Modification of the existing maximum residue level for flonicamid in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dienstleistungszentrum Ländlicher Raum submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRL) for the active substance flonicamid in radishes. Furthermore, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ISK Biosciences Europe N.V. submitted a request to the competent national authority in the Netherlands to modify the existing MRLs for the active substance flonicamid in strawberries, cane fruits, other small fruits and berries, lettuces and other salad plants, and pulses (dry beans, lentils, peas, lupins). The data submitted in support of the request were found to be sufficient to derive MRL proposals for strawberries, blackberries, raspberries, other small fruits and berries, radishes, lettuces and other salad plants, and pulses (dry beans, lentils, peas and lupins). Adequate analytical methods for enforcement are available to control the residues of flonicamid in the commodities under consideration. 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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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dienstleistungszentrum Ländlicher Raum submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance fonicamid in radishes. The EMS DE 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 1 June 2017. To accommodate for the intended use of fonicamid, the EMS DE proposed to raise the existing MRL from the limit of quantification (LOQ) 0.03* mg/kg to 0.6 mg/kg.

Furthermore, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ISK Biosciences Europe N.V. submitted a request to the competent national authority in the Netherlands (EMS NL) to modify the MRLs for the active substance fonicamid in strawberries, cane fruits, other small fruit and berries, lettuce and other salad plants including endives/scaroles, and pulses (dry beans, lentils, peas and lupins). The EMS NL 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 2 October 2017. To accommodate for the intended uses of fonicamid, the EMS NL proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.03* mg/kg to 0.5 mg/kg for strawberries, to 1.0 mg/kg for blackberries and raspberries, to 0.7 mg/kg for other small fruits and berries, to 0.08 mg/kg for outdoor lettuce and other salad plants including escaroles/endives and to 1.0 mg/kg for beans (dry), lentils, peas (dry) and lupins.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS DE and EMS NL in the framework of these applications, the following conclusions are derived.

The metabolism of fonicamid in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC and the MRL review in the fruit, root and cereal/grass crop groups.

Studies investigating the effect of processing on the nature of residues (standard hydrolysis studies) demonstrated that fonicamid and its main metabolites are stable.

Due to fast degradation of fonicamid and its metabolites in the soil, further investigation of residues in rotational crops is not required. Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites, the residue definition for plant products were proposed as sum of fonicamid, TFNA and TFNG, expressed as fonicamid for enforcement and risk assessment. These residue definitions are applicable to primary crops and processed products.

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

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at 0.03 mg/kg in the crops assessed (LOQ).

As some of the crops under consideration are used as feed products, a potential carry-over into food of animal origin was assessed.

The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, the contribution of fonicamid residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of fonicamid was assessed in the framework of the 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 consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2007).

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 18.4% of the ADI (WHO cluster diet B). The contribution of crops assessed to the total consumer exposure accounted for a maximum of 0.49% of ADI for dry beans (UK toddler).
An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration. The highest acute consumer exposure was calculated to be 25.8% of the ARfD for radishes, 20.7% of the ARfD for blackberries, 17.5% of the ARfD for escarole and 16.6% for strawberries. For the remaining commodities, the exposure accounted for less than 15% of the ARfD.

EFSA concluded that the proposed use of flonicamid on crops under consideration 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 Appendix B. Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|----------------------------|-------------------------|-------------------------|-----------------------------------------------------------|
| 0152000 | Strawberries               | 0.03*                   | 0.5                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely |
| 0153010 | Blackberries              | 0.03*                   | 1.0                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation from data on blackberries |
| 0153030 | Raspberries               | 0.03*                   | 1.0                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation to the group of cane fruits not possible. Two additional trials are required |
| 0154000 | Other small fruit and berries | 0.03* 0.07             | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation from data on black currant |
| 0213080 | Radishes                  | 0.03*                   | 0.6                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely |
| 0251000 | Lettuce and salad plants  | 0.03*                   | 0.07                    | The MRL proposal reflects the intended SEU use. Risk for consumers unlikely. Extrapolation to the whole group of lettuce and other salad plants including escaroles/endives |
| 0300010 | Beans (dry)               | 0.03*                   | 0.8                     | The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300020 | Lentsils                  | 0.03*                   | 0.8                     | Extrapolated from data on beans and peas (dry). The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300030 | Peas (dry)                | 0.03*                   | 0.8                     | The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300040 | Lupins                    | 0.03*                   | 0.8                     | Extrapolated from data on beans and peas (dry). The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |

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In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, EFSA identified that hydrolysis studies on the flonicamid metabolites TFNG and TFNA investigating the nature of residues in processed commodities are missing. Since this information was provided in the current application, the footnote to the MRL for wheat and rye established in the MRL regulation related to this data gap can be deleted.

