                                                                                                                    |
| 1012040         | Bovine, kidney         | 0.2<sup>(ft 2)</sup>        | 0.07         | Further risk management consideration required                                                                                                                                                                    |
| 1012050         | Bovine, edible offal   | 0.05*<sup>(ft 2)</sup>      | Further risk management consideration required                                                                                                                |
| 1012990         | Bovine, other products | 0.05*<sup>(ft 2)</sup>      | Further risk management consideration required                                                                                                                |
| 1013010         | Sheep, muscle          | 0.04<sup>(ft 2)</sup>       | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1013020         | Sheep, fat             | 0.2<sup>(ft 2)</sup>        | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1013030         | Sheep, liver           | 0.2<sup>(ft 2)</sup>        | 0.02         | Further risk management consideration required                                                                                                                                                                    |
| 1013040         | Sheep, kidney          | 0.2<sup>(ft 2)</sup>        | 0.03         | Further risk management consideration required                                                                                                                                                                    |
| 1013050         | Sheep, edible offal    | 0.05*<sup>(ft 2)</sup>      | Further risk management consideration required                                                                                                                |
| 1013990         | Sheep, other products  | 0.05*<sup>(ft 2)</sup>      | Further risk management consideration required                                                                                                                |
| 1014010         | Goat, muscle           | 0.04<sup>(ft 2)</sup>       | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1014020         | Goat, fat              | 0.2<sup>(ft 2)</sup>        | 0.01*        | Further risk management consideration required                                                                                                                                                                    |
| 1014030         | Goat, liver            | 0.2<sup>(ft 2)</sup>        | 0.02         | Further risk management consideration required                                                                                                                                                                    |
| 1014040         | Goat, kidney           | 0.2<sup>(ft 2)</sup>        | 0.03         | Further risk management consideration required                                                                                                                                                                    |

The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues.

The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient bovine tissues (muscle, fat, liver and kidney).

The option to lower existing EU MRL should be further discussed by risk managers.

Risk for consumer is unlikely.

The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. The MRLs for edible offal and other products are usually derived by risk managers by extrapolation from other animal tissues.

The data gap identified in the MRL review for a new feeding study in ruminants has been satisfactorily addressed. According to the new feeding study, lower MRL values would be sufficient sheep tissues (muscle, fat, liver and kidney).

The option to lower existing EU MRL should be further discussed by risk managers.

Risk for consumer is unlikely.

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

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval; NEU: northern Europe; SEU: southern Europe.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): Although formally, no data gap was identified for swine products, EFSA re-assessed the MRLs, since the new feeding study in ruminants allowed to update the MRLs.
(d): Although formally, no data gap was identified for milk, EFSA re-assessed the MRLs, since the new feeding study allowed to update the MRLs for milk.
(F): Fat-soluble

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1)

ft 2: The European Food Safety Authority identified some information on a livestock feeding study as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 30 January 2016, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).
### Appendix C – Pesticide Residue Intake Model (PRiMo)

#### Fludioxonil (F)

| Toxicological reference values | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Not necessary |
|--------------------------------|------------------------|----------------|---------------|
| LOQs (mg/kg) range from:       | 0.01 to: 0.05          |                |               |
| Source of ADI:                 | EFSA PRiMo revision 3.0; 2017/12/11 |
| Year of evaluation:           |                         |                |               |

