REASONED OPINION

efsa JOURNAL

APPROVED: 24 July 2023

doi: 10.2903/j.efsa.2023.8202

Modification of the existing maximum residue levels or for flonicamid in kales, Chinese cabbages and kohlrabies

European Food Safety Authority (EFSA),
Giulia Bellisai, Giovanni Bernasconi, Luis Carrasco Cabrera, Irene Castellan, Monica del Aguila, Lucien Ferreira, German Giner Santonja, Luna Greco, Samira Jarrah, Renata Leuschner, Javier Martinez Perez, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Manuela Tiramani and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant DLR-Rheinpfalz submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in Chinese cabbages, kales and kohlrabies. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the commodities under assessment. Adequate analytical methods for enforcement are available to control the residues of flonicamid, 4-trifluoromethylnicotinic acid (TFNA) and *N*-(4-trifluoromethylnicotinoyl) glycine (TFNG) (sum expressed as flonicamid) in the commodities under consideration at the validated combined limit of quantification (LOQ) of 0.03 mg/kg and the residues of flonicamid and TFNA-AM in animal matrices at the validated combined LOQ of 0.02 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of flonicamid according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: flonicamid, kales, Chinese cabbages, kohlrabies, insecticide, MRL, consumer risk assessment

Requestor: European Commission

Question numbers: EFSA-Q-2022-00268

Correspondence: pesticides.mrl@efsa.europa.eu

Declarations of interest: If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

Acknowledgements: EFSA wishes to thank: Stathis Anagnos, Andrea Mioč, Marta Szot, for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai, G., Bernasconi, G., Carrasco Cabrera, L., Castellan, I., del Aguila, M., Ferreira, L., Giner Santonja, G., Greco, L., Jarrah, S., Leuschner, R., Perez, J. M., Miron, I., Nave, S., Pedersen, R., Reich, H., Ruocco, S., Santos, M., … Verani, A. (2023). Modification of the existing maximum residue levels or for flonicamid in kales, Chinese cabbages and kohlrabies. *EFSA Journal*, *21*(8), 1–31. https://doi.org/10.2903/j.efsa.2023.8202

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, DLR-Rheinpfalz submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in kales, Chinese cabbages and kohlrabies. 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 28 February 2022. To accommodate for the intended NEU uses of flonicamid, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.03 to 0.5 mg/kg in Chinese cabbages and kales and to 0.15 mg/kg in kohlrabies.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 14 June 2023 the EMS submitted the requested information in a revised evaluation report, which replaced the previously submitted evaluation report.

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 in the framework of this application, the following conclusions are derived.

The metabolism of flonicamid following foliar application was investigated in crops belonging to the groups of fruit crops, root crops and cereals/grass. The parent compound and the two metabolites 4-trifluoromethylnicotinic acid (TFNA) and *N*-(4-trifluoromethylnicotinoyl) glycine (TFNG) were found to be the main residues in plant commodities tested.

As flonicamid and its metabolites TFNA and TFNG have short DT_{90} soil degradation values, ranging from 1.5 to 8.7 days, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of flonicamid (hydrolysis studies) demonstrated that flonicamid and its metabolites TFNG and TFNA are stable under standard hydrolysis conditions.

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological relevance of metabolites and the capabilities of enforcement analytical methods, the residue definitions for plant products were proposed as 'sum of flonicamid and the metabolites 4-(trifluoromethyl) nicotinic acid (TFNA) and *N*-[4-(trifluoromethyl)nicotinoyl]glycine (TFNG), expressed as flonicamid' for both enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

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

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry detection (HPLC–MS/MS) are available to quantify residues in the commodities assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above the individual LOQ of 0.01 mg/kg (combined LOQ of 0.03 mg/kg) in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 0.5 mg/kg for Chinese cabbages and kales and 0.15 mg/kg for kohlrabies.

Specific studies investigating the magnitude of flonicamid residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) of the commodities under assessment is individually below 10% of the acceptable daily intake (ADI).

Among the crops under assessment, kales may be used for feed purposes, therefore the potential carry-over into food of animal origin was assessed. The calculated EU livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species; however, the calculated exposure was significantly lower than the livestock exposure calculated by the JMPR, based on which the existing EU MRLs for flonicamid in commodities of animal origin were set and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

The toxicological profile of flonicamid was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.025 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.025 mg/kg bw. The metabolites included in the residue definition are not of higher toxicity than the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo).

The short-term exposure assessment was performed for the commodities assessed in the present MRL application in accordance with the internationally agreed methodology. The short-term exposure did not exceed the ARfD and accounted for 42.2%, 30.8% and 12.5% of the ARfD for kales, Chinese cabbages/pe-tsai and kohlrabies, respectively.

The long-term exposure assessment performed in the most recent EFSA reasoned opinion published after the MRL review was updated with the risk assessment values derived from the residue trials submitted in support of the present MRL application. The highest estimated long-term dietary intake was 31% of the ADI (NL toddler). The highest contribution of residues of flonicamid in the crops under consideration to the overall long-term exposure was 0.12% of ADI for Chinese cabbages.

EFSA concluded that the proposed use of flonicamid on Chinese cabbages, kales and kohlrabies will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

It must be noted that the investigation of possible risk to bees related to the use of flonicamid is outside the scope of this reasoned opinion. National competent authorities at Member State level are responsible for bee risk assessment when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2011/540 (flonicamid).

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

Full details of all end points 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
Enforcement residue definition: sum of flonicamid, TFNA and TFNG, expressed as flonicamid				
0243010	Chinese cabbages/pe-tsai	0.03*	0.5	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0243020	Kales	0.03*	0.5	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0244000	Kohlrabies	0.03*	0.15	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.

MRL: maximum residue level; TFNA: 4-(trifluoromethyl) nicotinic acid; TFNG: N-[4-(trifluoromethyl)nicotinoyl]glycine; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: 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.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for flonicamid in kales, Chinese cabbages and kohlrabies. The detailed description of the intended uses of flonicamid, which are the basis for the current MRL application, is reported in Appendix A.

