Modification of the existing maximum residue levels for flonicamid in strawberries and other berries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service Health, Food chain Safety and Environment of Belgium, submitted an application to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in blueberries, cranberries, currants, gooseberries and strawberries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops assessed. Adequate analytical methods for enforcement are available to control the residues of flonicamid in plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg for each analyte included in the residue definition (combined LOQ of 0.03 mg/kg). Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flonicamid according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Keywords: flonicamid, blueberries, cranberries, currants, gooseberries, strawberries, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service of Belgium, FPS Health, Food chain Safety and Environment, submitted an application to modify the existing maximum residue levels (MRLs) for the active substance fonicamid in blueberries, cranberries, currants, gooseberries and strawberries. The national competent authority in Belgium (evaluating Member State (EMS)) drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 12 December 2018. To accommodate for the intended uses of fonicamid, the EMS proposed to raise the existing MRLs from 0.03* mg/kg (0.7 mg/kg recently proposed amendment in an EFSA Reasoned Opinion) to 0.8 mg/kg for blueberries, cranberries, currants and gooseberries and from 0.03* mg/kg (0.5 mg/kg recently proposed amendment in an EFSA Reasoned Opinion) to 0.7 mg/kg for strawberries.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC (EC), the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of the present application, the following conclusions are derived.

The metabolism of fonicamid was investigated in the framework of the peer review under Directive 91/414/EEC and the MRL review in crops belonging to the groups of fruit crops (peach, pepper), root crops (potato), and cereals/grass (wheat).

Studies investigating the effect of processing on the nature of fonicamid (hydrolysis studies) demonstrated that the active substance and its metabolites are hydrolytically stable under the representative conditions.

Strawberries and berries may be grown in rotation with other crops. Due to the fast degradation of fonicamid and its metabolites in the soil, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the residue definition for plant products was proposed as ‘sum of fonicamid, 4-trifluoromethylnicotinic acid (TFNA) and N-(4-trifluoromethyl nicotinoyl)glycine (TFNG), expressed as fonicamid’ for enforcement and risk assessment.

This residue definition is applicable to primary crops and processed products.

EFSA concluded that for the crops assessed in the present application, the metabolism of fonicamid in primary crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg for each analyte included in the residue definition (combined limit of quantification (LOQ) of 0.03 mg/kg).

The available residue trials are sufficient to derive MRL proposals for strawberries, blueberries, cranberries, currants and gooseberries.

Residues of fonicamid in commodities of animal origin were not assessed since the crops under consideration in this MRL application are not used for feed purposes.

The toxicological profile of fonicamid was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.025 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.025 mg/kg bw. The toxicological reference values set for the parent fonicamid are also applicable to the metabolites TFNA and TFNG, which are included in the residue definition for plant products.

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure assessment was performed only with regard to the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The estimated maximum exposure in percentage of the ARfD accounted for up to 29%. EFSA concluded that the short-term intake of residues of fonicamid resulting from the intended uses is unlikely to present a risk to consumer health.

The long-term exposure assessment performed in the framework of the MRL review was updated with the risk assessment values derived from the residue trials submitted in support of the present MRL application, with the relevant risk assessment values derived in EFSA reasoned opinions published after the MRL review, and the ones derived in Codex MRL assessments for the Codex Maximum Residue Limits (CXLs) taken over in the EU MRL legislation. The highest estimated long-term dietary...
intake was 28% of the ADI (NL toddler). The contributions of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were all less than 1% of ADI. EFSA concluded that the long-term intake of residues of flonicamid resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

EFSA concluded that the proposed use of flonicamid on blueberry, cranberry, currant, gooseberry and strawberry will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B-D.

| Code(a) | Commodity       | Existing EU MRL(b)/recently proposed amendment(c) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------------|----------------------------------------------------------|-------------------------|-----------------------|
| 152000  | Strawberries    | 0.03*/0.5                                                 | 0.7                     | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154010  | Blueberries     | 0.03*/0.7                                                 | 0.8                     | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154020  | Cranberries     | 0.03*/0.7                                                 | 0.8                     | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154030  | Currants        | 0.03*/0.7                                                 | 0.8                     | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154040  | Gooseberries    | 0.03*/0.7                                                 | 0.8                     | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |

**Enforcement residue definition:** Flonicamid (sum of flonicamid, TFNA and TFNG expressed as flonicamid)

MRL: maximum residue level; TFNA: 4-trifluoromethylnicotinic acid; TFNG: N-(4-trifluoromethylnicotinoyl)glycine.

*: 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 established in Commission Regulation (EU) 2018/687.
(c): MRL proposal derived in the EFSA reasoned opinion on the modification of the existing maximum residue level for flonicamid in various crops issued in August 2018 (EFSA, 2018b).
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Assessment

The detailed description of the intended uses of flonicamid, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A. Flonicamid is the ISO common name for $N$-cyanomethyl-4-(trifluoromethyl)nicotinamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Flonicamid was evaluated in the framework of Directive 91/414/EEC with France designated as the rapporteur Member State (RMS); the representative uses assessed were foliar spray applications on potato, wheat, apple and pear in northern and southern European Union (EU) and on peach in southern EU. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2010). Flonicamid was approved for use as an insecticide on 1 September 2010.

The EU MRLs for flonicamid are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for flonicamid (EFSA, 2015, 2016, 2017, 2018b,c). The proposals from these reasoned opinions have been considered in the MRL legislation, except the most recent opinions of EFSA (2018b). Certain Codex Maximum Residue Limits (CXLs) for flonicamid, for which the EU expressed its support during the CCPR meeting, have been transposed into EU legislation by Commission Regulation (EU) 2018/687.5

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service of Belgium, FPS Health, Food chain Safety and Environment, submitted an application to modify the existing MRL for the active substance flonicamid in blueberries, cranberries, currants, gooseberries and strawberries. The national competent authority in Belgium (evaluating Member State, EMS) drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 12 December 2018. To accommodate for the intended uses of flonicamid, the EMS proposed to raise the existing MRLs to 0.8 mg/kg for blueberries, cranberries, currants and gooseberries, and to 0.7 mg/kg for strawberries.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2018), the DAR (and its addendum) (France, 2005, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on flonicamid (European Commission, 2010a), the conclusion on the peer review of the pesticide risk assessment of the active substance flonicamid (EFSA, 2010), as well as the conclusions from previous EFSA opinions on flonicamid including the Article 12 MRL review (EFSA, 2014, 2015, 2016, 2017, 2018b,c).