#### Calculated exposure (% of ADI)

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Pears                          | 20% 75.67 7% 3% 3%                |                                               |
| Potatoes                       | 19% 70.41 8% 6% 1%                |                                               |
| Potatoes                       | 11% 42.11 4% 2% 1%                |                                               |
| Grapefruits                    | 11% 39.69 4% 1% 1.0%              |                                               |
| Potatoes                       | 9% 31.69 5% 1% 0.6%               |                                               |
| Mandarins                      | 8% 28.79 2% 2% 1%                |                                               |
| Mandarins                      | 7% 26.21 2% 2% 0.7%              |                                               |
| Potatoes                       | 7% 26.11 3% 0.9% 0.7%             |                                               |
| Mandarins                      | 7% 25.59 2% 1% 0.9%              |                                               |
| Lettuces                       | 7% 25.10 3% 1% 1%                |                                               |
| Lettuces                       | 7% 24.97 3% 2% 0.4%              |                                               |
| Carrots                        | 6% 23.53 2% 1% 0.7%              |                                               |
| Oranges                        | 6% 22.27 2% 0% 0.6%              |                                               |
| Tomatoes                       | 4% 15.75 2% 0% 0.8%              |                                               |
| Spinaches                      | 4% 13.81 2% 0% 1%                |                                               |
| Pears                          | 3% 12.37 1% 0% 0.6%              |                                               |
| Lettuces                       | 3% 11.60 1% 0% 1%                |                                               |
| Oranges                        | 3% 9.50 1% 0% 0.6%               |                                               |
| Oranges                        | 2% 9.03 1% 0% 0.6%               |                                               |
| Potatoes                       | 1% 8.45 1% 0% 0.2%               |                                               |
| Oranges                        | 1% 8.01 1% 0% 0.3%               |                                               |
| Potatoes                       | 1% 7.50 1% 0% 0.2%               |                                               |

##### Refined calculation mode

#### Exposure resulting from

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Pears                          | 20% 75.67 7% 3% 3%                |                                               |
| Potatoes                       | 19% 70.41 8% 6% 1%                |                                               |
| Potatoes                       | 11% 42.11 4% 2% 1%                |                                               |
| Grapefruits                    | 11% 39.69 4% 1% 1.0%              |                                               |
| Potatoes                       | 9% 31.69 5% 1% 0.6%               |                                               |
| Mandarins                      | 8% 28.79 2% 2% 1%                |                                               |
| Mandarins                      | 7% 26.21 2% 2% 0.7%              |                                               |
| Potatoes                       | 7% 26.11 3% 0.9% 0.7%             |                                               |
| Mandarins                      | 7% 25.59 2% 1% 0.9%              |                                               |
| Lettuces                       | 7% 25.10 3% 1% 1%                |                                               |
| Lettuces                       | 7% 24.97 3% 2% 0.4%              |                                               |
| Carrots                        | 6% 23.53 2% 1% 0.7%              |                                               |
| Oranges                        | 6% 22.27 2% 0% 0.6%              |                                               |
| Tomatoes                       | 4% 15.75 2% 0% 0.8%              |                                               |
| Spinaches                      | 4% 13.81 2% 0% 1%                |                                               |
| Pears                          | 3% 12.37 1% 0% 0.6%              |                                               |
| Lettuces                       | 3% 11.60 1% 0% 1%                |                                               |
| Oranges                        | 3% 9.50 1% 0% 0.6%               |                                               |
| Oranges                        | 2% 9.03 1% 0% 0.6%               |                                               |
| Potatoes                       | 1% 8.45 1% 0% 0.2%               |                                               |
| Oranges                        | 1% 8.01 1% 0% 0.3%               |                                               |
| Potatoes                       | 1% 7.50 1% 0% 0.2%               |                                               |

### Summary

The estimated long-term dietary intake (TMDI/IEDI/NDI) 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.

### Unprocessed commodities

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

**Results for children**

No. of commodities for which ARfD/ADI is exceeded (IESTI):

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

**Results for adults**

No. of commodities for which ARfD/ADI is exceeded (IESTI):

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

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

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

**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) |
|---------------------------------------------|-------------------------|---------------------|
|                                             |                         |                     |

**Results for children**

No. of processed commodities for which ARfD/ADI is exceeded (IESTI):

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

**Results for adults**

No. of processed commodities for which ARfD/ADI is exceeded (IESTI):