Flonicamid[1] is the ISO common name for*N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide (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[2] with France designated as rapporteur Member State (RMS) for the representative uses as foliar spray applications on potatoes, wheat, apples and pears in northern and southern European Union (EU) and on peaches in the southern EU. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010). Flonicamid was approved[3] 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[4]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for flonicamid (EFSA, 2015, 2016a, 2017, 2018b,c, 2019b, 2020a,b). The proposals from these reasoned opinions, except the latest one (EFSA, 2020b), have been considered in recent MRL regulations.[5] Although the MRL proposals derived in EFSA (2020b) have not been implemented in the MRL legislation yet, the conclusions of this opinion will be considered for the present assessment. Certain Codex maximum residue limits (CXLs) have been taken over in the EU MRL legislation[6] (EFSA, 2016b, 2018).

It must be noted that the investigation of possible risk to bees related to the use of flonicamid as insecticide is outside the scope of this reasoned opinion. National competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products according to the provisions laid out in the Regulation (EU) 2011/540.

In accordance with Article 6 of Regulation (EC) No 396/2005, DLR-Rheinpfalz submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for the active substance flonicamid in kales, Chinese cabbages and kohlrabies. 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 EFSA on 28 February 2022. To accommodate for the intended NEU uses of flonicamid, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) 0.03 to 0.5 mg/kg for Chinese cabbages and kales and to 0.15 mg/kg for kohlrabies.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 14 June 2023 the EMS submitted the requested information in a revised evaluation report (Germany, 2022), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2022), the DAR and its addendum (France, 2005, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on flonicamid (European Commission, 2010a,b,c), the conclusion on the

[1] It should be noted that flonicamid and its metabolites, TFNA, TFNG, TFNA-AM and OH-TFNA-AM are identified as a pesticide active substance/metabolites, that meet the definition of per- and polyfluoroalkyl substances (PFAS) based on their chemical structures (https://echa.europa.eu/hot-topics/perfluoroalkyl-chemicals-pfas).

[2] 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, pp. 1–32.

[3] 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, pp. 9–11.

[4] 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, pp. 1–16.

[5] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as.

[6] Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products C/2018/2627 OJ L 121, 16.5.2018, pp. 63–104.

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 (EFSA, 2015, 2016a,b, 2017, 2018b,c,d, 2019b, 2020a,b, 2021), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005.

For this application, the data requirements established in Regulation (EU) No 544/2011[7] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1996, 1997a–g, 2000, 2010b,c, 2017, 2020; 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[8].

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

The evaluation report submitted by the EMS (Germany, 2022) 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.[9]

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 (peach, pepper), root crops (potato) and cereals/grass (wheat) following foliar application has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2010, 2014).

In the crops tested, the parent compound and the two metabolites 4-trifluoromethylnicotinic acid (TFNA) and *N*-(4-trifluoromethylnicotinoyl) glycine (TFNG) were found to be the main residues.

In wheat grain, most of the radioactivity was identified as TFNG (39% TRR, 0.11 mg eq./kg) and the parent flonicamid (29.9% TRR, 0.083 mg eq./kg). In wheat straw and chaff, most of the radioactivity was identified as the parent flonicamid at 50% TRR and 41% TRR respectively with TFNG accounting for 19.6% TRR (straw) and 16.6% TRR (chaff). TFNA was also identified in straw, chaff and grain but was present at < 10% TRR.

In potato tubers, most of the radioactivity was identified as TFNG at 39.5% TRR (0.042 mg/kg) and TFNA at 34.4% TRR (0.036 mg/kg), with the parent flonicamid accounting for 5.6% (0.006 mg/kg).

In pepper fruits, most of the radioactivity was parent compound (91.4% TRR [0.155 mg/kg] and 76.6% TRR [0.082 mg/kg] for 7 and 14 DAT respectively). TFNA and TFNG were also identified, but were present at levels below 10% of the TRR.

The flonicamid metabolic pathway is similar in wheat, potato, peach and pepper which involves hydrolysis of the cyano and amide functional groups leading to two major metabolites, TFNA and TFNG. Quantitative variations in the metabolite profile did occur in the crops considered; however parent flonicamid, TFNG and TFNA constituted the most important components of the residue. In all the crops considered, metabolites TFNA-AM and TFNG-AM[10] were also identified, but were present at levels below 10% of the TRR.

For the intended uses under assessment, the metabolic behaviour in primary crops is sufficiently addressed.

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

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, pp. 127–175.

[9] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00268.

[10] TFNG-AM: *N*-(4-trifluoromethylnicotinoyl)glycinamide, see Appendix E.

1.1.2. Nature of residues in rotational crops

Chinese cabbages/pe-tsai, kales and kohlrabies may be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2010), the DT_{90} value of flonicamid and its metabolites TFNA and TFNG 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

The effect of processing on the nature of flonicamid and its metabolites TFNG and TFNA was investigated in the framework of the EU pesticides peer review, MRL review and a previous MRL application (EFSA, 2010, 2014, 2018b). The studies showed that flonicamid and its metabolites TFNG and TFNA are stable under standard hydrolysis conditions.

1.1.4. Analytical methods for enforcement purposes in plant commodities

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, the MRL review and the recently evaluated Art. 12 confirmatory data (EFSA, 2010, 2014, 2020a).

Sufficiently validated methods are available for the monitoring of residues of flonicamid and its metabolites TFNG and TFNA in high water, high acid, high oil, dry commodities, fresh and dried hops, based on high-performance liquid chromatography with tandem mass spectrometry detection (HPLC-MS/MS). The methods allow quantifying residues for each analyte included in the residue definition at the individual LOQ of 0.01 mg/kg (combined LOQ of 0.03 mg/kg) for high water, high acid, high oil, dry commodities and fresh hops and at the LOQ of 0.05 mg/kg (combined LOQ of 0.15 mg/kg) for dried hops (EFSA, 2010, 2014, 2020a). Details on the analytical method are presented in Appendix B.1.1.1.