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

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2010/29/EU of 27 April 2010 amending Council Directive 91/414/EEC to include flonicamid (KI-220) as active substance, OJ L 106, 28.4.2010, p. 9–11.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzo[1,2,3-cd]pyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, methafenone, pendimethalin and tefluafenfen in or on certain products. OJ L 121/63, 16.5.2018, p. 63–104.
6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation report submitted by the EMS (Belgium, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

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

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

The metabolism of fonicamid in primary crops belonging to the group of fruit crops (peach, pepper), root crops (potato) and cereals/grass (wheat) has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). When primary crops were treated with 3-14C-phenyl fonicamid, parent compound and the two metabolites 4-trifluoromethylnicotinic acid (TFNA) and N-(4-trifluoromethylnicotinoyl)glycine (TFNG) were found to be the main residues.

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

Strawberries may be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2010), the DT90 value of fonicamid and its metabolites ranged from 1.5 to 8.7 days, which is far below the trigger value of 100 days (European Commission, 1997c). Thus, further studies on rotational crops are not required.

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

Standard hydrolysis studies investigating the nature of residues in processed commodities and simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the EU pesticides peer review and the MRL review and in a previous MRL application (EFSA, 2010, 2014, 2018b). It was concluded that the parent compound fonicamid and its metabolites are hydrolytically stable under the representative conditions. The residue definition for primary crops is also applicable for processed commodities.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of fonicamid residues and its metabolites (TFNG and TFNA) in plant commodities were assessed during the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). Sufficiently validated methods are available to control residues of fonicamid and its metabolites in high water, high acid and high oil content matrices and in dry commodities. The methods allow quantifying residues for each analyte included in the residue definition individually at the LOQ of 0.01 mg/kg (combined limit of quantification (LOQ) of 0.03 mg/kg) (EFSA, 2014). EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs for fonicamid in the crops under consideration.

1.1.5. **Storage stability in plant matrices**

The storage stability of fonicamid and its metabolites in plant matrices under frozen conditions was investigated in the framework of the EU pesticides peer review in commodities classified as high water content and as dry commodities; according to these studies fonicamid and its metabolites are stable for up to 18 months when stored at −18°C (EFSA, 2010). In a previous MRL application, storage stability was investigated in high oil content and in high protein content commodities and according to these studies fonicamid and its metabolites are stable for up to 12 months when stored at −20°C (EFSA, 2015). In addition, in a previous MRL application, storage stability was investigated in high acid content commodities and according to these studies, fonicamid and its metabolites are stable for up to 6 months when stored at −18°C (EFSA, 2018b).
EFSA concludes that the storage stability data cover the storage time for the supervised residue trials submitted in this application where the samples were stored for a period of less than 5 months. Thus, the residue trials are valid with regard to storage stability.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and degradation products, the following residue definition for plant commodities was proposed in the framework of the MRL Review (EFSA, 2014):

- Residue definition for enforcement and for risk assessment: sum of flonicamid and the metabolites 4-(trifluoromethyl)nicotinic acid (TFNA) and N-[4-(trifluoromethyl)nicotinoyl]glycine (TFNG) expressed as fonicamid

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition. Taking into account the available information for the uses assessed in this application, EFSA concluded that the existing residue definition is appropriate, and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the proposed uses on in the present MRL application, the applicant submitted residue trials performed in blueberry, currant and strawberry.

**Strawberry**

In support of the proposed Good Agricultural Practice (GAP) (greenhouse use) on strawberry (2 × 70 g a.s./ha, 3-day preharvest interval (PHI)), eight GAP-compliant indoor residue trials were conducted on strawberry in Germany and the United Kingdom in 2016 (Belgium, 2018). Applications were performed with a 7- (two trials), 8- (one trial) or 10-day (five trials) application interval, at growth stages BBCH 81–85 (first application) and BBCH 85–87 (second application), in compliance with the proposed use GAP (7- to 10-day application interval, up to BBCH 87). Sampling was performed at 3-day PHI. In four trials, additional samples were taken 5 days after the last application (residue decline studies). The residue trials are acceptable and sufficiently representative of the intended use on strawberry.

The residue trials samples were analysed for fonicamid and the metabolites TFNA and TFNG expressed as total fonicamid equivalent, in accordance with the residue definition for enforcement and for risk assessment. According to the assessment of the EMS, the methods of analysis used were sufficiently validated and fit for purpose, with individual LOQs for each component of the residue definition of 0.01 mg/kg. The samples were stored under conditions for which integrity of residues has been demonstrated.

The number and quality of the trials is sufficient to derive an MRL proposal of 0.7 mg/kg for strawberries on the basis of the intended indoor GAP.

**Blueberry, cranberry, currant and gooseberry**

In support of the proposed GAPs for greenhouse uses on blueberry, cranberry, currant and gooseberry (2 × 70 g a.s./ha, 3-day PHI), a total of six GAP-compliant indoor residue trials were conducted on blueberries (two trials) and currants (four trials) (Belgium, 2018).

Residue trials on blueberries were conducted in the United Kingdom in 2016. Applications were performed with an 8-day application interval, at growth stages BBCH 81 or 85 (first application) and BBCH 85 (second application), in compliance with the proposed use GAPs (7- to 10-day application interval, up to BBCH 87). Sampling was performed at 3-day PHI, and residue decline sampling was performed in one trial at 5-day PHI.

Residue trials on currants were conducted in Germany in 2016 (one trial, blackcurrant) and in Belgium in 2017 (three trials, redcurrant). Applications were performed with a 7- (two trials), 8- (one trial) or 10-day (one trial) application interval, at growth stages BBCH 78–85 (first application) and BBCH 83–87 (second application), in compliance with the proposed use GAPs. Samples were taken at 3-day PHI; additional samples were taken in two trials at 5-day or 7-day PHI (residue decline studies). Two trials conducted at the same location in Belgium were not geographically independent; however,
these trials were performed with different application dates and on different varieties and were judged to be sufficiently independent and representative of the proposed indoor uses.