Furthermore, it is noted that the footnote included in the current MRL legislation related to the citrus fruits requesting the submission of information on storage stability can be deleted since data demonstrating stability of flonicamid during storage were provided with the current applications.
Modification of the existing MRLs for flonicamid in various crops

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Assessment

The detailed description of the intended uses of flonicamid, which is 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 rapporteur Member State (RMS) for the representative uses as a foliar spray applications on potatoes, wheat, apples and pears in all the European Union (EU) countries and on peaches in southern Europe (SEU). 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 the use as 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. The proposals from these reasoned opinions have been considered in several regulations for EU MRL legislation. In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Dienstleistungszentrum Ländlicher Raum submitted an application to the competent national authority in Germany (evaluating Member State, EMS DE) to modify the existing MRL for the active substance flonicamid in radishes. The EMS DE 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 EFSA on 1 June 2017. To accommodate for the intended use of flonicamid, the EMS DE proposed to raise the existing MRL from the limit of quantification (LOQ) 0.03 mg/kg to 0.6 mg/kg.

In accordance with Article 6 of Regulation (EC) No 396/2005, ISK Biosciences Europe N.V. submitted an application to the competent national authority in the Netherlands (EMS NL) to modify the existing MRL for the active substance flonicamid in strawberries, cane fruits, other small fruit and berries, lettuces and other salad plants including escaroles/endives, beans (dry), lentils, peas (dry) and lupins. The EMS NL 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 EFSA on 2 October 2017. To accommodate for the intended uses of flonicamid, the EMS NL proposed to raise the existing MRLs from the LOQ of 0.03* mg/kg to 0.5 mg/kg for strawberries, to 1.0 mg/kg for blackberries and raspberries, to 0.7 mg/kg for other small fruits and berries, to 0.07 mg/kg for outdoor lettuces and to 1.0 mg/kg for pulses (i.e. dry beans, lentils, peas and lupins).

EFSA identified points which needed further clarification, which were requested from the EMS NL. On 8 January 2018, the EMS NL submitted a revised evaluation report, and on July 2018 EMS NL submitted another revised evaluation report, which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation report submitted by the EMS DE (Germany, 2017), EMS NL (Netherlands, 2017), the draft assessment report (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).

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, 2010b,c, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

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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 (IKI-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, 16.3.2005, 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
A selected list of end points of the studies assessed by EFSA in the framework of these MRL applications, including the end points of relevant studies assessed previously, is presented in Appendix B. The evaluation report submitted by the EMS DE (Germany, 2017) and EMS NL (Netherlands, 2017) 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 flonicamid in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010) and reviewed in the Article 12 MRL review (EFSA, 2014) in the fruit, root/tuber and cereal crop groups.

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

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops should be assessed. The soil degradation studies demonstrated that the degradation rate of flonicamid and its metabolites is rapid, with a maximum DT₉₀ of 1.5–8.7 days (EFSA, 2010), 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 simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the conclusion of the peer review and the MRL review (EFSA, 2010, 2014). It was concluded that the parent compound flonicamid is hydrolytically stable under the representative conditions.

Hydrolysis studies investigating the effect of processing on the nature of the two metabolites TFNA and TFNG were requested as confirmatory data in the framework of the MRL review (EFSA, 2014); this information was submitted with the current application (Netherlands, 2017). It is concluded that the two metabolites are hydrolytically stable under the representative conditions.

Therefore, the footnote included in the current MRL legislation related to rye and wheat requesting the submission of hydrolysis studies for the two metabolites can be deleted. The previously derived conclusion that the residue definition for primary crops is also applicable for processed commodities is confirmed.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of flonicamid 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 to control residues of flonicamid and its metabolites in high water, high acid and high oil content matrices and in dry commodities were provided. The methods allow quantifying residues for each analyte included in the residue definition individually at the LOQ of 0.01 mg/kg (combined LOQ of 0.03 mg/kg) (EFSA, 2014).

EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for flonicamid in the crops under consideration.

1.1.5. **Stability of residues in plants**

The storage stability of flonicamid and its metabolites was investigated in the framework of the EU pesticides peer review in high water content and in dry commodities and according to these studies flonicamid 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 flonicamid and its metabolites are stable for up to 12 months when stored at –20°C (EFSA, 2015).
Additionally, storage stability of flonicamid and its metabolites TFNA and TFNG in whole fruit orange samples was submitted with this application to address high acid commodities and according to this study flonicamid and its metabolites are stable for up to 6 months when stored at −18°C (Netherlands, 2017).

EFSA concludes that the storage stability data cover the storage time for the supervised residue trials of the crops under consideration and the residue data are valid with regard to storage stability. Furthermore, EFSA recommends deleting the footnote included in the current MRL legislation related to the citrus fruits requesting the submission of information on storage stability.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and in processing studies, the Article 12 MRL review (EFSA, 2014) concluded on a residue definition for enforcement and for risk assessment as the sum of flonicamid and the metabolites TFNA and TFNG expressed as flonicamid.

The available information for the uses assessed in this application is sufficient to conclude that the previously derived residue definitions are applicable for the crops under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

All samples of the supervised residue trials submitted with the MRL applications were analysed individually and the total residue was calculated as sum of flonicamid and its metabolites TFNA and TFNG, expressed as flonicamid. According to the EMS DE and EMS NL, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. (Germany, 2017; Netherlands, 2017).

