Modification of the existing maximum residue levels for flonicamid in various root crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Council submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue levels (MRL) for the active substance flonicamid in beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the commodities concerned. Adequate analytical methods for enforcement are available to control the residues of flonicamid in the crops under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg for each analyte of the residue definition and in animal matrices at the validated LOQ of 0.01 mg/kg for each analyte of the residue definition. 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, various root crops, pesticide, MRL, consumer risk assessment

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Question number: EFSA-Q-2018-00463
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Council submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas and turnips. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2018. To accommodate for the intended uses of flonicamid, the EMS proposed to raise the existing MRLs for the concerned commodities from the limit of quantification (LOQ) to 0.3 mg/kg.

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

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the data evaluated under previous MRL assessments, the following conclusions are derived.

- The metabolism of flonicamid following foliar application was investigated in crops belonging to the groups of fruit crops, root and tuber vegetables and cereals.
- Studies investigating the effect of processing on the nature of residues (standard hydrolysis studies) demonstrated that flonicamid and its main metabolites are stable.
- Rotational crops studies were not triggered since the DT90 value for flonicamid and its metabolites in the soil are all expected to be far below the trigger value of 100 days.
- Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites, the residue definitions for plant products were proposed as sum of flonicamid, 4-trifluoromethylnicotinic acid (TFNA) and N-(4-trifluoromethylnicotinoyl)glycine (TFNG) expressed as flonicamid 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 flonicamid 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).
- The available residue trials are sufficient to derive MRL proposals of 0.3 mg/kg for the crops under assessment.
- As some of the root crops for which a modification of the EU MRL was requested 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 species/animal species. However, based on the estimated dietary burdens and the results of livestock feeding studies, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.
- The toxicological profile of flonicamid and its metabolites 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). The short-term exposure did not exceed the ARfD for any the crops assessed in this application. The estimated long-term dietary intake was in the range of 2.2–20% of the ADI.
- EFSA concluded that the proposed use of flonicamid on the 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 summary table below.
Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------------|-------------------------|-------------------------|------------------------|
| 0213020        | Carrots          | 0.03*                   | 0.3                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely |
| 0213010        | Beetroots        | 0.03*                   | 0.3                     | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. Risk for consumers unlikely |
| 0213030        | Celeriacs        | 0.03*                   | 0.3                     |                         |
| 0213040        | Horseradishes    | 0.03*                   | 0.3                     |                         |
| 0213050        | Jerusalem artichokes | 0.03*                   | 0.3                     |                         |
| 0213060        | Parsnips         | 0.03*                   | 0.3                     |                         |
| 0213070        | Parsley root     | 0.03*                   | 0.3                     |                         |
| 0213080        | Radishes         | 0.03*/0.6               | 0.3/0.6                 | The MRL proposal of 0.3 mg/kg was derived by extrapolation from carrots, reflecting the intended NEU use. A higher MRL proposal of 0.6 mg/kg was recently derived by EFSA (2018), which is not yet implemented in legislation |
| 0213090        | Salsifies        | 0.03*                   | 0.3                     | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. Risk for consumers unlikely |
| 0213100        | Swedes           | 0.03*                   | 0.3                     |                         |
| 0213110        | Turnips          | 0.03*                   | 0.3                     |                         |

**Enforcement residue definition for commodities of plant origin**: sum of fonicamid, TFNA and TFNG expressed as fonicamid.

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* MRL: maximum residue level; NEU: northern Europe.
* \(^{(a)}\): 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.
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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 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. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2010). Flonicamid was approved\(^1\) for the use as an insecticide on 1 September 2010.

The EU MRLs for flonicamid are established in Annex II of Regulation (EC) No 396/2005\(^3\). 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\(^4\) for EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Council submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing MRLs for the active substance flonicamid in root crops (i.e. beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas and turnips). The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 1 June 2018. To accommodate for the intended uses of flonicamid, the EMS proposed to raise the existing MRLs for the root crops listed above from the limit of quantification (LOQ) to 0.3 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 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, EFSA, 2017, 2018).

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, 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.

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

The evaluation report submitted by the EMS (United Kingdom, 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.

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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.
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 belonging to the group of fruit crops, root crops and cereals/grass 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-^{14}\text{C}-phenyl flonicamid, parent compound and the two metabolites 4-trifluoromethylnicotinic acid (TFNA) and \textit{N}-(4-trifluoromethylnicotinoyl)glycine (TFNG) were found to be the main residues.

1.1.2. Nature of residues in rotational crops

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2010), the DT_{90} value of flonicamid 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 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, 2018). It was concluded that the parent compound flonicamid and its metabolites are hydrolytically stable under the representative conditions.

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 \(-18^\circ\text{C}\) (EFSA, 2010).

In addition, 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 \(-20^\circ\text{C}\) (EFSA, 2015).

Ultimately, storage stability was investigated in high acid content commodities and according to these studies, flonicamid and its metabolites are stable for up to 6 months when stored at \(-18^\circ\text{C}\) (EFSA, 2018).

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.