Overall, two residue trials performed on blueberry and four residue trials performed on currants are acceptable and sufficiently representative of the critical GAPs for the proposed uses on blueberry, cranberry, currants and gooseberry. In accordance with the guidelines on comparability, extrapolation, group tolerances and the data requirements for setting MRLs for treatments before and after forming the edible part, it is possible to extrapolate from four trials on currants and two trials on any representative crop of the subgroup (d) ‘other small fruits and berries’ (0154000) to the whole subgroup (d) ‘other small fruits and berries’ (0154000) (European Commission, 2017). Therefore, extrapolation from the available trials performed on blueberry and currants to the proposed uses on blueberry, cranberry, currant and gooseberry is acceptable.

The residue trials samples for blueberry and currant were analysed for fonicamid and the metabolites TFNA and TFNG expressed as total fonicamid equivalent, in accordance with the residue definition for enforcement and for risk assessment. According to the assessment of the EMS, the methods of analysis used were sufficiently validated and fit for purpose, with individual LOQs for each component of the residue definition of either 0.01 mg/kg (2016 trials on blueberry and currant) or 0.02 mg/kg (2017 trials on currant). The samples were stored under conditions for which integrity of residues has been demonstrated.

The number and quality of the trials is sufficient to derive an MRL proposal of 0.8 mg/kg for blueberries, cranberries, currants and gooseberries on the basis of the intended indoor GAPs.

1.2.2. Magnitude of residues in rotational crops

The soil degradation studies evaluated in the framework of the peer review (EFSA, 2010) demonstrated that the DT90 value of fonicamid and its metabolites ranged from 1.5 to 8.7 days which is far below the trigger value of 100 days (European Commission, 1997c). Thus, further studies on rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

For the crops assessed in the present application, investigation of the magnitude of residues in processed commodities is not required, considering that the standard hydrolysis studies have demonstrated that fonicamid and its metabolites are stable under the representative conditions (EFSA, 2010, 2014, 2018b) and considering that the expected residues in the crops concerned contribute to a low extent to the overall long-term exposure (less than 1% of the ADI).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for the commodity under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Residues in livestock are not relevant as the commodities under consideration are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3 of the EFSA PRIMo (EFSA, 2018a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for fonicamid used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2010; European Commission, 2010a). The toxicological reference values set for the parent fonicamid are also applicable to the metabolites TFNA and TFNG, which are included in the residue definition residue definition for plant products (EFSA, 2010).
Short-term (acute) dietary risk assessment

The short-term exposure assessment focussed on the commodities assessed in the present MRL application and was performed in accordance with the internationally agreed methodology (EFSA, 2018a). The calculations were based on the highest residue concentrations (HR values) derived from supervised field trials; the list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The estimated maximum exposure in percentage of the ARfD accounted for up to 29% (see Appendix B.3). EFSA concluded that the short-term intake of residues of fionicamid resulting from the intended uses is unlikely to present a risk to consumer health.

Long-term (chronic) dietary risk assessment

A comprehensive long-term exposure assessment was performed in the framework of the MRL review, taking into account the existing uses at EU level (EFSA, 2014). EFSA updated the calculation, using PRIMo revision 3, including the supervised trials median residue concentrations (STMR values) derived for strawberries, blueberries, cranberries, currants and gooseberries from the residue trials submitted in support of the present MRL application, and the relevant STMR values derived in EFSA reasoned opinions published after the MRL review (EFSA, 2015, 2016, 2017, 2018b,c), and the relevant STMR values derived in Codex MRL assessments for the CXLs taken over in the EU MRL legislation (FAO, 2016). The input values used in the exposure calculations are summarised in Appendix D.2.

The highest estimated long-term dietary intake was 28% of the ADI (NL toddler). The contributions of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were all less than 1% of ADI. The results of the long-term dietary risk assessment are presented in Appendix B.3.

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

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for strawberries, blueberries, cranberries, currants and gooseberries.

Adequate analytical methods for enforcement are available to control the residues of fionicamid in plant matrices under consideration.

EFSA concluded that the proposed use of fionicamid on blueberry, cranberry, currant, gooseberry and strawberry will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

- a.s. active substance
- ADI acceptable daily intake
- ARFD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CAC Codex Alimentarius Commission
- CAS Chemical Abstract Service
- CCPR Codex Committee on Pesticide Residues
- CF conversion factor for enforcement to risk assessment residue definition
| Acronym | Description |
|---------|-------------|
| CXL     | Codex maximum residue limit |
| DAR     | draft assessment report |
| DAT     | days after treatment |
| DM      | dry matter |
| DT90    | period required for 90% dissipation (define method of estimation) |
| EMS     | evaluating Member State |
| GAP     | Good Agricultural Practice |
| HPLC-MS/MS | high-performance liquid chromatography with tandem mass spectrometry |
| HR      | highest residue |
| IEDI    | international estimated daily intake |
| IESTI   | international estimated short-term intake |
| 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 |
| MS      | Member States |
| NEU     | northern Europe |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant-back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| RA      | risk assessment |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SEU     | southern Europe |
| STMR    | supervised trials median residue |
| TAR     | total applied radioactivity |
| TFNA    | 4-trifluoromethylnicotinic acid |
| TFNG    | N-(4-trifluoromethyl nicotinoyl)glycine |
| UV      | ultraviolet (detector) |
| WG      | water-dispersible granule |
| WHO     | World Health Organization |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F, G or I (a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|--------------|-----------------------------------|-------------|----------------|------------------------------|
|                       |                         |              |                                   | Type(b)     | Conc. a.s. Method kind | Range of growth stages & season(c) | Number min-max | Interval between appl. (min) | g a.s./hL min-max | Water L/ha min-max | Rate | Unit | PHI (days) | Remarks |
| Strawberries          | NEU (BE)                | G            | Aphids                            | WG 50%      | Foliar treatment – broadcast spraying | Until BBCH 87 | 2 | 7–10 days | – | – | 70 | g/ha | 3 | – |
| Blueberries           | NEU (BE)                | G            | Aphids                            | WG 50%      | Foliar treatment – broadcast spraying | Until BBCH 87 | 2 | 7–10 days | – | – | 70 | g/ha | 3 | – |
| Currants              | NEU (BE)                | G            | Aphids                            | WG 50%      | Foliar treatment – broadcast spraying | Until BBCH 87 | 2 | 7–10 days | – | – | 70 | g/ha | 3 | – |
| Cranberries           | NEU (BE)                | G            | Aphids                            | WG 50%      | Foliar treatment – broadcast spraying | Until BBCH 87 | 2 | 7–10 days | – | – | 70 | g/ha | 3 | – |
| Gooseberries          | NEU (BE)                | G            | Aphids                            | WG 50%      | Foliar treatment – broadcast spraying | Until BBCH 87 | 2 | 7–10 days | – | – | 70 | g/ha | 3 | – |

MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                      | Peach       | Foliar: 2 × 100 and 2 × 500 g/ha | 21             | Radiolabelled active substance: 3-14C-phenyl (EFSA, 2010, 2014) |
|                                  | Pepper      | Foliar: 1 x 100 g/ha | 7, 14          |                 |
| Root crops                       | Potato      | Foliar: 2 × 100 and 2 × 500 g/ha | 14             |                 |
| Cereals/grass                    | Wheat       | Foliar: 2 × 100 and 2 × 500 g/ha | 21             |                 |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
|                                     |             |         |                |           | Not triggered EFSA (2010) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Yes        |         | Parent flonicamid: EFSA (2010) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        |         | TFNG and TFNA: EFSA (2018b) |
| Other processing conditions             | –          |         |                |

Can a general residue definition be proposed for primary crops?
Rotational crop and primary crop metabolism similar?
Residue pattern in processed commodities similar to residue pattern in raw commodities?
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)

Validated analytical methods to control residues of flonicamid and its metabolites TFNG and TFNA in high water, high acid and high oil content matrices and in dry commodities based on HPLC–MS/MS allow quantifying residues for each analyte included in the residue definition at the LOQ of 0.01 mg/kg (combined LOQ of 0.03 mg/kg) (EFSA, 2010, 2014).

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; TFNA: 4-trifluoromethylnicotinic acid; TFNG: N-(4-trifluoromethylnicotinoyl) glycine.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------|-------------------|----------------|
|                                   | High water content | Apple, potatoes | −18 | 18 Months | Parent and its metabolites TFNG, TFNA, TFNA-AM | EFSA (2010) |
|                                   | High oil content | Rape seed | −20 | 12 Months | Parent and its metabolites TFNG, TFNA | EFSA (2015) |
|                                   | High protein content | Beans | −20 | 12 Months | Parent and its metabolites TFNG, TFNA | EFSA (2015) |
|                                   | Dry/High starch | Wheat grain, wheat straw | −18 | 18 Months | Parent and its metabolites TFNG, TFNA, TFNA-AM | EFSA (2010) |
|                                   | High water content | Orange (whole fruit) | −18 | 6 Months | Parent and its metabolites TFNG, TFNA | EFSA (2018b) |
|                                   | High water content | Apple, potatoes | −18 | 18 Months | Parent and its metabolites TFNG, TFNA, TFNA-AM | EFSA (2010) |
|                                   | Processed products | — | — | — | — | — |
|                                   | Others | — | — | — | — | — |

TFNA: 4-trifluoromethylnicotinic acid; TFNG: N-(4-trifluoromethylnicotinoyl)glycine.
### 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\(^{(d)}\) |
|--------------------|---------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|----------------------|-----------------------|-------------|
| Strawberries       | Indoor                    | 0.072, 0.084, 0.094, 0.126, 0.150, 0.170, 0.284, 0.450             | Residue trials on strawberry compliant with GAP                                | 0.7                    | 0.45                 | 0.14                  | –           |
| Blueberries        | Indoor                    | Currants: 0.170, 0.280, 0.300, 0.462                                | Residue trials on currants and blueberries compliant with GAP. Extrapolation to blueberry, currant, cranberry and gooseberry possible | 0.8                    | 0.46                 | 0.23                  | –           |
| Cranberries        | Indoor                    |                                                                   |                                                                                 |                        |                      |                       |             |
| Currants           | Indoor                    |                                                                   |                                                                                 |                        |                      |                       |             |
| Gooseberries       |                           |                                                                   |                                                                                 |                        |                      |                       |             |

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

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Not triggered | Studies not triggered. DT₉₀ values for flonicamid and its metabolites in soil are all expected to range between 1.5 and 8.7 days, which is below the trigger value of 100 days (EFSA, 2010) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Not triggered | EFSA (2010) |

DT₉₀: period required for 90% dissipation.

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant to the commodities under consideration in the present MRL application.

B.3. Consumer risk assessment

| ARfD | 0.025 mg/kg bw (EFSA, 2010) |
| Highest IESTI, according to EFSA PRIMo | Strawberries: 29% of ARfD (children)  
Blueberries: 17% of ARfD (adults)  
Currants: 15% of ARfD (children)  
Gooseberries: 11% of ARfD (children)  
Cranberries: 5% of ARfD (children)  
Processed commodities:  
Currants: 26% of ARfD (children, processed commodities) |

Assumptions made for the calculations

The calculation is performed using PRIMo version 3.0. The short-term exposure assessment focussed on the commodities under assessment using the highest residue levels expected in raw agricultural commodities.