A study investigating extraction efficiency of the analytical methods used for enforcement in high-water content commodities was submitted in the framework of the current application (Germany, 2022). This study sufficiently demonstrates efficiency of the extraction procedures using methanol for the quantification of residues in high-water content commodities (method described in report n. A-22-06-09) *via* cross-validation against the extraction procedures used in the peach metabolism study (extractions with acetonitrile/water/phosphoric acid [40/60/0.1 v/v/v], France, 2009). This is in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2017). On the other hand, efficiency of the extraction procedures using acetonitrile/water/acetic acid (60/40/0.1 v/v/v) (method described in report ISK/IKI/06001) was not investigated and is therefore not considered demonstrated.

The crops under consideration in the present MRL application belong to the high-water content commodity group (European Commission, 2010b). Therefore, it is concluded that sufficiently validated methods for the enforcement of flonicamid residues in Chinese cabbages/pe-tsai, kales and kohlrabies are available.

1.1.5. Storage stability of residues in plants

The storage stability of flonicamid and its metabolites TFNA and TFNG in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and previous MRL applications (EFSA, 2010, 2015, 2018b, 2020a,b).

According to the studies available, flonicamid and its metabolites TFNA and TFNG are stable for at least 23 months when stored at −18°C in high-water content, high-oil content and dry commodities, at least 12 months when stored at −20°C in high-protein content commodities and at least 6 months when stored at −18°C in high-acid content commodities.

Information on the storage stability of residues of flonicamid and its metabolites TFNA and TFNG in processed commodities were also submitted in the context of a previous MRL application (EFSA, 2020a,b).

Details on storage stability data are presented in Appendix B.1.1.2.

It was demonstrated that in the commodities assessed in the framework of this application, belonging to the high-water content matrix group, residues of flonicamid and its metabolites TFNA and TFNG are stable for at least 23 months when stored at −18°C. No further data are required for the present assessment.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the residue definition for enforcement and risk assessment in all plant commodities was proposed as 'sum of flonicamid and the metabolites 4-(trifluoromethyl) nicotinic acid (TFNA) and *N*-[4-(trifluoromethyl) nicotinoyl]glycine (TFNG), expressed as flonicamid' in the framework of the MRL Review (EFSA, 2014). The same residue definition is applicable to rotational crops and processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Taking into account the available information for the uses assessed in this application, EFSA concluded that the existing residue definition is appropriate for the crops under assessment and no modification is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted nine independent and GAP-compliant outdoor residue trials performed in kales (4) and kohlrabies (5). The trials were performed in Germany in 2011, 2012 and 2022 and consisted of two foliar treatments at a nominal application rate of 70 g a.s./ha, performed at BBCH 33–49 (for kales) and 17–49 (for kohlrabies) at last application, with an interval between applications ranging from 11 to 14 days in the trials on kales and from 13 to 16 days in the trials on kohlrabies.

Half of the trials (i.e. two for kales and two for kohlrabies) were designed as decline trials (i.e. samples were taken 0 (following application), 7, 14, 21 (corresponding to the intended pre-harvest interval, PHI) and 28 days after the treatment. The data indicate residue decline over this period of time.

The samples of the residue trials were stored under conditions for which integrity of the samples has been demonstrated (Germany, 2022). The samples were analysed in accordance with the residue definition for monitoring and risk assessment (i.e. 'sum of flonicamid, TFNA and TFNG, expressed as flonicamid'). The methods used in the analysis of samples in the context of the residue trials are based on liquid chromatography with tandem mass spectrometry detection (LC–MS/MS) and allowed a quantification of residues of flonicamid and its metabolites TFNA and TFNG (considered separately) at the LOQs of 0.01 and 0.02 mg/kg, depending on the method used. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2022).

A study investigating extraction efficiency of the analytical methods used for risk assessment in high-water content commodities was submitted in the framework of the current application (Germany, 2022). This study sufficiently demonstrates efficiency of the extraction procedures in high-water content commodities *via* cross-validation against the extraction procedures used in the peach metabolism study, in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2017).

The submitted data are sufficient to derive MRL proposals of 0.5 mg/kg for kales and Chinese cabbages (via extrapolation from kales) and 0.15 mg/kg for kohlrabies. The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

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 flonicamid and its metabolites TFNA and TFNG 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

Specific studies investigating the magnitude of flonicamid residues in processed commodities were not submitted and are not required according to Regulation (EC) No 544/2011, considering that the contribution of residues in the commodities under consideration to the overall dietary exposure is individually below 10% of the ADI for any European consumer group diet (European Commission, 1997d).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for Chinese cabbages/pe-tsai, kales and kohlrabies (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on this commodities resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Among the crops under assessment, kales may be used for feed purposes. Hence, it was necessary to update the previous dietary burden calculation for livestock performed by EFSA in the framework of the modification of existing MRLs for flonicamid in various crops and products of animal origin (EFSA, 2020b) to estimate whether residues in kale from the intended use of flonicamid would have an impact on the residues expected in 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 Section B.2. The exposure to flonicamid residues exceeds the trigger value of 0.1 mg/kg DM in all animal species but remains within the same levels as calculated in the previous EFSA assessment. The calculated dietary burdens are significantly lower than the dietary burdens calculated for Australian cattle and EU poultry by the JMPR (FAO, 2016b), based on which the existing EU MRLs for animal commodities are currently set. Nevertheless, the nature and magnitude of flonicamid residues in livestock were assessed further.

2.1. Nature of residues and methods of analysis in livestock

Metabolism studies in goat and poultry have been assessed 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 in products of animal origin are available (EFSA, 2014). These are based on HPLC–MS/MS and allow quantification of flonicamid and TFNA-AM residues with a combined LOQ of 0.02 mg/kg. In the framework of the peer review, the residues of flonicamid and TFNA-AM were considered not to be fat soluble (EFSA, 2010).

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

The storage stability of flonicamid and the metabolite TFNA-AM in commodities of animal origin was investigated in the framework of the EU pesticides peer review (EFSA, 2010). It was demonstrated that flonicamid and the metabolite TFNA-AM are stable for up to 8 months when stored at −18°C in poultry matrices (muscle, fat and eggs) and up to 9 months when stored at −18°C in goat matrices (muscle, fat and milk). Details on storage stability data are presented in Appendix B.2.1.2.