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

In support of the MRL application, the applicant submitted residue trials performed in carrots. All samples were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the analytical methods used to analyse the residue trial samples were sufficiently validated and fit for purpose (United Kingdom, 2018).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Carrots

In total eight outdoor trials on carrots (0213020) compliant with the intended northern Europe (NEU) Good Agricultural Practice (GAP) were provided. In all trials, residues were measured in both the roots and the tops (leaves) of the crop. The available studies are sufficient to derive a MRL proposal for carrots.

Other root crops

The applicant proposed to use the residue trials in carrots to extrapolate to the other root crops, which is in line with the EU guidance document (European Commission, 2017) which specifies that at least eight residue trials on carrot are required to extrapolate the MRL to the whole group of root and tuber vegetables except sugar beets (0213000). Therefore, the available and valid trials on carrot can be used for the setting of MRL also for the following crops: beetroots (0213010), celeriacs (0213030), horseradishes (0213040), Jerusalem artichokes (0213050), parsnips (0213060), parsley root (0213070), radishes (0213080), salsifies (0213090), swedes (0213100) and turnips (0213110).

The residue concentration measured in carrot tops were used for the calculation of the animal dietary burden in relation to turnip tops which are used as feed item.

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 DT$_{90}$ value of fionicamid 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 this application, there is no need to investigate 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, 2018) and considering that the expected residues in the crops concerned contribute to the overall long-term exposure to a low extent ($\leq$ 1.1% of the acceptable daily intake (ADI)).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B). 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

Carrots, swedes, turnips and turnip tops may be used for feed purposes. When these crops were added as input values for the exposure calculations of livestock, they had an 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, 2018). Therefore, EFSA assessed whether the intended use of fionicamid would require a modification of the MRLs set for food 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.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in goat and poultry have been assessed previously in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014). The residue definitions for enforcement and risk assessment in all commodities of animal origin were defined as the ‘sum of flonicamid and TFNA-AM, expressed as flonicamid’. Validated analytical methods for enforcement of the proposed residue definition are available. In the framework of the peer review, the proposed residue definitions were considered to be not fat soluble.

EFSA concluded that the metabolism of flonicamid in livestock was sufficiently elucidated.

2.2. Magnitude of residues in livestock

Feeding studies with lactating cows and laying hens were assessed previously in the framework of the EU pesticides peer review and MRL review (EFSA, 2010, 2014).

Based on the results of the feeding studies and considering the updated animal burden calculations, EFSA concluded that the intended uses do not have a significant impact on the residues expected in food of animal origin. Therefore, there is no need to modify the existing EU MRLs in products of animal origin.

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 flonicamid 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 for the commodities assessed in this application in accordance with the internationally agreed methodology. The calculations were based on the highest residue (HR) derived from supervised field trials (Appendix D.2).

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix C).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses approved in the EU and sufficiently supported import tolerances or Codex MRLs (EFSA, 2014). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for the root crops assessed; in addition, STMR values derived in EFSA opinions published after the MRL review (EFSA, 2014, 2015, 2016, 2017, 2018) were included in the dietary exposure assessment. The input values used in the exposure calculations are summarised in Appendix D.2.

The estimated long-term dietary intake was in the range of 2.2–20% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C.

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.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedess/rutabagas and turnips.
EFSA concluded that the proposed uses of flonicamid 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**

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  
ISO  International Organisation for Standardisation  
IUPAC  International Union of Pure and Applied Chemistry  
LC  liquid chromatography  
LOQ  limit of quantification  
MRL  maximum residue level  
MS  Member States  
MS/MS  tandem mass spectrometry detector  
NEU  northern Europe  
OECD  Organisation for Economic Co-operation and Development  
PBI  plant-back interval  
PF  processing factor  
PHI  pre-harvest interval  
PRIMo (EFSA)  Pesticide Residues Intake Model  
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  
TFNA  4-trifluoromethylnicotinic acid  
TFNG  N-(4-trifluoromethylnicotinoyl)glycine  
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 | Member State | Product Name | NEU SEU or G | Pests or Group of pests controlled | Preparation Type | Conc. a.s. | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days) | Remarks |
|----------------------|--------------|--------------|--------------|-----------------------------------|-----------------|-----------|------------|-----------------------------|----------------|-------------------------------|-------------------------------|-----------|---------|
| Beetroot (red beet, table beet) | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Carrots | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Celeriac | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Horseradish | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Jerusalem artichoke | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Parsnips | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Parsley root | UK | Teppeki | NEU | Aphids | WG | 500 g/kg | Spraying | BBCH 00-49 | 1-2 | 14 | 0.0175-0.035 | 200-400 | 0.07 | 21 Estimated period of use May to October |
| Crop and/or situation<sup>(a)</sup> | Member State | Product Name | NEU or SEU or G<sup>(b)</sup> | Pests or Group of pests controlled<sup>(c)</sup> | Preparation | Application | Application rate per treatment | PHI (days)<sup>(m)</sup> | Remarks |
|----------------------------------|--------------|--------------|-----------------------------|---------------------------------|-------------|----------------|-----------------------------|----------------|---------|
| Radishes UK Teppeki NEU Aphids   | Spraying     | BBCH 00-49   | 1-2                         | 14                              | 0.0175-0.035 | 200-400       | 0.07            | 21             | Estimated period of use May to October |
| Salsify UK Teppeki NEU Aphids    | Spraying     | BBCH 00-49   | 1-2                         | 14                              | 0.0175-0.035 | 200-400       | 0.07            | 21             | Estimated period of use May to October |
| Swedes UK Teppeki NEU Aphids     | Spraying     | BBCH 00-49   | 1-2                         | 14                              | 0.0175-0.035 | 200-400       | 0.07            | 21             | Estimated period of use May to October |
| Turnips UK Teppeki NEU Aphids    | Spraying     | BBCH 00-49   | 1-2                         | 14                              | 0.0175-0.035 | 200-400       | 0.07            | 21             | Estimated period of use May to October |