For commodities not included in the present MRL application the short-term exposure assessment was performed using the risk assessment values derived in previous EFSA reasoned opinions (HR values), which indicated exceedance of the ARfD due to differences in the revised version PRIMo exposure estimates. Further refinement of the exposure estimates for these commodities may be possible, such as by the use of processing factors.
A DI 0.025 mg/kg bw per day (EFSA, 2010)

Highest IEDI, according to EFSA PRIMo

| Crop         | Contribution of crops assessed |
|--------------|--------------------------------|
| Currants     | 0.31% of ADI (NL toddler)     |
| Strawberries | 0.28% of ADI (DE child)       |
| Gooseberries | 0.04% of ADI (PL general)     |
| Blueberries  | 0.03% of ADI (NL toddler)     |
| Cranberries  | 0.02% of ADI (GEMS/Food G10)  |

Assumptions made for the calculations

The calculation is based on the median residue (STMR) levels derived for raw agricultural commodities for which MRL proposals were derived by EFSA (2014, 2015, 2016, 2017, 2018b,c) as well as the STMR values corresponding to CXL values taken over in the EU legislation. The contributions of commodities where no GAP was reported in the framework of the MRL review or in succeeding applications were not included in the calculation.

B.4. Recommended MRLs

| Code | Commodity     | Existing EU MRL(b)/recently proposed amendment(c) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------|---------------|-----------------------------------------------------------|------------------------|-----------------------|
| 152000 | Strawberries | 0.03*/0.5                                                  | 0.7                    | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154010 | Blueberries  | 0.03*/0.7                                                  | 0.8                    | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154020 | Cranberries  | 0.03*/0.7                                                  | 0.8                    | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154030 | Currants     | 0.03*/0.7                                                  | 0.8                    | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |
| 154040 | Gooseberries | 0.03*/0.7                                                  | 0.8                    | The submitted data are sufficient to derive an MRL proposal for the indoor use. Risk for consumers unlikely |

MRL: maximum residue level; TFNA: 4-trifluoromethylnicotinic acid; TFNG: N-(4-trifluoromethylnicotinoyl)glycine.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL established in Commission Regulation (EU) 2018/687.
(c): MRL proposal derived in the EFSA reasoned opinion on the modification of the existing maximum residue level for flonicamid in various crops issued in August 2018 (EFSA, 2018b).
### Appendix C – Pesticide Residue Intake Model (PRiMo)

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|-------------------------------|-----------------------------------|-----------------------------------------------|
| 28% 6.97                        | ---                               |                                               |
| 21% 5.24                        | ---                               |                                               |
| 19% 4.73                        | ---                               |                                               |
| 17% 4.35                        | ---                               |                                               |
| 16% 4.11                        | ---                               |                                               |
| 16% 4.04                        | ---                               |                                               |
| 15% 3.86                        | ---                               |                                               |
| 15% 3.79                        | ---                               |                                               |
| 14% 3.53                        | ---                               |                                               |
| 14% 3.46                        | ---                               |                                               |
| 13% 3.22                        | ---                               |                                               |
| 13% 3.15                        | ---                               |                                               |
| 12% 3.08                        | ---                               |                                               |
| 12% 3.01                        | ---                               |                                               |
| 12% 2.90                        | ---                               |                                               |
| 11% 2.84                        | ---                               |                                               |
| 11% 2.81                        | ---                               |                                               |
| 10% 2.62                        | ---                               |                                               |
| 10% 2.59                        | ---                               |                                               |
| 9% 2.44                         | ---                               |                                               |
| 9% 2.41                         | ---                               |                                               |
| 8% 2.26                         | ---                               |                                               |
| 8% 2.23                         | ---                               |                                               |
| 7% 2.11                         | ---                               |                                               |
| 7% 2.08                         | ---                               |                                               |
| 6% 1.99                         | ---                               |                                               |
| 6% 1.96                         | ---                               |                                               |
| 5% 1.85                         | ---                               |                                               |
| 5% 1.82                         | ---                               |                                               |
| 4% 1.70                         | ---                               |                                               |
| 4% 1.66                         | ---                               |                                               |
| 3% 1.55                         | ---                               |                                               |
| 3% 1.52                         | ---                               |                                               |
| 2% 1.40                         | ---                               |                                               |
| 2% 1.37                         | ---                               |                                               |
| 1% 1.27                         | ---                               |                                               |
| 1% 1.24                         | ---                               |                                               |
| 0.9% 1.10                       | ---                               |                                               |
| 0.9% 1.07                       | ---                               |                                               |
| 0.8% 0.95                       | ---                               |                                               |

**Comments:**
- **FI adult:** Rye
- **DK adult:** Wheat
- **IT toddler:** Wheat
- **Wheat:** Milk: Cattle
- **Milk: Cattle:** Milk: Cattle
- **ES child:** GEMS/Food G08
- **SE general:** GEMS/Food G07
- **UK infant:** GEMS/Food G15
- **IE child:** GEMS/Food G10
- **FR toddler 2 3 yr:** GEMS/Food G06
- **RO general:** GEMS/Food G11
- **UK toddler:** GEMS/Food G09
- **NL toddler:** GEMS/Food G05
- **FR child 3 15 yr:** DE child
- **GEMS/Food G04:** DE child
- **DE child:** DE child
- **NL child:** NL child
- **FR child:** FR child
- **DE women 14-50 yr:** DE woman
- **DE general:** DE woman
- **NL adult:** NL adult
- **FR adult:** FR adult
- **FI 6 yr:** FI 6 yr
- **FI 3 yr:** FI 3 yr
- **UK adult:** UK adult
- **DK adult:** DK adult
- **IT adult:** IT adult
- **NL adult:** NL adult
- **ES adult:** ES adult
- **FR infant:** FR infant
- **FR adult:** FR adult
- **IE adult:** IE adult
- **PT general:** PT general
- **IT general:** IT general
- **NL general:** NL general
- **DE general:** DE general
- **ES adult:** ES adult
- **RR infant:** RR infant
- **RR adult:** RR adult
- **LT adult:** LT adult
- **R adult:** R adult
- **P adult:** P adult
- **R vegetable:** R vegetable
- **UK vegetable:** UK vegetable
- **UK adult:** UK adult
- **UK child:** UK child
- **Bovine: Muscle/meat:** Bovine: Muscle/meat
- **Rye:** Rye
- **Tomatoes:** Tomatoes
- **Beans (with pods):** Beans (with pods)
- **Beans:** Beans
- **Wheat:** Wheat
- **Milk: Cattle:** Milk: Cattle
- **Barley:** Barley
- **Rye:** Rye
- **Potatoes:** Potatoes
- **Ripe:** Ripe
- **Flonicamid:** Flonicamid
- **Chronic risk assessment: JMPR methodology (IEDI/TMDI)**
- **Toxicological reference values**
- **Refined calculation mode**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Flonicamid is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Table: Show results of IESTI calculation only for crops with GAPs under assessment