Radishes

Five outdoor residue trials on radishes compliant with the intended northern Europe (NEU) Good Agricultural Practice (GAP) were submitted. The number of trials is sufficient for setting a MRL for a minor crop.

Strawberries

Eight outdoor residue trials compliant with the intended NEU GAP were submitted. The number of trials is sufficient for setting an MRL for a major crop.

Raspberries, blackberries

Four outdoor residue trials on raspberries compliant with the intended NEU GAP were submitted. It is possible to extrapolate from raspberries to blackberries, as there are enough residue trials for the MRL setting.

Other small fruit and berries

Six outdoor residue trials on blackcurrants performed according to the requested GAP were submitted. Blackcurrants are part of the subgroup of other small fruit and berries which encompasses only minor crops. Therefore, in accordance to EU guidance document (European Commission, 2017), the number of trials on blackcurrants is also sufficient for extrapolation to the whole subgroup of other small fruits and berries.

Lettuce and other salad plants

Eight residue trials compliant with SEU GAP in lettuce have been provided. Although it was not specified whether the trials were performed in open leaf or head forming varieties, they were accepted to be extrapolated to the whole crop group, because the variety is not considered relevant for type of application (drenching before transplanting).

Dry peas, dry beans, other pulses

The applicant provided four NEU trials in peas and four SEU trials in chick peas; the trials were compliant with the intended GAP in terms of application rate. The samples in the NEU trials were taken
20–32 days after the treatment; the preharvest interval (PHI) in the SEU trials ranged from 28 to 65 days. It is noted that the PHI was not specified in the GAP.

In addition, four NEU trials and four SEU trials in dry beans compliant with the intended GAP in terms of application rate were provided. The samples in the NEU trials were taken 37–63 days after the treatment; the PHI in the SEU trials ranged from 40 to 67 days.

Trials with dry peas and beans in NEU have been pooled for MRL calculations. Similarly, trials with dry peas and beans in SEU have been pooled to calculate a MRL proposal.

In accordance to EU guidance document (European Commission, 2017), trials with dry peas and dry beans can be extrapolated to each of the other pulses.

1.2.2. Magnitude of residues in rotational crops

The soil degradation studies demonstrated that the degradation rate of fionicamid and its metabolites is rapid, with a maximum DT$_{90}$ of 1.5–8.7 days (EFSA, 2010), 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

EFSA considers that there is no need to investigate, for the crops assessed under this application, the magnitude of residues in processed commodities considering that the standard hydrolysis studies have demonstrated that fionicamid and its metabolites are stable under the representative conditions (EFSA, 2010, 2014; Netherlands, 2017) and considering that the expected residues in the crops concerned contribute to the overall long-term exposure to a low extent (maximum contribution for dry beans accounting 0.49% of the acceptable daily intake (ADI)).

1.2.4. Proposed MRLs

EFSA proposes to amend the existing MRLs as reported in the Appendix B.

2. Residues in livestock

Beans dry, lupins and peas may be used for feed purposes. When these crops were added as input values for the exposure calculation in livestock, they had no major impact on the overall dietary burden, compared with the result of the dietary burden calculation performed in 2017, where the current MRLs for animal products were derived (EFSA, 2017).

Therefore, EFSA concludes that there is no need to modify the existing EU MRLs in products of animal origin.

The input values for the exposure calculations for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Appendix B.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups 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 (EFSA, 2007).

The toxicological reference values for fionicamid used in the risk assessment (i.e. ADI and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2010). The metabolites included in the risk assessment residue definition were considered to be not more toxic than the parent compound.

**Short-term (acute) dietary risk assessment**

The short-term exposure assessment was performed only with regard to the commodities under consideration in accordance with the internationally agreed methodology. The calculations were based on the risk assessment values derived from the supervised field trials, i.e. the supervised trials median residue (STMR) for pulses and the highest residue (HR) for the remaining commodities (Appendix D.2).

An acute consumer risk was not identified in relation to the MRL proposals for the crops under consideration. The highest acute consumer exposure was calculated to be 25.8% of the ARfD for
radishes, 20.7% of the ARfD for blackberries, 17.5% of the ARfD for escarole and 16.6% for strawberries. For the remaining commodities, the exposure accounted for less than 15% of the ARfD.

Long-term (chronic) dietary risk assessment

In the framework of the review of the existing MRLs for fionicamid according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level and sufficiently supported import tolerances or Codex MRL (EFSA, 2014).

EFSA updated this risk assessment with the relevant STMR values derived from the residue trials conducted on the crops under consideration in this MRL application. In addition, STMR values derived in EFSA opinions published after the MRL review (EFSA, 2015, 2016, 2017) were included in the dietary exposure assessment.