2.2. Magnitude of residues in livestock

Feeding studies with lactating cows and laying hens were assessed in the framework of the EU pesticides peer review and MRL review (EFSA, 2010, 2014). The data from the available feeding studies were compared with the updated dietary burdens that took into consideration additional contribution of flonicamid residues in kales according to the intended use in NEU. Results indicate that there is no need to modify the existing EU MRLs for flonicamid in commodities of animal origin (see Appendix B.2.2.1).

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016a).

The toxicological reference values for flonicamid used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2010a,b,c). The metabolites included in the risk assessment residue definition were considered to be less toxic than the parent compound (EFSA, 2010).

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 (FAO, 2016a). The calculations were based on the HR values derived from supervised field trials submitted in the framework of the present MRL application. The list of input values can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application. The contribution of residues expected in the commodities under assessment to the acute consumer exposure accounted for 42.2%, 30.8% and 12.5% of the ARfD for kales, Chinese cabbages/pe-tsai and kohlrabies, respectively (see Appendix B.3).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed using rev.2 of EFSA PRIMo and taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2014). EFSA updated the calculation using rev 3.1. of EFSA PRIMo with the relevant STMR values derived from the residue trials submitted in support of this MRL application for Chinese cabbages, kales and kohlrabies (Germany, 2022); in addition, STMRs derived in EFSA opinions published after the MRL review (EFSA, 2015, 2016a,b, 2017, 2018a,b,c, 2019b, 2020a,b, 2021) were used as input values to refine the exposure calculation. The crops on which no uses have been reported in the MRL review or in the subsequent EFSA outputs were not included in the exposure calculation. The input values used in the exposure calculations are summarised in Appendix D.2.

The highest estimated long-term dietary intake accounted for 31%[11] of the ADI (NL toddler diet). The contribution of residues expected in Chinese cabbages, kales and kohlrabies to the overall long-term exposure accounted for 0.12% (SE general diet), 0.11% (PT general diet) and 0.01% (GEMS/Food G08 diet) of the ADI, respectively.

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

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for Chinese cabbages, kales and kohlrabies.

The livestock exposure to flonicamid residues from the intake of kale leaves treated according to intended uses would not require modification of the existing EU MRLs for flonicamid in commodities of animal origin.

EFSA updated the most recent consumer risk assessment for flonicamid and concluded that the proposed use of flonicamid on Chinese cabbages, kales and kohlrabies will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment ofthe active substance flonicamid. EFSA Journal 2010;8(5):1445, 63 pp. https://doi.org/10.2903/j.efsa.2010.1445

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flonicamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12 (6):3740, 49 pp. https://doi.org/10.2903/j.efsa.2014.3740

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing MRLs for flonicamid in several crops. EFSA Journal 2015;13(5):4103, 26 pp. https://doi.org/10.2903/j.efsa.2015.4103

EFSA (European Food Safety Authority), 2016a. Reasoned opinion on the modification of the MRL for flonicamid in herbs and edible flowers. EFSA Journal 2016;14(4):4467, 19 pp. https://doi.org/10.2903/j.efsa.2016.4467

EFSA (European Food Safety Authority), 2016b. Scientific Report of EFSA on scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2016;14 (8):4571, 166 pp. https://doi.org/10.2903/j.efsa.2016.4571

[11] Provided that MRL proposals assessed recently by EFSA (EFSA, 2020b) for flonicamid will be adopted in the EU MRL legislation.

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Reasoned opinion on the modification of existing maximum residue levels for flonicamid in various commodities. EFSA Journal 2017;15(3):4748, 20 pp. https://doi.org/10.2903/j.efsa.2017.4748

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018a. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018b. Reasoned opinion on the modification of the existing maximum residue level for flonicamid in various crops. EFSA Journal 2018;16(9):5410, 25 pp. https://doi.org/10.2903/j.efsa.2018.5410

EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018c. Reasoned opinion on the modification of the existing maximum residue levels for flonicamid in various root crops. EFSA Journal 2018;16(9):5414, 26 pp. https://doi.org/10.2903/j.efsa.2018.5414

EFSA (European Food Safety Authority), 2018d. Scientific Report of EFSA on scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16(7):5306, 229 pp. https://doi.org/10.2903/j.efsa.2018.5306

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA supporting publication 2019:EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2019b. Reasoned opinion on themodification of the existing maximum residue levels for flonicamid in strawberries and other berries. EFSA Journal 2019;17(8):5745, 24 pp. https://doi.org/10.2903/j.efsa.2019.5745

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020a. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for flonicamid. EFSA Journal 2020;18(5):6117, 31 pp. https://doi.org/10.2903/j.efsa.2020.6117

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G,Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I,Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020b. Reasoned opinion on the setting of import tolerances for flonicamid in various crops and products of animal origin. EFSA Journal 2020;18(6):6136, 37 pp. https://doi.org/10.2903/j.efsa.2020.6136

EFSA (European Food Safety Authority), 2021. Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021;19(8):6766, 342 pp. https://doi.org/10.2903/j.efsa.2021.6766

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/VI/95-rev. 4, 22 July 1996.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev. 3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.

European Commission, 2010a. Review report for the active substance flonicamid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 12 March 2010 in view of the inclusion of flonicamid in Annex I of Council Directive 91/414/EEC. SANCO/10479/2010-Final, 12 March 2010.

European Commission, 2010b. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010c. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2017. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods. SANTE 2017/10632, rev. 3, 22 November 2017.

European Commission, 2020. Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation on residue data on products from plant and animal origin. SANTE/2019/12752, 23 November 2020.

FAO (Food and Agriculture Organization of the United Nations), 2016a. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Ed. FAO Plant Production and Protection Paper 225, 298 pp.

FAO (Food and Agriculture Organization of the United Nations), 2016b. Flonicamid. In: Pesticide residues in food – 2016. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 229.

France, 2005. Draft assessment report on the active substance flonicamid prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, February 2005.