#### Results for children

| Commodity                  | MRL/ADI | Exposure (µg/kg bw) |
|----------------------------|---------|---------------------|
| Peaches                    | 0.40/0.3 | 29                  |
| Pears                      | 0.30/0.19 | 26                  |
| Cucumbers                  | 0.40/0.22 | 22                  |
| Apples                     | 0.30/0.19 | 20                  |
| Courgettes                 | 0.50/0.34 | 16                  |
| Tomatoes                   | 0.50/0.24 | 14                  |
| Melons                     | 0.40/0.07 | 11                  |
| Head cabbages              | 0.50/0.23 | 10                  |
| Carrots                    | 0.48/0.95 | 9.5                 |
| Oranges                    | 0.15/0.07 | 9.3                 |
| Potatoes                   | 0.09/0.06 | 9.2                 |
| Sweet peppers/bell peppers | 0.30/0.15 | 8.9                 |
| Watermelons                | 0.40/0.07 | 8.6                 |
| Celeriacs/turp rooted      | 0.30/0.15 | 8.3                 |
| Currants (red, black and green) | 0.70/0.46 | 3.0                 |
| Strawberries               | 0.50/0.45 | 7.4                 |
| Radishes                   | 0.60/2.9 | 7.1                 |
| Beetroots                  | 0.30/0.15 | 6.6                 |
| Milk: Cattle               | 0.15/0.05 | 6.2                 |
| Aberginis/egg plants       | 0.50/2.4 | 6.0                 |
| Beans (with pods)          | 1.50/6.7 | 5.9                 |
| Grapesfruits               | 0.15/0.07 | 5.5                 |
| Plums                      | 0.30/1.3 | 5.5                 |
| Parsnips                   | 0.30/1.5 | 5.4                 |
| Tumips                     | 0.30/1.5 | 5.4                 |
| Blackberries              | 1.0/4.8 | 5.1                 |
| Wheat                     | 2.0/35 | 5.1                 |
| Quinces                    | 0.30/1.9 | 4.7                 |
| Salsifies                  | 0.30/1.5 | 4.7                 |
| Apricots                   | 0.30/1.3 | 4.4                 |
| Raspberries (red and yellow) | 0.10/4.8 | 4.4                 |
| Mandarins                  | 0.15/0.07 | 4.1                 |
| Cherries                   | 6/3 | 3.9                 |
| Lemos                      | 0.15/0.07 | 3.6                 |
| Currants (red, black and green) | 0.70/0.46 | 1.8                 |
| Parsley                   | 6/3 | 3.3                 |
| Beans                      | 0.8/16 | 2.9                 |
| Peas (without pods)        | 0.70/35 | 2.9                 |
| Gooseberries (green, red and yellow) | 0.70/46 | 1.9                 |
| Brussels sprouts           | 0.60/32 | 1.7                 |
| Medlar                     | 0.30/1.9 | 1.6                 |
| Chives                     | 6/3 | 2.5                 |
| Peas (with pods)           | 1.50/67 | 2.3                 |
| Sage                       | 6/3 | 2.3                 |
| Rye                        | 2.0/35 | 2.2                 |
| Basil and edible flowers   | 6/3 | 2.2                 |
| Cherries (sweet)           | 0.40/17 | 2.1                 |
| Escaroles/broad-leaved     | 0.07/0.05 | 2.0                 |
| Leettuces                  | 0.07/0.05 | 1.9                 |
| Pumpkins                   | 0.30/1.9 | 1.9                 |
| Blueberries                | 0.70/46 | 1.8                 |
| Eggs: Chicken              | 0.15/0.12 | 1.5                 |
| Limes                      | 0.15/0.07 | 1.4                 |
| Bovine: Liver              | 0.2/0.17 | 1.4                 |
| Bovine: Edible offals (other) | 0.15/0.07 | 1.2                 |
| Bovine: Muscle/meat        | 0.10/0.8 | 1.4                 |
| Bovine: Edible offals (other) | 0.15/0.07 | 1.2                 |
| Milk: Muscle/meat          | 0.15/0.05 | 1.2                 |
| Milk: Goat                 | 0.15/0.05 | 1.2                 |
| Peas (without pods)        | 0.70/35 | 1.1                 |
| Horsemeatshides            | 0.30/1.5 | 1.1                 |
| Bears                      | 0.80/16 | 1.1                 |
| Pumpkins                   | 0.40/17 | 1.0                 |
| Escaroles/broad-leaved     | 0.07/0.05 | 1.0                 |
| Lentils                    | 0.80/16 | 0.98                |
| Milk: Goat                 | 0.15/0.05 | 0.92                |
| Poultry: Muscle            | 0.10/0.8 | 0.89                |
| Barley                     | 0.40/17 | 0.82                |
| Poultry: Edible offals (other) | 0.15/0.09 | 0.76                |
| Milk: Sheep                | 0.15/0.05 | 0.76                |
| Bovine: Liver              | 0.2/0.17 | 0.66                |
| Leettuces                  | 0.07/0.05 | 0.61                |
| Sage                       | 6/3 | 0.60                |