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

(a): For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(c): e.g. biting and sucking insects, soil born insects, foliar fungi, weeds.
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(f): All abbreviations used must be explained.
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated.
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j): 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.
(k): Indicate the minimum and maximum number of applications possible under practical conditions of use.
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200,000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha.
(m): 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 |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
|                                     |             |         |                |           | Not triggered (EFSA, 2010) |

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

- **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)

**DAT:** days after treatment; **PBI:** plant-back interval; **LOQ:** limit of quantification.

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B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------------|-------------------|----------------|
|                                   | High water content | 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 acid content | Orange (whole fruit) | – 18 | 6 Months | Parent and its metabolites TFNG, TFNA | EFSA (2018) |

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) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|--------------|----------------|-------|
| Carrot root NEU | 0.039, 0.045, 0.046, 0.054, 0.055, 0.075, 0.087, 0.15 | Residue trials on carrot compliant with GAP; Extrapolation to the following crops possible: beetroot (0213010), Celeriac (0213030), Horseradish (0213040), Jerusalem artichoke (0213050), Parsnips (0213060), Parsley root (0213070), Radishes (0213080), Salsifies (0213090), Swedes (0213100), Turnips (0213110) | 0.3 | 0.15 | 0.05 | – |
| Carrot tops NEU | 0.036, 0.043, 0.061, 0.062, 0.081, 0.083, 0.17, 0.29 | Residue trials on carrot compliant with GAP | – | 0.29 | 0.07 | – |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: 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. DT$_{90}$ values for flonicamid and its metabolites in the soil are all expected to range between 1.5 and 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 |

DT$_{90}$: 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

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

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|---------------------------|------------------------|
|                             | Median | Maximum | Median | Maximum |                      |                          |
| Cattle (all)                | 0.073  | 0.086   | 2.39   | 2.91    | Dairy cattle          | Potato process waste    | Y                       |
| Cattle (dairy only)         | 0.073  | 0.086   | 1.91   | 2.23    | Dairy cattle          | Potato process waste    | Y                       |
| Sheep (all)                 | 0.077  | 0.091   | 2.32   | 2.74    | Ram/Ewe              | Potato process waste    | Y                       |
| Sheep (ewe only)            | 0.077  | 0.091   | 2.32   | 2.74    | Ram/Ewe              | Potato process waste    | Y                       |
| Swine (all)                 | 0.049  | 0.061   | 1.69   | 2.15    | Swine (finishing)     | Wheat milled by-products | Y                       |
| Poultry (all)               | 0.062  | 0.071   | 0.91   | 1.04    | Poultry layer         | Wheat milled by-products | Y                       |
| Poultry (layer only)        | 0.062  | 0.071   | 0.91   | 1.04    | Poultry layer         | Wheat milled by-products | Y                       |

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’.

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Time needed to reach a plateau concentration in milk and eggs (days)

| Commodity | Time (days) | Source |
|-----------|-------------|--------|
| Milk      | 2           | EFSA (2014) |
| Eggs      | 4           | EFSA (2014) |

Metabolism in rat and ruminant similar

Yes | EFSA (2014)

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)

LOQ: limit of quantification.

### 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                      | Parent and metabolites TFNA, TFNA-AM, OH-TFNA-AM, TFNG | EFSA (2010)     |
|                                    | Goat   | Muscle, fat, milk  | –18    | 9                      | Parent and metabolites TFNA, TFNA-AM, OH-TFNA-AM, TFNG | EFSA (2010)     |