France, 2009. Final addendum to the draft assessment report on the active substance flonicamid prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, October 2009.

Germany, 2022. Evaluation report on the modification of MRLs for flonicamid in kales, Chinese cabbages and kohlrabies. February 2022, revised in June 2023, 45 pp. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC	gas chromatography
GC–MS	gas chromatography with mass spectrometry
GC–MS/MS	gas chromatography with tandem mass spectrometry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography

LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC	raw agricultural commodity
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water-dispersible granule

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or Group of pests controlled	Preparation		Application			Application rate per treatment					PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (days) min–max	g a.s./ hL min–max	Water (L/ha) min–max	Rate min–max	Unit		
Kales	NEU	F	Aphids	WG	500 g/L	Foliar spray	BBCH 16–49	2	10–14 days	47–175	150–400	70	g a.i./ha	21	
Chinese cabbages/ pe-tsai	NEU	F	Aphids	WG	500 g/L	Foliar spray	BBCH 16–49	2	10–14 days	47–175	150–400	70	g a.i./ha	21	
Kohlrabies	NEU	F	Aphids	WG	500 g/L	Foliar spray	BBCH 16–49	2	10–14 days	47–175	150–400	70	g a.i./ha	21	

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

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum pre-harvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods 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, 2014)
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Flonicamid (EFSA, 2010) TFNG and TFNA (EFSA, 2018b)
	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 (2010, 2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2010, 2018b)
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)	Matrices with high water content, high acid content, high oil content, dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg individually for flonicamid, TFNG and TFNA (combined LOQ of 0.03 mg/kg). ILV available (EFSA, 2010, 2014). Efficiency of the extraction procedures using methanol is demonstrated for high-water content commodities (Germany, 2022). Hops: - Fresh hops: HPLC–MS/MS, LOQ 0.01 mg/kg individually for flonicamid, TFNG and TFNA (combined LOQ of 0.03 mg/kg). - Dried hops: HPLC–MS/MS, LOQ of 0.05 mg/kg individually for flonicamid, TFNG and TFNA (combined LOQ of 0.15 mg/kg). ILV available (EFSA, 2020a).

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance; MRL: maximum residue level; GC–MS: gas chromatography with mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; ILV: independent laboratory validation.

B.1.1.2. Storage stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ source**
				Value	**Unit**		
	High-water content	Apple	−18	18	Months	Parent and metabolites TFNG, TFNA, TFNA-AM	EFSA (2010)
		Spinach, tomatoes	−18	23	Months	Parent and metabolites TFNG, TFNA	EFSA (2020)
	High-oil content	Rape seed	−20	12	Months	Parent and metabolites TFNG, TFNA	EFSA (2015)
		Cotton seed	−18	23	Months	Parent and metabolites TFNG, TFNA	EFSA (2020a,b)
	High-protein content	Beans	−20	12	Months	Parent and metabolites TFNG, TFNA	EFSA (2015)
	Dry/high starch	Wheat grain, wheat straw	−18	18	Months	Parent and metabolites TFNG, TFNA, TFNA-AM	EFSA (2010)
		Potato tuber, wheat grain	−18	23	Months	Parent and metabolites TFNG, TFNA	EFSA (2020a,b)
	High-acid content	Orange (whole fruit)	−18	6	Months	Parent and metabolites TFNG, TFNA	EFSA (2018b)
	Processed products	Apple juice, cotton oil and processed cereals	−18	23	Months	Parent and metabolites TFNG, TFNA	EFSA (2020a,b)
		Mint oil	−18	–	–	Parent and metabolites TFNG, TFNA	Flonicamid and metabolites TFNG, TFNA degrade more than 50% within a year (EFSA, 2020a,b)
	Others	–	–	–	–	–	–

B.1.2. Magnitude of residues in plants

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

Commodity	Region[(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)]
Kales and Chinese cabbages	NEU	**Mo/RA:** 0.09; 0.13; 0.17; 0.24	Residue trials on kales compliant with intended GAP. Extrapolation to Chinese cabbages possible.	0.5	0.24	0.15	1
Kohlrabi	NEU	**Mo/RA:** Tuber: < 0.03; 0.04; 0.05; 2 × 0.06 Leaves: 0.03; 0.07	Residue trials on kohlrabi compliant with intended GAP. MRL derived based on trials on kohlrabi tubers, in accordance with Part A of Reg. 2018/62 replacing Annex I of Reg. 396/2005.	0.15	0.06	0.05	1

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe; SEU: Outdoor trials conducted in southern Europe; EU: 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 soil are all expected to range between 1.5 and 8.7 days, which is below the trigger value of 100 days (EFSA, 2010, 2014)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	EFSA (2010, 2014)

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Dietary burden calculation according to OECD (2013).

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)	Previous assessment (EFSA, 2020b)	FAO (2016b)[c]
	mg/kg bw per day		mg/kg DM					Max burden	
	Median	Max	Median	Max				mg/kg DM	
Cattle (all)	0.132	0.144	4.40	4.92	Dairy cattle	Potato, process waste	Yes	4.91	27.7
Cattle (dairy only)	0.132	0.144	3.42	3.74	Dairy cattle	Potato, process waste	Yes	3.73	22.2
Sheep (all)	0.145	0.158	4.34	4.74	Ram/Ewe	Potato, process waste	Yes	4.74	27.7
Sheep (ewe only)	0.145	0.158	4.34	4.74	Ram/Ewe	Potato, process waste	Yes	4.74	27.7
Swine (all)	0.056	0.066	2.42	2.88	Swine (breeding)	Potato, process waste	Yes	2.87	27.7
Poultry (all)	0.062	0.071	0.91	1.04	Poultry layer	Wheat, milled bypdts	Yes	1.04	2.8
Poultry (layer only)	0.062	0.071	0.91	1.04	Poultry layer	Wheat, milled bypdts	Yes	1.04	2.8
Fish	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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 DM'.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg DM'.
(c): The existing EU MRLs in animal commodities have been set on the basis of Codex MRLs, estimated for these dietary burdens.