The input values used for the dietary exposure calculation are summarised in Appendix D.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMO. The highest chronic intake was calculated to be 18.4% of the ADI (WHO cluster diet B). The contribution of crops assessed to the total consumer exposure accounted for a maximum of 0.49% of ADI for dry beans (UK toddler).

EFSA concludes that the intended uses of fionicamid on the commodities under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a health concern to consumers.

4. Conclusion and Recommendations

The data submitted in support of these MRL applications were found to be sufficient to derive MRL proposals for radishes, strawberries, raspberries, blackberries, and other small fruits and berries, lettuce and other salad plants (including escaroles/endives), and pulses (dry peas, beans, lupins, and lentils).

EFSA concluded that the proposed uses of fionicamid 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.

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**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| a.s. | active substance |
| ADI | acceptable daily intake |
| AR | applied radioactivity |
| 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 |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| DT\(_{90}\) | period required for 90% dissipation (define method of estimation) |
| EMS | evaluating Member State |
| FAO | Food and Agriculture Organization of the United Nations |
| GAP | Good Agricultural Practice |
| 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 |
| LC | liquid chromatography |
| LOQ | limit of quantification |
| Mo | monitoring |
| MRL | maximum residue level |
| MS/MS | tandem mass spectrometry detector |
| NEU | northern Europe |
| OECD | Organisation for Economic Co-operation and Development |
| Acronym | Description                                      |
|---------|--------------------------------------------------|
| 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                                  |
| SMILES  | simplified molecular-input line-entry system     |
| STMR    | supervised trials median residue                 |
| 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) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|------------|--------------------------------|------------|---------|
|                       |                         |            |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min–max | Interval between application (min) | g a.s./hl/min | Water L/ha min–max | Rate | Unit |          |
| Radishes              | NEU                     | F          | Aphids                           | Spraying   | BBCH 12   | 2 | 13.33 | 600 | 80 | g/ha | 7 | – |
| Strawberries          | NEU                     | F          | Aphids                           | Spraying   | BBCH 11-89 (April–August) | 2 | 7 | 140 | 200–1,200 | 70 | g/ha | 3 |
| Raspberries           | NEU                     | F          | Aphids                           | Spraying   | BBCH 11-89 (April–August) | 2 | 7 | 140 | 200–1,200 | 70 | g/ha | 3 |
| Blackberries          | NEU                     | F          | Aphids                           | Spraying   | BBCH 11-89 (April–August) | 2 | 7 | 140 | 200–1,200 | 70 | g/ha | 3 |
| Other small fruits and berries | NEU | F | Aphids | Spraying | BBCH 11-89 (April–August) | 2 | 7 | 140 | 200–1,200 | 70 | g/ha | 10 |
| Lettuce and other salad plants | SEU | F | White fly | Drenching | Pretransplant (1) | 1 | – | (2) | (2) | (2) | 49 |
| Endive                | SEU                     | F          | White fly                        | Drenching  | Pretransplant (1) | 1 | – | (2) | (2) | (2) | 49 |
| Peas (dry)            | NEUSEU                  | F          | Aphids                           | Spraying   | BBCH 71   | 1 | – | 140 | 200–600 | 70 | g/ha | – |

Remarks:
- (1) Pretransplant, maximum 1 day before the planned transplant date. Clods are dipped in solution to deliver concentration of (2) 1 mg a.s./plant.
- (1) Pretransplant, maximum 1 day before the planned transplant date. Clods are dipped in solution to deliver concentration of (2) 1 mg a.s./plant.
| Crop and/or situation | NEU, SEU, MS or country | F or G or I(a) | Pests or Group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min−max | Interval between application (min) | Application rate per treatment | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|--------------------------|---------------|-----------------------------------|-------------|---------|-----------|------------|-------------------------------|----------------|-----------------------------|-------------------------------|-----------------------------|----------------|---------|
| Beans (dry)          | NEUSEU F                | Aphids       | WG 500 g/kg                       | Spraying    | BBCH 71 | 1         | –          | 140 g a.s./ha                  | 200–600        | 70 L/ha                     | –                            | Determined by growth stage |                |         |
| Lupins               | NEUSEU F                | Aphids       | WG 500 g/kg                       | Spraying    | BBCH 71 | 1         | –          | 140 g a.s./ha                  | 200–600        | 70 L/ha                     | –                            | Determined by growth stage |                |         |
| Lentils              | NEUSEU F                | Aphids       | WG 500 g/kg                       | Spraying    | BBCH 71 | 1         | –          | 140 g a.s./ha                  | 200–600        | 70 L/ha                     | –                            | Determined by growth stage |                |         |

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; BBCH: growth stages of mono- and dicotyledonous plants.