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

#### B.2.2.2. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF |
|------------------|----------------------------------------------|-----------------------|----------------------|----|
|                  | Mean | Highest | STMR (mg/kg) | HR (mg/kg) | |
| Cattle (all)     |      |         |              |            |    |
| Closest feeding level (0.086 mg/kg bw; 1.0 N rate) |      |         |              |            |    |
| Muscle           | 0.04 | 0.04    | 0.04         | 0.04       | 0.04 |
| Fat              | 0.02 | 0.02    | 0.02         | 0.02       | 0.03 |
| Liver            | 0.06 | 0.06    | 0.06         | 0.06       | 0.06 |
| Kidney           | 0.06 | 0.06    | 0.06         | 0.06       | 0.06 |
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF |
|------------------|---------------------------------------------|-----------------------|----------------------|----|
|                  | Mean | Highest | STMR (mg/kg) | HR (mg/kg) |
| Cattle (dairy only) | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 |
| Closest feeding level (0.086 mg/kg bw; 1.0 N rate) |  
| Milk | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 |
| Sheep (all) | 0.04 | 0.04 | 0.02 | 0.03 |
| Closest feeding level (0.086 mg/kg bw; 0.9 N rate) |  
| Muscle | 0.04 | 0.04 | 0.04 | 0.04 |
| Fat | 0.02 | 0.02 | 0.02 | 0.02 |
| Liver | 0.06 | 0.06 | 0.06 | 0.06 |
| Kidney | 0.06 | 0.06 | 0.06 | 0.06 |
| Sheep (ewe only) | 0.06 | 0.06 | 0.06 | 0.06 |
| Closest feeding level (0.086 mg/kg bw; 0.9 N rate) |  
| Milk | 0.02 | 0.02 | 0.02 | 0.03 |
| Swine (all) | 0.04 | 0.04 | 0.04 | 0.04 |
| Closest feeding level (0.086 mg/kg bw; 1.4 N rate) |  
| Muscle | 0.04 | 0.04 | 0.04 | 0.04 |
| Fat | 0.02 | 0.02 | 0.02 | 0.02 |
| Liver | 0.06 | 0.06 | 0.06 | 0.06 |
| Kidney | 0.06 | 0.06 | 0.06 | 0.06 |
| Poultry (all) | 0.02 | 0.02 | 0.04 | 0.04 |
| Closest feeding level (0.017 mg/kg bw; 0.2 N rate) |  
| Muscle | 0.02 | 0.02 | 0.04 | 0.04 |
| Fat | 0.02 | 0.02 | 0.03 | 0.03 |
| Liver | 0.02 | 0.02 | 0.04 | 0.04 |
| Poultry (layer only) | 0.02 | 0.02 | 0.08 | 0.09 |
| Closest feeding level (0.017 mg/kg bw; 0.2 N rate) |  
| Eggs | 0.02 | 0.02 | 0.08 | 0.1 |

MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue; bw: body weight.
## B.3. Consumer risk assessment

| ARfD | 0.025 mg/kg bw (EFSA, 2010) |
|------|-----------------------------|
| Highest IESTI, according to EFSA PRIMo | Carrots: 38% of ARfD  
Celeriac: 33.2% of ARfD  
Swedes: 31% of ARfD  
Other crops assessed: < 30% 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 |

| ADI | 0.025 mg/kg bw (EFSA, 2010) |
|-----|-----------------------------|
| Highest IEDI, according to EFSA PRIMo | 20% ADI (diet)  
Contribution of crops assessed:  
Beetroot: 0.136% of ADI  
Carrots: 0.530% of ADI  
Celeriac: 0.025% of ADI  
Horseradish: 0.007% of ADI  
Jerusalem artichokes: 0.019% of ADI  
Parsnips: 0.126% of ADI  
Parsley root: 0.012% of ADI  
Radishes: see EFSA (2018)  
Salsify: 0.017% of ADI  
Swedes: 0.051% of ADI  
Turnips: 0.053% of ADI |
| 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; MRL: maximum residue level.
**B.4. Recommended MRLs**

| Code(a) | Commodity      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|---------|----------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0213020 | Carrots        | 0.03*                   | 0.3                     | The MRL proposal reflects the intended NEU use. Risk for consumers unlikely                                                                                          |
| 0213010 | Beetroots      | 0.03*                   | 0.3                     | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. Risk for consumers unlikely                                   |
| 0213030 | Celeriacs      | 0.03*                   | 0.3                     |                                                                                                                                                                |
| 0213040 | Horseradishes  | 0.03*                   | 0.3                     |                                                                                                                                                                |
| 0213050 | Jerusalem artichokes | 0.03*     | 0.3                     |                                                                                                                                                                |
| 0213060 | Parsnips       | 0.03*                   | 0.3                     | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. Risk for consumers unlikely                                   |
| 0213070 | Parsley root   | 0.03*                   | 0.3                     |                                                                                                                                                                |
| 0213080 | Radishes       | 0.03*/0.6               | 0.3/0.6                 | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. A higher MRL proposal of 0.6 mg/kg was recently derived by EFSA (2018), which is not yet implemented in legislation |
| 0213090 | Salsifies      | 0.03*                   | 0.3                     | The MRL proposal was derived by extrapolation from carrots, reflecting the intended NEU use. Risk for consumers unlikely                                   |
| 0213100 | Swedes         | 0.03*                   | 0.3                     |                                                                                                                                                                |
| 0213110 | Turnips        | 0.03*                   | 0.3                     |                                                                                                                                                                |

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

- MRL: maximum residue level; NEU: northern 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)