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

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

Livestock (available studies)	**Animal**	**Dose (mg/kg bw per day)**	**Duration (days)**	**Comment/source**
	Laying hen	0.78	5	3-^{14}C-phenyl (EFSA, 2014)
	Lactating goat	1.69	5	3-^{14}C-phenyl (EFSA, 2014)

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	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	
Animal residue definition for risk assessment (RD-RA)	Sum of flonicamid and TFNA-AM, expressed as flonicamid	
Fat soluble residues	No	EFSA (2014)
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	Validated analytical methods based on HPLC–MS/MS 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). ILV method available (EFSA, 2014).	

HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	**Animal**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ source**
				Value	**Unit**		
	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

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

Calculations performed with Animal model 2017.[12]

Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated value at 1N		MRL proposal (mg/kg)	Current MRL (Reg. 2022/85) (mg/kg)
	Mean	Highest	STMR[(a)] (mg/kg)	HR[(b)] (mg/kg)		
Cattle (all diets) Closest feeding level (0.086 mg/kg bw; 0.6 N Dairy cattle [highest diet])[(c)]						
Muscle	0.04	0.04	0.04	0.04	**0.05**	**0.15**
Fat	0.02	0.02	0.02	0.02	**0.03**	**0.05**
Liver	0.06	0.06	0.06	0.06	**0.06**	**0.2**
Kidney	0.06	0.06	0.06	0.06	**0.06**	**0.2**
Cattle (dairy only) Closest feeding level (0.086 mg/kg bw; 0.6 N Dairy cattle)[(c)]						
Milk[(d)]	0.02	0.02	0.03	0.03	**0.03**	**0.15**
Sheep (all diets)[(e)] Closest feeding level (0.086 mg/kg bw; 0.5 N Ram/Ewe [highest diet])[(c)]						
Muscle	0.04	0.04	0.04	0.04	**0.05**	**0.15**
Fat	0.02	0.02	0.02	0.02	**0.03**	**0.05**
Liver	0.06	0.06	0.06	0.06	**0.06**	**0.2**
Kidney	0.06	0.06	0.06	0.06	**0.06**	**0.2**
Sheep (dairy only)[(e)] Closest feeding level (0.086 mg/kg bw; 0.5 N Ewe)[(c)]						
Milk[(d)]	0.02	0.02	0.03	0.03	**0.03**	**0.15**
Swine (all diets)[(e)] Closest feeding level (0.086 mg/kg bw; 1.3 N Breeding [highest diet])[(c)]						
Muscle	0.04	0.04	0.04	0.04	**0.04**	**0.15**
Fat	0.02	0.02	0.02	0.02	**0.03**	**0.05**
Liver	0.06	0.06	0.06	0.06	**0.06**	**0.2**
kidney	0.06	0.06	0.06	0.06	**0.06**	**0.2**
Poultry (all diets) Closest feeding level (0.017 mg/kg bw; 0.2 N Layer [highest diet])[(c)]						
Muscle	0.02	0.02	0.04	0.04	**0.04**	**0.1**
Fat	0.02	0.02	0.03	0.03	**0.03**	**0.05**
Liver	0.02	0.02	0.04	0.04	**0.04**	**0.1**
Poultry (layer only) Closest feeding level (0.017 mg/kg bw; 0.2 N Layer)[(c)]						
Eggs[(f)]	0.02	0.02	0.08	0.09	**0.1**	**0.15**

bw: body weight; STMR: supervised trials median residue; HR: highest residue; n.a.: not applicable; n.r.: not reported; MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition; STMR: supervised trials median residue; HR: highest residue.

(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

(d): Highest residue level from day 1 to day 28 (daily mean of three cows).

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.

(f): Highest residue level from day 1 to day 28 (daily mean of 10 laying hens).

[12] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en.

B.3. Consumer risk assessment

ARfD	0.025 mg/kg bw (European Commission, 2010)
Highest IESTI, according to EFSA PRIMo	Kales: 42.2% ARfD Chinese cabbages/pe-tsai: 30.8% ARfD Kohlrabies: 12.5% ARfD
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the highest residue levels (HR values) expected in raw agricultural commodities under assessment, expressed as flonicamid equivalents.

ADI	0.025 mg/kg bw per day (European Commission, 2010)
Highest IEDI, according to EFSA PRIMo	31% ADI (NL toddler diet) Contribution of crops assessed: Chinese cabbages/pe-tsai: 0.12% ADI (SE general diet) Kales: 0.11% ADI (PT general diet) Kohlrabies: 0.01% (GEMS/Food G08 diet)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the median residue levels (STMR values) derived for the raw agricultural commodities under assessment. For the remaining commodities, the input values as derived in the MRL review and in succeeding EFSA assessments (EFSA, 2014, 2015, 2016a,b, 2017, 2018a,b, 2019, 2020a,b) and, where applicable, in JMPR assessments (FAO, 2016b) were used. For cucurbits with inedible peel, the STMR value in melon pulp was used. The contributions of commodities where no GAP was reported in the framework of the MRL review and in succeeding applications 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; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; CXL: codex maximum residue limit.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: sum of flonicamid, TFNA and TFNG, expressed as flonicamid				
0243010	Chinese cabbages/pe-tsai	0.03*	0.5	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0243020	Kales	0.03*	0.5	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0244000	Kohlrabies	0.03*	0.15	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: 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)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Flonicamid

LOQs (mg/kg) range from:	0.02	to:	0.10
Toxicological reference values			
ADI (mg/kg bw per day):	0.025	ARfD (mg/kg bw):	0.025
Source of ADI:	EFSA, EC	Source of ARfD:	EFSA, EC
Year of evaluation:	2010	Year of evaluation:	2010