(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 × 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 |
|--------------------------------------|-------------|---------|----------------|------------|----------------|
| Rotational crop and primary crop metabolism similar? | Yes | EFSA (2010) |
| Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes | EFSA (2010) and Netherlands (2017) |

| 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 | TFNG and TFNA: (Netherlands, 2017) |
| Sterilisation (20 min, 120°C, pH 6)      | Yes        |         |
| Other processing conditions              | –          |         |

Can a general residue definition be proposed for primary crops? Yes | EFSA (2010) |
Rotational crop and primary crop metabolism similar? Not triggered | EFSA (2014) |
Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes | EFSA (2010) and Netherlands (2017) |
Plant residue definition for monitoring (RD-Mo) Sum of flonicamid, TFNA and TFNG expressed as flonicamid |
Plant residue definition for risk assessment (RD-RA) Sum of flonicamid, TFNA and TFNG expressed as flonicamid |
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 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, 2014); (Netherlands, 2017). |

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                  | Commodity                  | T (°C) | Stability period | Value | Unit | Compounds covered | Comment/Source                  |
|-----------------------------------|---------------------------|----------------------------|--------|-----------------|-------|------|-------------------|---------------------------------|
|                                   | High water content        | Apple, potato              | –18    | 18 Months       | 18    | Months | Parent and its metabolites TFNG, TFNA, TFNA-AM | EFSA (2010)                     |
|                                   | High oil content          | Rape seed                 | –20    | 12 Months       | 20    | Months | Parent and its metabolites TFNG, TFNA | EFSA (2015)                     |
|                                   | Dry/High starch           | Wheat                     | –18    | 18 Months       | 18    | Months | Parent and its metabolites TFNG, TFNA, TFNA-AM | EFSA (2010)                     |
|                                   | High acid content         | Orange (whole fruit)      | –18    | 6 Months        | –18   | 6     | Parent and its metabolites TFNG, TFNA | Netherlands (2017)               |
|                                   | High protein content      | Bean                       | –20    | 12 Months       | 20    | 12    | Months | Parent and its metabolites TFNG, TFNA | EFSA (2015)                     |

### 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) |
|---------------------------|------------------|-----------------------------------------------------------------|-----------------|------------------------|---------------|----------------|-------|
| Radishes (2 × 80 g/ha, PHI 7 days) | NEU               | 0.053, 0.183, 0.217, 0.224, 0.294                                 | MRL\_OECD: 0.58/0.6 | 0.6                    | 0.29          | 0.22           | –     |
| Strawberries (2 × 70 g/ha, PHI 3 days) | NEU               | 0.06, 0.077, 0.079, 0.087, 0.145, 0.164, 0.177, 0.266            | MRL\_OECD: 0.41/0.5 | 0.5                    | 0.266         | 0.12           | –     |
| Raspberries, blackberries (2 × 70 g/ha, PHI 3 days) | NEU | Raspberries: 0.118, 0.285, 0.426, 0.483                      | MRL\_OECD: 0.98/1.0 Extrapolation from raspberries to blackberries | 1.0                    | 0.48          | 0.36           | –     |
| Other small fruit and berries (2 × 70 g/ha, PHI 10 days) | NEU | Black currants: 0.067, 0.153, 0.156, 0.192, 0.256, 0.370      | MRL\_OECD: 0.61/0.70 Extrapolation from black currant to whole group of other small fruits and berries | 0.7                    | 0.37          | 0.17           | –     |
| Lettuce and other salad plants (1 mg/plant, PHI 49 days) | SEU               | Lettuce (variety not specified): 4 × < 0.03, 0.03, 2 × 0.04, 0.05 | MRL\_OECD: 0.07/0.07 Extrapolation from lettuce to other salad plants including escaroles/endives | 0.07               | 0.05          | 0.03           | –     |
| 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\(^{(d)}\) |
|-----------|---------------------|--------------------------------------------------------------|-----------------|------------------------|----------------------|-----------------------|----------|
| Peas and beans dry (70 g/ha, PHI determined by growth stage) | NEU | Peas: 0.097, 0.177, 0.259, 0.404<br>Beans: 0.136, 0.140, 0.142, 0.176 | MRL\(^{OECD}\): 0.58/0.6<br>Extrapolation to lentils and lupins | 0.6 | 0.40 | 0.16 | – |
|  | SEU | Peas: < 0.03, 0.071, 0.085, 0.136<br>Beans: 0.190, 0.269, 0.377, 0.415 | MRL\(^{OECD}\): 0.77/0.8<br>Extrapolation to lentils and lupins | 0.8 | 0.42 | 0.16 | – |

**MRL**: maximum residue level; **OECD**: Organisation for Economic Co-operation and Development.

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

(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 the soil are all expected to range between 1.5-8.7 days which is far below the trigger value of 100 days (EFSA, 2010).