#### Flonicamid

| Status of the active substance: | Approved |

| LOQ (mg/kg bw) | Proposed LOQ |

| Toxicological endpoints |

| ADI (mg/kg bw per day) | 0.025 |

| Source of ADI: |

| EFSA |

| ARfD (mg/kg bw) | 0.025 |

| Source of ARfD: |

| EFSA |

| Year of evaluation: |

| 2010 |

| Year of evaluation: |

| 2010 |

| No of diets exceeding ADI: | --- |

| Highest calculated TMDI values in % of ADI MS Diet |

| Commodity/ group of commodities |

| 20.0 DK child 7.7 Wheat 6.2 Rye 2.5 Milk and cream 1.5 Apples 0.6 Milk and cream 1.5 Beans (with pods) 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 19.7 NL child 6.6 Wheat 5.9 Milk and cream 1.7 Tomatoes 0.6 Milk and cream 1.5 Beans (with pods) 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 19.4 WHO Cluster diet B 11.9 Wheat 3.7 Wheat 2.9 Apples 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 17.9 FR toddler 7.9 Milk and cream 3.7 Wheat 2.9 Apples 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 17.2 DE child 5.8 Wheat 3.7 Wheat 2.9 Apples 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 16.1 UK infant 7.7 Milk and cream 3.7 Wheat 2.9 Apples 2.9 Milk and cream 1.2 Sugar beet (root) 0.6 Rye |

| 15.8 UK Toddler 5.5 Wheat 4.1 Milk and cream 2.7 Sugar beet (root) 0.6 Rye |

| 14.2 WHO cluster diet D 9.1 Wheat 1.0 Milk and cream 0.5 Tomatoes 0.3 Apples 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 12.6 ES child 6.2 Wheat 2.5 Milk and cream 0.5 Tomatoes 0.3 Apples 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 11.6 IT toddler/toddler 9.3 Wheat 0.8 Tomatoes 0.2 Apples 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 11.2 WHO cluster diet E 5.5 Wheat 0.6 Rye 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 11.0 SE general population 90th percentile 4.5 Wheat 2.5 Milk and cream 0.5 Potatoes 0.3 Apples 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 10.8 FR infant 5.1 Milk and cream 1.2 Wheat 1.1 Beans (with pods) 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 10.4 WHO Cluster diet F 5.0 Wheat 1.1 Rye 0.8 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 9.8 IE adult 3.2 Wheat 0.8 Barley 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye |

| 9.6 WHO regional European diet 4.2 Wheat 1.0 Milk and cream 0.6 Tomatoes 0.3 Potatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes |

| 8.2 PT General population 5.5 Wheat 0.6 Potatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes |

| 7.9 IT adult 5.8 Wheat 0.7 Tomatoes 0.2 Beans (with pods) 0.3 Potatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes |

| 7.5 NL general 2.9 Wheat 1.3 Milk and cream 0.3 Potatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes 0.5 Tomatoes |

| 7.3 ES adult 3.3 Wheat 1.0 Milk and cream 0.4 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes |

| 6.9 FR all population 4.6 Wheat 0.5 Milk and cream 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes 0.2 Tomatoes |

| 6.4 DK adult 2.8 Wheat 1.1 Milk and cream 1.0 Rye 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye 1.0 Rye 1.0 Rye |

| 6.3 LT adult 1.5 Rye 1.5 Wheat 0.6 Milk and cream 0.8 Beans (with pods) 1.1 Rye 1.0 Rye 1.0 Rye 1.0 Rye |

| 5.9 UK vegetarian 2.9 Wheat 0.7 Milk and cream 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) |

| 4.8 FI adult 1.4 Wheat 1.1 Milk and cream 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) |

| 4.8 UK Adult 2.3 Wheat 0.6 Milk and cream 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) 0.5 Sugar beet (root) |

| 3.3 PL general population 0.5 Tomatoes 0.5 Apples 0.4 Potatoes 0.4 Potatoes 0.4 Potatoes 0.4 Potatoes 0.4 Potatoes 0.4 Potatoes |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of flonicamid is unlikely to present a public health concern.
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. 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 9 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 MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

### Table: Highest % of ARfD/ADI Commodities

| 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 (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|
| IESTI 1 *) **) IESTI 1 *) **) IESTI 1 *) **) IESTI 2 *) **) | IESTI 2 *) **) IESTI 2 *) **) IESTI 2 *) **) IESTI 2 *) **) | IESTI 1 *) **) IESTI 1 *) **) IESTI 1 *) **) IESTI 1 *) **) | IESTI 2 *) **) IESTI 2 *) **) IESTI 2 *) **) IESTI 2 *) **) |
| Highest % of ARfD/ADI Commodities pTMRL/ | threshold MRL | Highest % of ARfD/ADI Commodities pTMRL/ | threshold MRL | Highest % of ARfD/ADI Commodities pTMRL/ | threshold MRL | Highest % of ARfD/ADI Commodities pTMRL/ | threshold MRL |
| Carrots 0.15/- | 38.0 | Celeriac 0.15/- | 33.2 | Celeriac 0.15/- | 14.9 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 0.15/- |
| Celeriac 0.15/- | 33.2 | Ceders 0.15/- | 14.9 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 0.15/- |
| Ceders 0.15/- | 31.0 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 0.15/- |
| Ceders 0.15/- | 31.0 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 14.4 | Ceders 0.15/- | 0.15/- |
| Swedes 0.15/- | 26.3 | Swedes 0.15/- | 10.1 | Swedes 0.15/- | 9.2 | Swedes 0.15/- | 9.2 | Swedes 0.15/- | 0.15/- |
| Swedes 0.15/- | 26.3 | Swedes 0.15/- | 10.1 | Swedes 0.15/- | 9.2 | Swedes 0.15/- | 9.2 | Swedes 0.15/- | 0.15/- |
| Beetroot 0.15/- | 25.4 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 0.15/- |
| Beetroot 0.15/- | 25.4 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 6.5 | Beetroot 0.15/- | 0.15/- |
| Radishes 0.29/- | 23.6 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 0.15/- |
| Radishes 0.29/- | 23.6 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 6.1 | Radishes 0.29/- | 0.15/- |
| Salsify 0.15/- | 21.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 0.15/- |
| Salsify 0.15/- | 21.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 5.7 | Salsify 0.15/- | 0.15/- |
| Parsnips 0.15/- | 21.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 0.15/- |
| Parsnips 0.15/- | 21.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 4.6 | Parsnips 0.15/- | 0.15/- |
| Turnips 0.15/- | 1.2 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 |
| Turnips 0.15/- | 1.2 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 | Turnips 0.15/- | 0.0 |
| Parsley root 0.15/- | 0.1 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 0.15/- |
| Parsley root 0.15/- | 0.1 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 3.4 | Parsley root 0.15/- | 0.15/- |
| Horseradish 0.15/- | 0.1 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.15/- |
| Horseradish 0.15/- | 0.1 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.4 | Horseradish 0.15/- | 0.15/- |
| Jerusalem artichokes 0.15/- | 0.1 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.15/- |
| Jerusalem artichokes 0.15/- | 0.1 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.3 | Jerusalem artichokes 0.15/- | 0.15/- |