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

Conclusion:
### Appendix D – Input values for the exposure calculations

#### D.1. Input values for the dietary burden calculation

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

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

#### D.2. Consumer risk assessment

| Code  | Commodity               | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment(a) | Input value (mg/kg) | Comment |
|-------|-------------------------|------------------------|--------------------|---------------------------|---------------------|---------|
| 110010| Grapefruits             | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 110020| Oranges                 | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 110030| Lemons                  | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 110040| Limes                   | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 110050| Mandarins               | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 110990| Other citrus fruit      | 10                     | Existing EU MRL    | STMR-RAC                  | 5.3                 |         |
| 120100| Pistachios              | 0.2                    | Existing EU MRL    | STMR-RAC                  | 0.06                |         |
| 130010| Apples                  | 5                      | Existing EU MRL    | STMR-RAC                  | 2.3                 |         |
| 130020| Pears                   | 5                      | Existing EU MRL    | STMR-RAC                  | 2.3                 |         |
| 130030| Quinces                 | 5                      | Existing EU MRL    | STMR-RAC                  | 2.3                 |         |
| 130040| Medlar                  | 5                      | Existing EU MRL    | STMR-RAC                  | 2.3                 |         |
| 130050| Loquats/Japanese medlars| 5                      | Existing EU MRL    | STMR-RAC                  | 2.3                 |         |
| 140010| Apricots                | 5                      | Existing EU MRL    | STMR-RAC                  | 1.06                |         |
| 140020| Cherries (sweet)        | 5                      | Existing EU MRL    | STMR-RAC                  | 0.8                 |         |
| Code | Commodity | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment<sup>(a)</sup> |
|------|-----------|----------------------|--------------------|----------------------------------|
|      |           |                      |                    | Input value (mg/kg) | Comment |
| 140030 | Peaches | 10 | Existing EU MRL | 3.65 | STMR-RAC |
| 140040 | Plums | 5 | Existing EU MRL | 1.06 | STMR-RAC |
| 151010 | Table grapes | 5 | Existing EU MRL | 0.38 | STMR-RAC |
| 151020 | Wine grapes | 4 | Existing EU MRL | 0.33 | STMR-RAC |
| 153010 | Blackberries | 5 | Existing EU MRL | 1 | STMR-RAC |
| 153030 | Raspberries (red and yellow) | 5 | Existing EU MRL | 1 | STMR-RAC |
| 153990 | Other cane fruit | 5 | Existing EU MRL | 1 | STMR-RAC |
| 154010 | Blueberries | 2 | Existing EU MRL | 0.37 | STMR-RAC |
| 154020 | Cranberries | 2 | Existing EU MRL | 0.37 | STMR-RAC |
| 154030 | Currants (red, black and white) | 2 | Existing EU MRL | 0.37 | STMR-RAC |
| 154040 | Gooseberries (green, red and yellow) | 2 | Existing EU MRL | 0.37 | STMR-RAC |
| 154080 | Elderberries | 0.8 | Existing EU MRL | 0.24 | STMR-RAC |
| 162010 | Kiwi fruits (green, red, yellow) | 15 | Existing EU MRL | 7.3 | STMR-RAC |
| 163010 | Avocados | 0.4 | Existing EU MRL | 0.05 | STMR-RAC |
| 163030 | Mangoes | 2 | Existing EU MRL | 0.02 | STMR-RAC |
| 163050 | Granate apples/pomegranates | 3 | Existing EU MRL | 0.95 | STMR-RAC |
| 163080 | Pineapples | 7 | Existing EU MRL | 2.14 | STMR-RAC |
| 211000 | Potatoes | 5 | Existing EU MRL | 1.5 | STMR-RAC |
| 212030 | Yams | 10 | Existing EU MRL | 3.76 | STMR-RAC |
| 213010 | Beetrots | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 213020 | Carrots | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 213030 | Celeriacs/turnip rooted celeries | 0.2 | Existing EU MRL | 0.196 | STMR-RAC*CF |
| 213040 | Horseradishes | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 213060 | Parsnips | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 213070 | Parsley roots/Hamburg roots parsley | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 213080 | Radishes | 0.3 | Existing EU MRL | 0.098 | STMR-RAC*CF |
| 213090 | Salsifes | 1 | Existing EU MRL | 1.148 | STMR-RAC*CF |
| 220010 | Garlic | 0.02 | Existing EU MRL | 0.056 | STMR-RAC*CF |
| 220020 | Onions | 0.5 | Existing EU MRL | 0.056 | STMR-RAC*CF |
| 220030 | Shallots | 0.02 | Existing EU MRL | 0.056 | STMR-RAC*CF |
| 220040 | Spring onions/green onions and Welsh onions | 5 | Existing EU MRL | 0.532 | STMR-RAC*CF |
| 231010 | Tomatoes | 3 | Existing EU MRL | 0.66 | STMR-RAC |
| 231020 | Sweet peppers/bell peppers | 1 | Existing EU MRL | 0.21 | STMR-RAC |
| 231030 | Aubergines/egg plants | 0.4 | Existing EU MRL | 0.12 | STMR-RAC |
| 232010 | Cucumbers | 0.4 | Existing EU MRL | 0.1 | STMR-RAC |
| 232020 | Gherkins | 0.4 | Existing EU MRL | 0.1 | STMR-RAC |
| 232030 | Courgettes | 0.4 | Existing EU MRL | 0.1 | STMR-RAC |
| Code       | Commodity                          | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment<sup>(a)</sup> |
|------------|------------------------------------|-----------------------|--------------------|---------------------------------------|
|            |                                    |                       |                    | Input value (mg/kg) Comment            |
| 232990     | Other cucurbits - edible peel      | 0.4                   | Existing EU MRL    | 0.1 STMR-RAC                          |