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
31%	NL toddler	7.68	12%	Milk: Cattle	6%	Wheat	3%	Beans (with pods)		31%
21%	DK child	5.30	8%	Rye	6%	Wheat	3%	Milk: Cattle		21%
20%	DE child	4.91	6%	Wheat	4%	Milk: Cattle	3%	Apples		20%
19%	NL child	4.68	6%	Wheat	5%	Milk: Cattle	1%	Apples		19%
18%	FR child 3 15 yr	4.55	6%	Wheat	5%	Milk: Cattle	2%	Beans (with pods)		18%
17%	FR toddler 2 3 yr	4.34	6%	Milk: Cattle	4%	Wheat	3%	Beans (with pods)		17%
17%	UK infant	4.29	8%	Milk: Cattle	4%	Wheat	1%	Peas (without pods)		17%
17%	GEMS/Food G06	4.19	10%	Wheat	2%	Tomatoes	0.5%	Milk: Cattle		17%
15%	UK toddler	3.85	5%	Wheat	4%	Milk: Cattle	1%	Beans		15%
15%	RO general	3.67	7%	Wheat	2%	Milk: Cattle	0.9%	Potatoes		15%
14%	ES child	3.43	6%	Wheat	2%	Milk: Cattle	0.8%	Beans (with pods)		14%
14%	GEMS/Food G15	3.41	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		14%
13%	SE general	3.30	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat		13%
13%	GEMS/Food G08	3.26	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		13%
13%	GEMS/Food G07	3.20	6%	Wheat	1%	Milk: Cattle	0.9%	Potatoes		13%
12%	GEMS/Food G10	3.03	5%	Wheat	1%	Milk: Cattle	0.7%	Potatoes		12%
12%	IT toddler	3.00	9%	Wheat	0.6%	Tomatoes	0.3%	Beans (with pods)		12%
12%	GEMS/Food G11	2.92	5%	Wheat	2%	Milk: Cattle	0.9%	Potatoes		12%
11%	IE adult	2.71	3%	Wheat	0.9%	Milk: Cattle	0.6%	Beans (with pods)		11%
10%	DE women 14-50 yr	2.56	3%	Wheat	2%	Milk: Cattle	0.7%	Rye		10%
10%	DE general	2.54	3%	Wheat	2%	Milk: Cattle	0.8%	Rye		10%
10%	PT general	2.42	5%	Wheat	1%	Potatoes	0.6%	Beans (without pods)		10%
9%	NL general	2.20	3%	Wheat	2%	Milk: Cattle	0.8%	Beans (with pods)		9%
9%	FR infant	2.13	3%	Milk: Cattle	2%	Beans (with pods)	1%	Wheat		9%
8%	IT adult	2.08	6%	Wheat	0.5%	Beans (with pods)	0.5%	Tomatoes		8%
8%	ES adult	2.03	3%	Wheat	1.0%	Milk: Cattle	0.8%	Beans (with pods)		8%
7%	FR adult	1.79	3%	Wheat	0.9%	Milk: Cattle	0.8%	Beans (with pods)		7%
7%	FI 3 yr	1.67	2%	Wheat	1%	Potatoes	0.9%	Rye		7%
7%	LT adult	1.66	2%	Rye	1%	Wheat	0.8%	Milk: Cattle		7%
6%	UK vegetarian	1.56	3%	Wheat	0.7%	Milk: Cattle	0.6%	Beans		6%
6%	DK adult	1.40	2%	Wheat	1%	Milk: Cattle	0.7%	Rye		6%
5%	FI 6 yr	1.37	1%	Wheat	0.9%	Potatoes	0.9%	Rye		5%
5%	UK adult	1.30	2%	Wheat	0.6%	Milk: Cattle	0.3%	Beans		5%
3%	IE child	0.79	2%	Wheat	0.7%	Milk: Cattle	0.2%	Beans (without pods)		3%
3%	FI adult	0.76	1.0%	Rye	0.4%	Wheat	0.3%	Potatoes		3%
3%	PL general	0.66	0.8%	Potatoes	0.5%	Apples	0.4%	Tomatoes		3%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Flonicamid is unlikely to present a public health concern.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): 2

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
114%	Peaches	0.4/0.3	29
105%	Pears	0.3/0.19	26
96%	Peas (without pods)	5/2.94	24
93%	Beans (without pods)	5/2.94	23
89%	Cucumbers	0.5/0.34	22
85%	Melons	0.4/0.14	21
82%	Apples	0.3/0.19	20
79%	Tomatoes	0.5/0.34	20
68%	Watermelons	0.4/0.14	17
68%	Potatoes	0.2/0.11	17
66%	Peas (with pods)	3/2.03	17
64%	Beans (with pods)	3/1.41	16
63%	Courgettes	0.5/0.34	16
42%	Kales	0.5/0.24	11
41%	Head cabbages	0.5/0.23	10
38%	Carrots	0.3/0.15	9.5
37%	Oranges	0.15/0.07	9.3
36%	Sweet peppers/bell peppers	0.3/0.15	8.9
34%	Beetroots	0.3/0.15	8.6
34%	Aubergines/egg plants	0.5/0.34	8.5
33%	Celeriacs/turnip rooted	0.3/0.15	8.3
31%	Swedes/rutabagas	0.3/0.15	7.8
31%	Chinese cabbages/pe-tsai	0.5/0.24	7.7
29%	Strawberries	0.7/0.45	7.4
29%	Beans	2/0.39	7.1
28%	Radishes	0.6/0.29	7.1
25%	Milk: Cattle	0.15/0.05	6.2
22%	Grapefruits	0.15/0.07	5.5
22%	Plums	0.3/0.13	5.5
22%	Parsnips	0.3/0.15	5.4
22%	Turnips	0.3/0.15	5.4
21%	Blackberries	1/0.48	5.1
20%	Wheat	2/0.35	5.1
19%	Quinces	0.3/0.19	4.7
19%	Salsifies	0.3/0.15	4.7
18%	Apricots	0.3/0.13	4.4
18%	Raspberries (red and	1/0.48	4.4
17%	Mandarins	0.15/0.07	4.1
16%	Chervil	6/3	3.9
15%	Pumpkins	0.4/0.14	3.7
15%	Currants (red, black and	0.8/0.46	3.6
13%	Parsley	6/3	3.3
12%	Kohlrabies	0.15/0.06	3.1
11%	Blueberries	0.8/0.46	2.7
11%	Gooseberries (green, red	0.8/0.46	2.7
11%	Brussels sprouts	0.6/0.32	2.7
11%	Medlar	0.3/0.19	2.6
10%	Lentils	2/0.39	2.6
10%	Peas	2/0.39	2.6
10%	Chives	6/3	2.5
10%	Lemons	0.15/0.07	2.4
9%	Sage	6/3	2.3
9%	Rye	2/0.35	2.2
9%	Cherries (sweet)	0.4/0.18	2.2
9%	Basil and edible flowers	6/3	2.2
8%	Cranberries	0.8/0.46	2.1
8%	Escaroles/broad-leaved	0.07/0.05	2.0
8%	Lettuces	0.07/0.05	1.9
6%	Swine: Muscle/meat	0.15/0.12	1.5
6%	Celery leaves	6/3	1.4