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

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 unprocessed commodity.

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

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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 |
| Risk assessment residue | definition: Flonicamid, TFNG and TFNA expressed as flonicamid |
| Barley (straw)          | 0.05                  | STMR (EFSA, 2015)      | 0.07    | HR (EFSA, 2015) |
| Beet, sugar (tops)      | 0.09                  | STMR (EFSA, 2017, 2018)| 0.20    | HR (EFSA, 2017, 2018) |
| Cabbage, heads (leaves) | 0.14                  | STMR (EFSA, 2017, 2018)| 0.23    | HR (EFSA, 2017, 2018) |
| Oat (straw)             | 0.05                  | STMR (EFSA, 2015)      | 0.07    | HR (EFSA, 2015) |
| Rye (straw)             | 0.18                  | STMR (EFSA, 2014)      | 0.48    | HR (EFSA, 2014) |
| Triticale (straw)       | 0.18                  | STMR (EFSA, 2014)      | 0.48    | HR (EFSA, 2014) |
| Turnip tops (leaves)    | 0.07                  | STMR                   | 0.29    | HR |
| Wheat (straw)           | 0.18                  | STMR (EFSA, 2014)      | 0.48    | HR (EFSA, 2014) |
| Carrot (culs)           | 0.05                  | STMR                   | 0.15    | HR |
| Potato (culs)           | 0.03                  | STMR (EFSA, 2014)      | 0.06    | HR (EFSA, 2014) |
| Swede (roots)           | 0.05                  | STMR                   | 0.15    | HR |
| Turnip (roots)          | 0.05                  | STMR                   | 0.15    | HR |
| Barley (grain)          | 0.14                  | STMR (EFSA, 2015)      | 0.14    | STMR (EFSA, 2015) |
| Bean (seed, dry)        | 0.16                  | STMR (EFSA, 2018)      | 0.16    | STMR (EFSA, 2018) |
| Cotton (undelinted seed)| 0.04                  | STMR (EFSA, 2016)      | 0.04    | STMR (EFSA, 2016) |
| Lupin (seed)            | 0.16                  | STMR (EFSA, 2018)      | 0.16    | STMR (EFSA, 2018) |
| Oat (grain)             | 0.14                  | STMR (EFSA, 2015)      | 0.14    | STMR (EFSA, 2015) |
| Pea (seed, dry)         | 0.16                  | STMR (EFSA, 2018)      | 0.16    | STMR (EFSA, 2018) |
| Rye (grain)             | 0.35                  | STMR (EFSA, 2014)      | 0.35    | STMR (EFSA, 2014) |
| Triticale (grain)       | 0.35                  | STMR (EFSA, 2014)      | 0.35    | STMR (EFSA, 2014) |
| Wheat (grain)           | 0.35                  | STMR (EFSA, 2014)      | 0.35    | STMR (EFSA, 2014) |
| Apple (pomace, wt)      | 0.30                  | STMR \times 5 \text{PF}^{(a)} (EFSA, 2014) | 0.30    | STMR \times 5 \text{PF}^{(a)} (EFSA, 2014) |
| Beet, sugar (dried pulp)| 1.62                  | STMR \times 18 \text{PF}^{(a)} (EFSA, 2017, 2018) | 1.62    | STMR \times 18 \text{PF}^{(a)} (EFSA, 2017, 2018) |
| Beet, sugar (ensiled pulp)| 0.27                | STMR \times 3 \text{PF}^{(a)} (EFSA, 2017, 2018) | 0.27    | STMR \times 3 \text{PF}^{(a)} (EFSA, 2017, 2018) |
| Beet, sugar (molasses)  | 2.52                  | STMR \times 28 \text{PF}^{(a)} (EFSA, 2017, 2018) | 2.52    | STMR \times 28 \text{PF}^{(a)} (EFSA, 2017, 2018) |
| Brewer’s grain          | 0.46                  | STMR \times 3.3 \text{PF}^{(a)} (EFSA, 2014) | 0.46    | STMR \times 3.3 \text{PF}^{(a)} (EFSA, 2014) |
| Citrus (dried pulp)     | 0.40                  | STMR \times 10 \text{PF}^{(a)} (EFSA, 2014) | 0.40    | STMR \times 10 \text{PF}^{(a)} (EFSA, 2014) |
| Cotton (meal)           | 0.05                  | STMR \times 1.3 \text{PF}^{(a)} (EFSA, 2016) | 0.05    | STMR \times 1.3 \text{PF}^{(a)} (EFSA, 2016) |
| Distiller’s grain (dried)| 1.16                 | STMR \times 3.3 \text{PF}^{(a)} (EFSA, 2014) | 1.16    | STMR \times 3.3 \text{PF}^{(a)} (EFSA, 2014) |
| Lupin seed (meal)       | 0.18                  | STMR \times 1.1 \text{PF}^{(a)} (EFSA, 2018) | 0.18    | STMR \times 1.1 \text{PF}^{(a)} (EFSA, 2018) |
| Potato (process waste)  | 0.60                  | STMR \times 20 \text{PF}^{(a)} (EFSA, 2014) | 0.60    | STMR \times 20 \text{PF}^{(a)} (EFSA, 2014) |
| Potato (dried pulp)     | 1.14                  | STMR \times 38 \text{PF}^{(a)} (EFSA, 2014) | 1.14    | STMR \times 38 \text{PF}^{(a)} (EFSA, 2014) |
| Feed commodity              | Median dietary burden | Maximum dietary burden |
|-----------------------------|-----------------------|------------------------|
|                            | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment |
| Wheat gluten (meal)         | 0.63                  | 0.35 STMR × 1.8 PF<sup>(a)</sup> (EFSA, 2014) | 0.63                  | 0.35 STMR × 1.8 PF<sup>(a)</sup> (EFSA, 2014) |
| Wheat (milled by-product)   | 2.45                  | 0.35 STMR × 7 PF<sup>(a)</sup> (EFSA, 2014) | 2.45                  | 0.35 STMR × 7 PF<sup>(a)</sup> (EFSA, 2014) |