| 233010     | Melons                             | 0.3                   | Existing EU MRL    | 0.01 STMR-RAC                         |
| 233020     | Pumpkins                           | 0.3                   | Existing EU MRL    | 0.01 STMR-RAC                         |
| 233030     | Watermelons                        | 0.3                   | Existing EU MRL    | 0.01 STMR-RAC                         |
| 233990     | Other cucurbits - inedible peel    | 0.3                   | Existing EU MRL    | 0.01 STMR-RAC                         |
| 241010     | Broccoli                           | 0.7                   | Existing EU MRL    | 0.23 STMR-RAC                         |
| 242020     | Head cabbages                      | 2                     | Existing EU MRL    | 0.24 STMR-RAC                         |
| 243010     | Chinese cabbages/pe-tsai           | 10                    | Existing EU MRL    | 1.2 STMR-RAC                          |
| 251010     | Lamb’s lettuce/corn salads         | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251020     | Lettuces                           | 40                    | Existing EU MRL    | 8.3 STMR-RAC                          |
| 251030     | Escaroles/broad-leaved endives     | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251040     | Cress and other sprouts and shoots | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251050     | Land cress                          | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251060     | Roman rocket/rucola                | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251070     | Red mustards                       | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 251080     | Baby leaf crops (including brassica species) | 20 | Existing EU MRL | 6.13 STMR-RAC |
| 251990     | Other lettuce and other salad plants | 20 | Existing EU MRL | 6.13 STMR-RAC |
| 252010     | Spinaches                          | 30                    | Existing EU MRL    | 5.8 STMR-RAC                          |
| 252020     | Purslanes                          | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 252030     | Chards/beet leaves                 | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256010     | Chervil                            | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256020     | Chives                             | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256030     | Celery leaves                      | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256040     | Parsley                            | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256050     | Sage                               | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256060     | Rosemary                           | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256070     | Thyme                              | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256080     | Basil and edible flowers           | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256090     | Laurel/bay leaves                  | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256100     | Tarragon                           | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 256990     | Other herbs                        | 20                    | Existing EU MRL    | 6.13 STMR-RAC                         |
| 260010     | Beans (with pods)                  | 1                     | Existing EU MRL    | 0.48 STMR-RAC                         |
| 260020     | Beans (without pods)               | 0.4                   | Existing EU MRL    | 0.02 STMR-RAC                         |
| 260030     | Peas (with pods)                   | 1                     | Existing EU MRL    | 0.48 STMR-RAC                         |
| 260040     | Peas (without pods)                | 0.3                   | Existing EU MRL    | 0.04 STMR-RAC                         |
| 260050     | Lentils (fresh)                    | 0.05                  | Existing EU MRL    | 0.02 STMR-RAC                         |
| 270010     | Asparagus                          | 0.01                  | Existing EU MRL    | 0.01 STMR-RAC                         |
| 270030     | Celeriac                           | 1.5                   | Existing EU MRL    | 0.32 STMR-RAC                         |
| 270040     | Florence fennels                   | 1.5                   | Existing EU MRL    | 0.32 STMR-RAC                         |
| Code   | Commodity                      | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment(1) |
|--------|--------------------------------|------------------------|--------------------|----------------------------|
|        |                                |                        |                    |                            |
| 300010 | Beans                          | 0.5                    | Existing EU MRL    | 0.04                       | STMR-RAC                   |
| 300020 | Lentils                        | 0.4                    | Existing EU MRL    | 0.02                       | STMR-RAC                   |
| 300030 | Peas                           | 0.4                    | Existing EU MRL    | 0.02                       | STMR-RAC                   |
| 300040 | Lupins/lupini beans            | 0.4                    | Existing EU MRL    | 0.02                       | STMR-RAC                   |
| 300990 | Other pulses                   | 0.4                    | Existing EU MRL    | 0.02                       | STMR-RAC                   |
| 401030 | Poppy seeds                    | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 401050 | Sunflower seeds                | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 401060 | Rapeseeds/canola seeds         | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 401070 | Soya beans                     | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 401090 | Cotton seeds                   | 0.01                   | Existing EU MRL    | 0.02                       | STMR-RAC                   |