#### Results for adults

| Commodity                  | MRL/ADI | Exposure (µg/kg bw) |
|----------------------------|---------|---------------------|
| Peaches                    | 0.50/0.23 | 9.7                 |
| Cucumbers                  | 0.30/0.19 | 9.5                 |
| Apples                     | 0.30/0.19 | 9.5                 |
| Courgettes                 | 0.40/3.3 | 5.6                 |
| Tomatoes                   | 0.35/1.9 | 5.3                 |
| Melons                     | 0.50/2.4 | 5.3                 |
| Head cabbages              | 0.30/1.5 | 5.1                 |
| Carrots                    | 0.30/1.5 | 5.1                 |
| Oranges                    | 0.70/4.6 | 4.2                 |
| Potatoes                   | 1.0/4.8 | 3.9                 |
| Sweet peppers/bell peppers | 0.25/4 | 3.8                 |
| Watermelons                | 0.6/3 | 3.6                 |
| Celeriacs/turp rooted      | 0.70/4.6 | 3.0                 |
| Strawberries               | 0.70/4.6 | 3.0                 |
| Radishes                   | 0.30/1.5 | 3.0                 |
| Wheat                     | 2/3.5 | 2.9                 |
| Quinces                    | 0.30/1.9 | 2.7                 |
| Salsifies                  | 0.30/1.5 | 2.7                 |
| Apricots                   | 0.30/1.3 | 2.6                 |
| Raspberries (red and yellow) | 0.5/34 | 2.1                 |
| Mandarins                  | 0.15/0.09 | 1.9                 |
| Cherries (sweet)           | 0.40/17 | 1.8                 |
| Rye                        | 2/35 | 1.7                 |
| Beans                      | 0.30/1.5 | 1.6                 |
| Peas (without pods)        | 0.70/35 | 1.5                 |
| %#0622                    | 1/46 | 1.4                 |
| Brussels sprouts           | 0.60/32 | 1.4                 |
| Medlar                     | 0.30/1.9 | 1.3                 |
| Chives                     | 6/3 | 1.8                 |
| Peas (with pods)           | 1.50/67 | 1.3                 |
| Grapefruits               | 0.15/0.07 | 1.3                 |
| Sage                       | 6/3 | 1.1                 |
| Rye                        | 2/35 | 1.0                 |
| Basil and edible flowers   | 6/3 | 1.0                 |
| Cherries (sweet)           | 0.40/17 | 1.0                 |
| Escaroles/broad-leaved     | 0.07/0.05 | 1.0                 |
| Leettuces                  | 0.80/16 | 0.98                |
| Milk: Goat                 | 0.15/0.05 | 0.92                |
| Poultry: Muscle            | 0.10/0.8 | 0.89                |
| Barley                     | 0.40/17 | 0.82                |
| Poultry: Edible offals (other) | 0.15/0.09 | 0.76                |
| Milk: Sheep                | 0.15/0.05 | 0.76                |
| Bovine: Liver              | 0.2/0.17 | 0.66                |
| Leettuces                  | 0.07/0.05 | 0.61                |
| Sage                       | 6/3 | 0.60                |

The acute risk assessment is based on the ARfD.
The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities. For processed commodities, no exceedance of the ARfD/ADI was identified.

**Conclusion:**

The total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) is 2.

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### Results for adults

| Processed commodities | ARfD/ADI exceeded (IESTI) |
|------------------------|---------------------------|
|                       |                           |

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### Results for children

| Processed commodities | ARfD/ADI exceeded (IESTI) |
|------------------------|---------------------------|
|                       |                           |

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### Conclusions

The estimated short term intake (IESTI) exceeded the toxicological reference value for 2 commodities. For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant to the present MRL application.