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

(a): For apple pomace, beet sugar (dried pulp), beet sugar (ensiled pulp), beet sugar (molasses), Brewer’s grain, citrus (dried pulp), cotton (meal), Distiller’s grain (dried), lupin seed (meal) potato (process waste), potato (dried pulp), wheat gluten (meal), wheat (milled by-product), in the absence of processing factors supported by data, default processing factors of 5, 18, 3, 28, 3, 10, 3, 3, 1.1, 20, 38, 1.8, 7 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

### D.2 Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Carrots                    | 0.05                    | STMR                  | 0.15                | HR      |
| Beetroot                   | 0.05                    | STMR                  | 0.15                | HR      |
| Celeriacs                  | 0.05                    | STMR                  | 0.15                | HR      |
| Horseradishes              | 0.05                    | STMR                  | 0.15                | HR      |
| Jerusalem artichokes       | 0.05                    | STMR                  | 0.15                | HR      |
| Parsnips                   | 0.05                    | STMR                  | 0.15                | HR      |
| Parsley root               | 0.05                    | STMR                  | 0.15                | HR      |
| Radishes                   | 0.22                    | STMR (EFSA, 2018)     | 0.29                | HR      |
| Salsifies                  | 0.05                    | STMR                  | 0.15                | HR      |
| Sweden                     | 0.05                    | STMR                  | 0.15                | HR      |
| Turnips                    | 0.05                    | STMR                  | 0.15                | HR      |
| Citrus fruit               | 0.04                    | STMR (EFSA, 2014)     |                      |         |
| Pome fruit                 | 0.06                    | STMR (EFSA, 2014)     |                      |         |
| Apricots                   | 0.10                    | STMR (EFSA, 2017, 2018)|                   |         |
| Cherries                   | 0.13                    | STMR (EFSA, 2014)     |                      |         |
| Peaches                    | 0.08                    | STMR (EFSA, 2014)     |                      |         |
| Plums                      | 0.09                    | STMR (EFSA, 2014)     |                      |         |
| Strawberries               | 0.12                    | STMR (EFSA, 2018)     |                      |         |
| Blackberries               | 0.36                    | STMR (EFSA, 2018)     |                      |         |
| Raspberries                | 0.36                    | STMR (EFSA, 2018)     |                      |         |
| Other small fruit & berries| 0.17                    | STMR (EFSA, 2018)     |                      |         |
| Potatoes                   | 0.03                    | STMR (EFSA, 2014)     |                      |         |
| Tomatoes                   | 0.14                    | STMR (EFSA, 2014)     |                      |         |
| Peppers                    | 0.06                    | STMR (EFSA, 2015)     |                      |         |
| Aubergines (egg plants)    | 0.14                    | STMR (EFSA, 2014)     |                      |         |
| Cucumbers                  | 0.15                    | STMR (EFSA, 2014)     |                      |         |
| Gherkins                   | 0.15                    | STMR (EFSA, 2014)     |                      |         |
| Courgettes                 | 0.15                    | STMR (EFSA, 2014)     |                      |         |
| Melons                     | 0.06                    | STMR (EFSA, 2014)     |                      |         |
| Pumpkins                   | 0.06                    | STMR (EFSA, 2014)     |                      |         |
| Watermelons                | 0.06                    | STMR (EFSA, 2014)     |                      |         |
| Other cucurbits-inedible peel| 0.06               | STMR (EFSA, 2014)     |                      |         |