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

Not triggered

–

B.1.2.3. Processing factors

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

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup | Most critical commodity | Trigger exceeded (Y/N) | Previous assessment Maximum burden (mg/kg bw) (EFSA, 2017) |
|-----------------------------|-----------------------------|------------------------|------------------------|-----------------------|----------------------------------------------------------|
|                             | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum |
| Cattle (all diets)          | 0.072            | 0.077    | 2.35   | 2.47    | Dairy cattle | Potato process waste | Y | 2.47 |
| Cattle (dairy only)         | 0.072            | 0.077    | 1.86   | 2.00    | Dairy cattle | Potato process waste | Y | 2.00 |
| Sheep (all diets)           | 0.076            | 0.077    | 2.27   | 2.30    | Ram/Ewe | Potato process waste | Y | 2.30 |
| Sheep (ewe only)            | 0.076            | 0.077    | 2.27   | 2.30    | Ram/Ewe | Potato process waste | Y | 2.30 |
| Swine (all diets)           | 0.048            | 0.048    | 1.64   | 1.70    | Swine finishing | Wheat milled by-products | Y | 1.70 |
| Poultry (all diets)         | 0.061            | 0.063    | 0.89   | 0.92    | Poultry layer | Wheat milled by-products | Y | 0.92 |
| Poultry (layer only)        | 0.061            | 0.063    | 0.89   | 0.92    | Poultry layer only | Wheat milled by-products | Y | 0.92 |

bw: body weight; DM: dry matter.

(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

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

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

| Livestock (available studies) | Animal            | Dose (mg/kg bw per day) | Duration (days) | Comment/Source                      |
|-------------------------------|-------------------|-------------------------|-----------------|------------------------------------|
| Laying hens                   | 0.78              | 5                       | 3-14C-phenyl (EFSA, 2014) |
| Lactating ruminants           | 1.69              | 5                       | Goat, 3-14C-phenyl (EFSA, 2014) |

bw: body weight.
Time needed to reach a plateau concentration in milk and eggs (days)

|                    | Milk: 2 days | EFSA (2014) |
|--------------------|--------------|-------------|
| Eggs: 4 days       |              | EFSA (2014) |

Metabolism in rat and ruminant similar

| Can a general residue definition be proposed for animals? | Yes | EFSA (2014) |

Animal residue definition for monitoring (RD-Mo)

| Sum of flonicamid and TFNA-AM expressed as flonicamid | EFSA (2014) |

Animal residue definition for risk assessment (RD-RA)

| Sum of flonicamid and TFNA-AM expressed as flonicamid | EFSA (2014) |

Fat soluble residues

| No | EFSA (2014) |

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

Validated analytical methods are available to enforce flonicamid and its metabolite TFNA-AM in milk, eggs, bovine muscle, fat, kidney and liver with an LOQ of 0.01 mg/kg for each analyte (combined LOQ of 0.02 mg/kg) (EFSA, 2014).

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

| Animal products (available studies) | Animal | Commodity          | T (°C) | Stability period Value | Compounds covered | Comment/ Source |
|-------------------------------------|--------|--------------------|--------|------------------------|-------------------|-----------------|
|                                     | Hen    | Muscle, fat, eggs  | −18    | 8 Months               | Parent and metabolites TFNA, TFNA-AM, OH-TFNA-AM, TFNG | EFSA (2010)     |
|                                     | Goat   | Muscle, fat, milk  | −18    | 9 Months               | Parent and metabolites TFNA, TFNA-AM, OH-TFNA-AM, TFNG | EFSA (2010)     |

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

Not relevant.
B.3. Consumer risk assessment

ARfD

Highest IESTI, according to EFSA PRIMo

| Commodity   | % of ARfD |
|-------------|-----------|
| Radishes    | 25.8%     |
| Blackberries| 20.7%     |
| Escarole    | 17.5%     |
| Strawberries| 16.6%     |
| Other commodities under consideration: < 15% of ARfD |

Assumptions made for the calculations

The calculation is performed only for the crops under assessment, considering the highest residue levels derived from the supervised field trials performed for the intended GAPs, except for pulses where the calculations were performed with the median residue derived from the supervised trials.

ADI

Highest IEDI, according to EFSA PRIMo

18.4% ADI (WHO Cluster diet B)

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; ADI: acceptable daily intake; IEDI: international estimated daily intake; WHO: World Health Organization; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(s) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|----------------------------|-------------------------|-------------------------|-----------------------|
| 0152000 | Strawberries               | 0.03*                   | 0.5                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely |
| 0153010 | Blackberries               | 0.03*                   | 1.0                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation from data on blackberries |
| 0153030 | Raspberries                | 0.03*                   | 1.0                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation to the group of cane fruits not possible. Two additional trials are required |
| 0154000 | Other small fruit and berries | 0.03*             | 0.7                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely. Extrapolation from data on black currant |

Modification of the existing MRLs for flonicamid in various crops

www.efsa.europa.eu/efsajournal 20 EFSA Journal 2018;16(9):5410
| Code<sup>(a)</sup> | Commodity                        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|------------------|----------------------------------|------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0213080          | Radishes                         | 0.03*                  | 0.6                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely            |
| 0251000          | Lettuce and salad plants         | 0.03*                  | 0.07                    | The MRL proposal reflects the intended SEU use. Risk for consumers unlikely Extrapolation to the whole group of lettuce and other salad plants including escaroles/endives |
| 0300010          | Beans (dry)                      | 0.03*                  | 0.8                     | The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300020          | Lentils                           | 0.03*                  | 0.8                     | Extrapolated from data on beans and peas (dry). The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300030          | Peas (dry)                       | 0.03*                  | 0.8                     | The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |
| 0300040          | Lupins                           | 0.03*                  | 0.8                     | Extrapolated from data on beans and peas (dry). The MRL proposal reflects the intended SEU use and covers the NEU use. Risk for consumers unlikely |