D.2. Consumer risk assessment

| Commodity              | Chronic risk assessment | Acute risk assessment |
|------------------------|-------------------------|-----------------------|
|                        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
|                        |                         |                       |                      |                       |
| Strawberries           | 0.14 STMR               | 0.45 HR               |                       |                       |
| Blueberries            | 0.23 STMR               | 0.46 HR               |                       |                       |
| Cranberries            | 0.23 STMR               | 0.46 HR               |                       |                       |
| Currants               | 0.23 STMR               | 0.46 HR               |                       |                       |
| Gooseberries           | 0.23 STMR               | 0.46 HR               |                       |                       |
| Citrus fruit           | 0.04 STMR (tentative) (EFSA, 2014) | 0.07 HR (tentative) (EFSA, 2014) |                       |                       |
| Pome fruit             | 0.06 STMR (EFSA, 2014)  | 0.19 HR (EFSA, 2014)  |                       |                       |
| Apricots               | 0.10 STMR (EFSA, 2017)  | 0.127 HR (EFSA, 2017) |                       |                       |
| Cherries               | 0.13 STMR (tentative) (EFSA, 2014) | 0.17 HR (tentative) (EFSA, 2014) |                       |                       |
| Peaches                | 0.08 STMR (EFSA, 2014)  | 0.30 HR (EFSA, 2014)  |                       |                       |
| Plums                  | 0.09 STMR (tentative) (EFSA, 2014) | 0.13 HR (tentative) (EFSA, 2014) |                       |                       |
| Blackberries           | 0.36 STMR (EFSA, 2018b) | 0.48 HR (EFSA, 2018b) |                       |                       |
| Raspberries            | 0.36 STMR (EFSA, 2018b) | 0.48 HR (EFSA, 2018b) |                       |                       |
| Potatoes               | 0.03 STMR (EFSA, 2014)  | 0.06 HR (EFSA, 2014)  |                       |                       |
| Beetroots              | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Carrots                | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Celeriacs              | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Horseradishes          | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Jerusalem artichokes   | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Parsnips               | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Parsley root           | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Radishes               | 0.22 STMR (EFSA, 2018b)  | 0.29 HR (EFSA, 2018b)  |                       |                       |
| Salsifies              | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Swedes                 | 0.05 STMR (EFSA, 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Turnips                | 0.05 STMR (EFSA et al., 2018a,b,cc) | 0.15 HR (EFSA, 2018a,b,c) |                       |                       |
| Tomatoes               | 0.14 STMR (tentative) (EFSA, 2014) | 0.24 HR (tentative) (EFSA, 2014) |                       |                       |
| Peppers                | 0.06 STMR (EFSA, 2015)  | 0.15 HR (EFSA, 2015)  |                       |                       |
| Aubergines (egg plants)| 0.14 STMR (tentative) (EFSA, 2014) | 0.24 HR (tentative) (EFSA, 2014) |                       |                       |
| Cucumbers              | 0.15 STMR (EFSA, 2014)  | 0.34 HR (EFSA, 2014)  |                       |                       |
| Gherkins               | 0.15 STMR (EFSA, 2014)  | 0.34 HR (EFSA, 2014)  |                       |                       |
| Courgettes             | 0.15 STMR (tentative) (EFSA, 2014) | 0.34 HR (tentative) (EFSA, 2014) |                       |                       |
| Other cucurbits - edible peel | 0.15 STMR (EFSA, 2014) | 0.34 HR (EFSA, 2014) |                       |                       |
| Cucurbit - inedible peel | 0.06 STMR (tentative) × PF (0.16 × 0.38) (EFSA, 2014) | 0.07 HR (tentative) × PF (0.184 × 0.38) (EFSA, 2014) |                       |                       |
| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
| Brussels sprouts | 0.07 STMR (EFSA, 2015) | 0.32 HR (EFSA, 2015) |
| Head cabbage | 0.14 STMR (EFSA, 2017) | 0.23 HR (EFSA, 2017) |
| Lettuce and other salad plants including Brassicaceae | 0.03 STMR (EFSA, 2018b) | 0.05 HR (EFSA, 2018b) |
| Herbs | 0.71 STMR (EFSA, 2016) | 3.00 HR (EFSA, 2016) |
| Beans (with pods) | 0.34 STMR (EFSA, 2017) | 0.67 HR (EFSA, 2017) |
| Peas (with pods) | 0.34 STMR (EFSA, 2017) | 0.67 HR (EFSA, 2017) |
| Peas (without pods) | 0.20 STMR (EFSA, 2015) | 0.35 HR (EFSA, 2015) |
| Beans (dry) | 0.16 STMR (EFSA, 2018b) | 0.16 STMR (EFSA, 2018b) |
| Lentils | 0.16 STMR (EFSA, 2018b) | 0.16 STMR (EFSA, 2018b) |
| Peas (dry) | 0.16 STMR (EFSA, 2018b) | 0.16 STMR (EFSA, 2018b) |
| Lupins | 0.16 STMR (EFSA, 2018b) | 0.16 STMR (EFSA, 2018b) |
| Cotton seed | 0.04 STMR (EFSA, 2015) | 0.04 STMR (EFSA, 2015) |
| Barley | 0.17 STMR (EFSA, 2015) | 0.17 STMR (EFSA, 2015) |
| Oats | 0.17 STMR (EFSA, 2015) | 0.17 STMR (EFSA, 2015) |
| Rye | 0.35 STMR (tentative) (EFSA, 2014) | 0.35 STMR (tentative) (EFSA, 2014) |
| Wheat | 0.35 STMR (tentative) (EFSA, 2014) | 0.35 STMR (tentative) (EFSA, 2014) |
| Hops (dried) | 0.61 STMR (tentative) (EFSA, 2014) | 1.29 HR (tentative) (EFSA, 2014) |
| Sugar beet (root) | 0.03 STMR (EFSA, 2017) | 0.03 HR (EFSA, 2017) |
| Swine, Bovine, Sheep, Goat, Horse: meat | 0.06 STMR (FAO, 2016) | 0.102 HR (FAO, 2016) |
| Swine, Bovine, Sheep, Goat, Horse: fat | 0.02 STMR (FAO, 2016) | 0.03 HR (FAO, 2016) |
| Swine, Bovine, Sheep, Goat, Horse: liver | 0.10 STMR (FAO, 2016) | 0.17 HR (FAO, 2016) |
| Swine, Bovine, Sheep, Goat, Horse: kidney | 0.10 STMR (FAO, 2016) | 0.17 HR (FAO, 2016) |
| Swine, Bovine, Sheep, Goat, Horse: edible offal | 0.10 STMR (FAO, 2016) | 0.17 HR (FAO, 2016) |
| Poultry: meat | 0.04 STMR (FAO, 2016) | 0.076 HR (FAO, 2016) |
| Poultry: fat | 0.04 STMR (FAO, 2016) | 0.04 HR (FAO, 2016) |
| Poultry: liver | 0.04 STMR (FAO, 2016) | 0.09 HR (FAO, 2016) |
| Poultry: kidney | 0.04 STMR (FAO, 2016) | 0.09 HR (FAO, 2016) |
| Poultry: edible offal | 0.04 STMR (FAO, 2016) | 0.09 HR (FAO, 2016) |
| Milk and cream | 0.05 STMR (FAO, 2016) | 0.05 STMR (FAO, 2016) |
| Bird’s eggs | 0.08 STMR (EFSA, 2018c) | 0.12 HR (EFSA, 2018c) |

STMR: supervised trials median residue; HR: highest residue.
## Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation/InChIKey<sup>(a)</sup> | Structural formula |
|------------------|--------------------------------------------------|--------------------|
| flonicamid       | \(N\)-cyanomethyl-4-(trifluoromethyl)nicotinamide \(O=C(NCC\#N)c1cncc1C(F)(F)F\) RLRQIEJISHYWON-UHFFFAOYSA-N | ![Structural formula for flonicamid] |
| TFNA             | 4-(trifluoromethyl)nicotinic acid or 4-(trifluoromethyl)pyridine-3-carboxylic acid \(O(-O)c1cncc1C(F)(F)F\) LMRJHNFECNKDKH-UHFFFAOYSA-N | ![Structural formula for TFNA] |
| TFNG             | \(N\)-[4-(trifluoromethyl)nicotinoyl]glycine or \(N\)-[4-(trifluoromethyl)pyridine-3-carbonyl]glycine \(O=C(NCC(-O)=O)c1cncc1C(F)(F)F\) AXMBYGGSBXWTEY-UHFFFAOYSA-N | ![Structural formula for TFNG] |
| TFNA-AM          | 4-(trifluoromethyl)nicotinamide or 4-(trifluoromethyl)pyridine-3-carboxamide \(O=C(N)c1cncc1C(F)(F)F\) JUIW2YBJXUPIJKF-UHFFFAOYSA-N | ![Structural formula for TFNA-AM] |

SMILES: simplified molecular-input line-entry system; InChIKey: International Chemical Identifier Key.

<sup>(a)</sup>: ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 November 2008).