Acute risk assessment was performed only for the commodities under assessment.
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg) | Comment               | Input value (mg/kg) | Comment |
| Brussels sprouts                              | 0.07                    | STMR (EFSA, 2015)     |                      |         |
| Head cabbage                                  | 0.14                    | STMR (EFSA, 2017, 2018) |                      |         |
| Herbs                                         | 0.71                    | STMR (EFSA, 2016)     |                      |         |
| Lettuce and other salad plants including Brassicaceae | 0.03 | STMR (EFSA, 2018)     |                      |         |
| Beans (with pods)                             | 0.34                    | STMR (EFSA, 2017, 2018) |                      |         |
| Beans (without pods)                          | 0.20                    | STMR (EFSA, 2016)     |                      |         |
| Peas (with pods)                              | 0.34                    | STMR (EFSA, 2017, 2018) |                      |         |
| Peas (without pods)                           | 0.20                    | STMR (EFSA, 2016)     |                      |         |
| Beans                                         | 0.16                    | STMR (EFSA, 2018)     |                      |         |
| Lentils                                       | 0.16                    | STMR (EFSA, 2018)     |                      |         |
| Peas                                          | 0.16                    | STMR (EFSA, 2018)     |                      |         |
| Lupins                                        | 0.16                    | STMR (EFSA, 2018)     |                      |         |
| Cotton seed                                   | 0.04                    | STMR (EFSA, 2016)     |                      |         |
| Barley                                        | 0.17                    | STMR (EFSA, 2015)     |                      |         |
| Oats                                          | 0.17                    | STMR (EFSA, 2015)     |                      |         |
| Rye                                           | 0.35                    | STMR (EFSA, 2014)     |                      |         |
| Wheat                                         | 0.35                    | STMR (EFSA, 2014)     |                      |         |
| Hops (dried), including hop pellets uncentracted powder | 0.61 | STMR (EFSA, 2014)     |                      |         |
| Sugar beet (root)                             | 0.03                    | STMR (EFSA, 2017, 2018) |                      |         |
| Swine, Bovine, Sheep, Goat, Horse: meat       | 0.06                    | STMR (FAO, 2016)      |                      |         |
| Swine, Bovine, Sheep, Goat, Horse: fat free of lean meat | 0.02 | STMR (FAO, 2016)      |                      |         |
| Swine, Bovine, Sheep, Goat, Horse: liver      | 0.10                    | STMR (FAO, 2016)      |                      |         |
| Swine, Bovine, Sheep, Goat, Horse: kidney     | 0.10                    | STMR (FAO, 2016)      |                      |         |
| Swine, Bovine, Sheep, Goat, Horse: edible offal | 0.10 | STMR (FAO, 2016)      |                      |         |
| Poultry: meat                                 | 0.04                    | STMR (FAO, 2016)      |                      |         |
| Poultry: fat                                  | 0.04                    | STMR (FAO, 2016)      |                      |         |
| Poultry: liver                                | 0.04                    | STMR (FAO, 2016)      |                      |         |
| Milk and cream                                | 0.05                    | STMR (FAO, 2016)      |                      |         |
| Bird’s eggs                                   | 0.08                    | STMR                  |                      |         |

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

| Code/trivial name | Chemical name/SMILES notation(a) | Structural formula(a) |
|-------------------|----------------------------------|-----------------------|
| fonicamid         | \( N\text{-cyanomethyl}-4\text{(trifluoromethyl)}\text{nicotinamide} \)  
                   | \( O=\text{C}(\text{NCC#N})\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |
| TFNA              | 4-(trifluoromethyl)nicotinic acid  
                   | or 4-(trifluoromethyl)pyridine-3-carboxylic acid  
                   | \( O\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |
| TFNG              | \( N\text{-}[4\text{(trifluoromethyl)}\text{nicotinoyl}]\text{glycine} \)  
                   | or \( N\text{-}[4\text{(trifluoromethyl)}\text{pyridin-3-yl}]	ext{carbonyl}]\text{glycine} \)  
                   | \( O\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |
| TFNA-AM           | 4-(trifluoromethyl)nicotinamide  
                   | or 4-(trifluoromethyl)pyridine-3-carboxamide  
                   | \( O\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |
| fonicamid         | \( N\text{-cyanomethyl}-4\text{(trifluoromethyl)}\text{nicotinamide} \)  
                   | \( O=\text{C}(\text{NCC#N})\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |
| fonicamid         | \( N\text{-cyanomethyl}-4\text{(trifluoromethyl)}\text{nicotinamide} \)  
                   | \( O=\text{C}(\text{NCC#N})\text{c1cnccc1C(F)(F)F} \)  
                   | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.

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