MRL: maximum residue level; 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.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Fronicamid

**Status of the active substance:** Approved

**LOQ (mg/kg bw):** Proposed LOQ

| Toxicological end points | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|--------------------------|------------------------|-----------------|
| Source of ADI            | EFSA 2010              | Source of ARfD: EFSA 2010 |

**Year of evaluation:** 2010

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

**Highest calculated TMDI values in % of ADI**

| Commodity/group of commodities | MS Diet |
|--------------------------------|---------|
| Wheat                          | 11.9    |
| Rye                            | 6.2     |
| Milk and cream                 | 2.1     |
| Apples                         | 2.9     |
| Tomatoes                       | 0.8     |
| Sugar beet (root)              | 2.7     |
| Sugar beet (root)              | 2.9     |
| Wheat                          | 3.7     |
| Milk and cream                 | 2.8     |
| Milk and cream                 | 0.9     |
| Rye                            | 0.5     |
| Tomatoes                       | 0.6     |
| Sugar beet (root)              | 1.1     |
| Sugar beet (root)              | 0.9     |
| Wheat                          | 5.5     |
| Milk and cream                 | 6.0     |
| Rye                            | 1.1     |
| Tomatoes                       | 0.8     |
| Sugar beet (root)              | 0.9     |
| Sugar beet (root)              | 0.0     |
| Wheat                          | 8.2     |
| Milk and cream                 | 8.0     |
| Milk and cream                 | 6.8     |
| Rye                            | 6.0     |
| Tomatoes                       | 5.6     |
| Sugar beet (root)              | 5.1     |
| Sugar beet (root)              | 0.5     |
| Wheat                          | 7.9     |
| Milk and cream                 | 7.7     |
| Milk and cream                 | 6.5     |
| Rye                            | 5.9     |
| Tomatoes                       | 5.5     |
| Sugar beet (root)              | 4.9     |
| Sugar beet (root)              | 0.1     |
| Wheat                          | 9.4     |
| Milk and cream                 | 9.2     |
| Milk and cream                 | 7.9     |
| Rye                            | 7.4     |
| Tomatoes                       | 6.9     |
| Sugar beet (root)              | 5.7     |
| Sugar beet (root)              | 0.0     |
| Wheat                          | 11.5    |
| Milk and cream                 | 11.3    |
| Milk and cream                 | 9.9     |
| Rye                            | 8.3     |
| Tomatoes                       | 7.5     |
| Sugar beet (root)              | 6.2     |
| Sugar beet (root)              | 0.2     |
| Wheat                          | 13.4    |
| Milk and cream                 | 13.2    |
| Milk and cream                 | 11.8    |
| Rye                            | 10.2    |
| Tomatoes                       | 9.0     |
| Sugar beet (root)              | 7.3     |
| Sugar beet (root)              | 0.1     |
| Wheat                          | 15.2    |
| Milk and cream                 | 15.0    |
| Milk and cream                 | 13.5    |
| Rye                            | 12.1    |
| Tomatoes                       | 10.4    |
| Sugar beet (root)              | 8.5     |
| Sugar beet (root)              | 0.1     |
| Wheat                          | 17.1    |
| Milk and cream                 | 16.9    |
| Milk and cream                 | 15.3    |
| Rye                            | 13.2    |
| Tomatoes                       | 11.5    |
| Sugar beet (root)              | 8.6     |
| Sugar beet (root)              | 0.1     |

**Conclusion:** The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of fronicamid is unlikely to present a public health concern.

Chronic risk assessment – refined calculations

| TMDI (range) in % of ADI | minimum – maximum |
|--------------------------|--------------------|
| highest calculated       | 11.9 – 0.5         |
| highest contributor      | 11.9 – 0.5         |
| 2nd contributor          | 11.9 – 0.5         |
| 3rd contributor          | 11.9 – 0.5         |
| pTMRLs at LOQ (in % of ADI) | 0.5 – 0.5 |

MRL according to Regulation (EU) 2016/1902 except the MRL proposed under the current MRL application.
The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002) for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRLs in the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

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| No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded: |
|----------------------------------------------------------|----------------------------------------------------------|---------------------------------|----------------------------------------------------------|----------------------------------------------------------|---------------------------------|
| Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI commodities pTMRL/ threshold MRL (mg/kg) |
| 23.8 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- | 28.2 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- | 23.8 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- | 23.8 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- | 23.8 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- | 23.8 Radishes 0.294/- 20.7 Blackberries 0.483/- 17.5 Strawberries 0.266/- 13.7 Currants (red, black 0.37/- 11.7 Beans 0.16/- 10.8 Raspberries 0.483/- 9.2 Gooseberries 0.37/- 5.4 Lettuce 0.05/- 4.8 Blueberries 0.37/- 3.9 Lentils 0.16/- 3.7 Peas 0.16/- 2.7 Cress 0.05/- 2.7 Cress 0.05/- 0.6 Rocklet, Rucola 0.05/- |

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No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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Conclusion:

For flonicamid, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any processed commodity.

No exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Dry peas, beans and lupins      | 0.16 STMR             |                         | 0.16 STMR           |                         |
| Lupins, meal                    | 0.18 STMR x PF (1.1)  |                         | 0.18 STMR x PF (1.1)|                         |
| Cabbages                        | 0.14 STMR (EFSA, 2017)| 0.23 HR (EFSA, 2017)   |                       |                         |
| Sugar beet tops                 | 0.085 STMR (EFSA, 2017)| 0.2 HR (EFSA, 2017)   |                       |                         |
| Sugar beet, ensiled pulps       | 0.26 STMR x PF (3) (EFSA, 2017)| 0.26 STMR x PF (3) (EFSA, 2017)|   |                         |
| Sugar beet, molasses            | 2.38 STMR x PF (28) (EFSA, 2017)| 2.38 STMR x PF (28) (EFSA, 2017)|   |                         |
| Citrus, dried pulps             | 0.4 STMR x PF (10) (EFSA, 2014)| 0.4 STMR x PF (10) (EFSA, 2014)|   |                         |
| Apple pomaces                    | 0.3 STMR x PF (5) (EFSA, 2014)| 0.3 STMR x PF (2.5) (EFSA, 2014)|   |                         |
| Wheat/Rye grains                | 0.35 STMR (EFSA, 2014)| 0.35 STMR (EFSA, 2014)|   |                         |
| Wheat milled by-products        | 2.45 STMR x PF (7) (EFSA, 2014)| 2.45 STMR x PF (7) (EFSA, 2014)|   |                         |
| Wheat/Rye straw                 | 0.18 STMR (EFSA, 2014)| 0.48 HR (EFSA, 2014)   |                       |                         |
| Barley/Oat grains               | 0.14 STMR (EFSA, 2015)| 0.18 HR (EFSA, 2015)   |                       |                         |
| Barley/Oat straw                | 0.05 STMR (EFSA, 2015)| 0.07 HR (EFSA, 2015)   |                       |                         |
| Potatoes                        | 0.03 STMR (EFSA, 2014)| 0.06 HR (EFSA, 2014)   |                       |                         |
| Potato process waste            | 0.6 STMR x PF (20) (EFSA, 2014)| 0.6 STMR x PF (20) (EFSA, 2014)|   |                         |
| Potato dry pulp                 | 1.14 STMR x PF (38) (EFSA, 2014)| 1.14 STMR x PF (38) (EFSA, 2014)|   |                         |
| Cotton meal                     | 0.05 STMR x PF (1.3) (EFSA, 2015)| 0.05 STMR x PF (1.3) (EFSA, 2015)|   |                         |
| Cotton (undelinted seed)        | 0.14 STMR (EFSA, 2015)| 0.14 STMR (EFSA, 2015)|   |                         |

Risk assessment residue definition: Flonicamid, TFNG and TFNA expressed as flonicamid

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

D.2. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Strawberries                                  | 0.12 STMR               | 0.27 HR               |                       |                       |
| Blackberries                                  | 0.36 STMR               | 0.48 HR               |                       |                       |
| Raspberries                                   | 0.36 STMR               | 0.48 HR               |                       |                       |
| Other small fruits and berries                | 0.17 STMR               | 0.37 HR               |                       |                       |
| Radishes                                      | 0.22 STMR               | 0.29 HR               |                       |                       |
| Lettuce and other salad plants (including escaroles/endives) | 0.03 STMR | 0.05 HR |                       |                       |
| Beans (dry), peas (dry), Lupins, Lentils      | 0.16 STMR               | 0.16 STMR             |                       |                       |
| Other commodities of plant and animal origin  | STMR                    | See table 7 (EFSA, 2017)| Acute risk assessment undertaken only with regard to the crop under consideration |                     |

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<sup>(b)</sup> |
|-------------------|------------------------------------------------------|----------------------------------|
| flonicamid        | N-cyanomethyl-4-(trifluoromethyl)nicotinamide        | ![Structural formula](attachment) |
| TFNA              | 4-(trifluoromethyl)nicotinic acid or 4-(trifluoromethyl)pyridine-3-carboxylic acid | ![Structural formula](attachment) |
| TFNG              | N-[4-(trifluoromethyl)nicotinoyl]glycine or N-[4-(trifluoromethyl)pyridine-3-carbonyl]glycine | ![Structural formula](attachment) |
| TFNA-AM           | 4-(trifluoromethyl)nicotinamide or 4-(trifluoromethyl)pyridine-3-carboxamide | ![Structural formula](attachment) |

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

<sup>(a)</sup> ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(b)</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).