| 500010 | Barley                         | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500020 | Buckwheat and other pseudo-cereals | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500030 | Maize/corn                     | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500040 | Common millet/proso millet     | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500050 | Oat                            | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500060 | Rice                           | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500070 | Rye                            | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500080 | Sorghum                        | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 500090 | Wheat                          | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 633020 | Ginseng root                   | 4                      | Existing EU MRL    | 0.8                        | STMR-RAC*CF                |
| 1011010| Swine: Muscle/meat             | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 1011030| Swine: Liver                   | 0.02                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1011040| Swine: Kidney                  | 0.03                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1012010| Bovine: Muscle/meat            | 0.01                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1012020| Bovine: Fat tissue             | 0.01                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1012030| Bovine: Liver                  | 0.06                   | Proposed new MRL   | 0.04                       | STMR-RAC                   |
| 1012040| Bovine: Kidney                 | 0.07                   | Proposed new MRL   | 0.05                       | STMR-RAC                   |
| 1013010| Sheep: Muscle/meat             | 0.01                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1013030| Sheep: Liver                   | 0.02                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1013040| Sheep: Kidney                  | 0.03                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1014010| Goat: Muscle/meat              | 0.01                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1014030| Goat: Liver                    | 0.02                   | Proposed new MRL   | 0.01                       | STMR-RAC                   |
| 1014040| Goat: Kidney                   | 0.03                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1016010| Poultry: Muscle/meat           | 0.01                   | Existing EU MRL    | 0.01                       | STMR-RAC                   |
| 1016020| Poultry: Fat tissue            | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| 1016030| Poultry: Liver                 | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| 1016040| Poultry: Kidney                | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| 1020010| Milk: Cattle                   | 0.02                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1020020| Milk: Sheep                    | 0.02                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1020030| Milk: Goat                     | 0.02                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1020040| Milk: Horse                    | 0.02                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1020990| Milk: Others                   | 0.02                   | Proposed new MRL   | 0.02                       | STMR-RAC                   |
| 1030010| Eggs: Chicken                  | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| 1030020| Eggs: Duck                     | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| 1030030| Eggs: Goose                    | 0.05                   | Existing EU MRL    | 0.05                       | STMR-RAC                   |
| Code    | Commodity       | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment<sup>(a)</sup> |
|---------|-----------------|------------------------|--------------------|--------------------------------------|
|         |                 |                        |                    | Input value (mg/kg) | Comment |
| 1030040 | Eggs: Quail     | 0.05                   | Existing EU MRL    | 0.05                  | STMR-RAC |
| 1030990 | Eggs: Others    | 0.05                   | Existing EU MRL    | 0.05                  | STMR-RAC |
|         | Other crops/commodities |            |                    |                      |         |

MRL: maximum residue level; STMR: supervised trials median residue; CF: conversion factor; RAC: raw agricultural commodity.

<sup>(a)</sup>: CF of 2.8 (derived from the metabolism study on spring onions) was used for residues resulting from foliar application on root crops (EFSA, 2007).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|---------------------------------|-------------------------------------------------|---------------------------------|
| **Fludioxonil**<br>CGA 173506   | 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile<br>N#Cc1c[NH]cc1c1cccc2OC(F)(F)Oc12<br>MUJOIMPVNIMKCUHFFFAOYSA-N | ![Structural formula](image) |
| **CGA 192155**                  | 2,2-difluoro-benzo[1,3]dioxole-4 carboxylic acid<br>O=C(O)c1ccccc2OC(F)(F)Oc12<br>ZGAQVJDFFV7WKUHFFFAOYSA-N | ![Structural formula](image) |

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

<sup>(a)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N201541, Build 75170, 19 December 2014).

<sup>(b)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).