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

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
63%	Peas (without pods)	5/2.94	16
46%	Beans (without pods)	5/2.94	12
43%	Beans (with pods)	3/1.41	11
39%	Head cabbages	0.5/0.23	9.7
38%	Cucumbers	0.5/0.34	9.5
37%	Aubergines/egg plants	0.5/0.34	9.2
32%	Courgettes	0.5/0.34	7.9
28%	Peas (with pods)	3/2.03	6.9
24%	Chinese cabbages/pe-tsai	0.5/0.24	6.1
23%	Pears	0.3/0.19	5.8
23%	Watermelons	0.4/0.14	5.7
22%	Peaches	0.4/0.3	5.6
22%	Melons	0.4/0.14	5.5
22%	Tomatoes	0.5/0.34	5.4
21%	Apples	0.3/0.19	5.3
20%	Swedes/rutabagas	0.3/0.15	5.1
18%	Kales	0.5/0.24	4.6
17%	Strawberries	0.7/0.45	4.2
17%	Blueberries	0.8/0.46	4.2
16%	Blackberries	1/0.48	3.9
14%	Parsley	6/3	3.6
14%	Beetroots	0.3/0.15	3.5
13%	Potatoes	0.2/0.11	3.3
12%	Currants (red, black and	0.8/0.46	3.0
12%	Radishes	0.6/0.29	3.0
12%	Carrots	0.3/0.15	3.0
12%	Wheat	2/0.35	2.9
12%	Quinces	0.3/0.19	2.9
10%	Raspberries (red and yellow)	1/0.48	2.6
10%	Beans	2/0.39	2.6
10%	Sweet peppers/bell peppers	0.3/0.15	2.4
10%	Lentils	2/0.39	2.4
9%	Plums	0.3/0.13	2.3
9%	Oranges	0.15/0.07	2.1
8%	Parsnips	0.3/0.15	2.1
8%	Gooseberries (green, red	0.8/0.46	2.1
8%	Gherkins	0.5/0.34	2.1
8%	Pumpkins	0.4/0.14	2.1
8%	Milk: Cattle	0.15/0.05	1.9
8%	Brussels sprouts	0.6/0.32	1.9
7%	HOPS (dried)	20/10.13	1.9
7%	Cherries (sweet)	0.4/0.18	1.8
7%	Celeriacs/turnip rooted	0.3/0.15	1.8
7%	Rye	2/0.35	1.7
7%	Turnips	0.3/0.15	1.7
6%	Salsifies	0.3/0.15	1.6
6%	Parsley roots/Hamburg roots	0.3/0.15	1.5
6%	Jerusalem artichokes	0.3/0.15	1.4
6%	Apricots	0.3/0.13	1.4
5%	Medlar	0.3/0.19	1.3
5%	Peas	2/0.39	1.3
5%	Mandarins	0.15/0.07	1.3
5%	Grapefruits	0.15/0.07	1.3
4%	Horseradishes	0.3/0.15	1.1
4%	Escaroles/broad-leaved	0.07/0.05	1.0
4%	Celery leaves	6/3	0.98
4%	Milk: Goat	0.15/0.05	0.92
4%	Poultry: Muscle	0.1/0.08	0.89
3%	Kohlrabies	0.15/0.06	0.85
3%	Barley	0.4/0.17	0.82

6%	Limes	0.15/0.07	1.4
5%	Bovine: Liver	0.2/0.17	1.4
5%	Poultry: Muscle/meat	0.1/0.08	1.3
5%	Eggs: Chicken	0.15/0.1	1.2
5%	Bovine: Edible offals (other	0.2/0.17	1.2
5%	Milk: Goat	0.15/0.05	1.2
4%	Pistachios	0.3/0.19	1.1
4%	Gherkins	0.5/0.34	0.96
4%	Barley	0.4/0.17	0.95
3%	Bovine: Muscle/meat	0.15/0.12	0.87
3%	Other farmed animals:	0.15/0.12	0.83
3%	Equine: Muscle/meat	0.15/0.12	0.72
3%	Parsley roots/Hamburg	0.3/0.15	0.67
3%	Sheep: Muscle/meat	0.15/0.12	0.65
3%	Bovine: Kidney	0.2/0.17	0.64
2%	Swine: Edible offals (other	0.2/0.17	0.51
2%	HOPS (dried)	20/10.13	0.42
1%	Azarole/Mediteranean	0.7/0.37	0.33
1%	Chestnuts	0.07/0.06	0.25
0.9%	Swine: Kidney	0.2/0.17	0.22
0.8%	Swine: Liver	0.2/0.17	0.21
0.8%	Walnuts	0.07/0.06	0.20
0.8%	Hazelnuts/cobnuts	0.07/0.06	0.20
0.8%	Oat	0.4/0.17	0.19
0.7%	Thyme	6/3	0.18
0.7%	Milk: Sheep	0.15/0.05	0.18
0.7%	Almonds	0.07/0.06	0.17
0.7%	Pecans	0.07/0.06	0.17
0.6%	Cashew nuts	0.07/0.06	0.15
0.6%	Lamb's lettuce/corn salads	0.07/0.05	0.14
0.5%	Roman rocket/rucola	0.07/0.05	0.13
0.4%	Poultry: Liver	0.1/0.09	0.10
0.4%	Rosemary	6/3	0.09
0.2%	Bovine: Fat tissue	0.05/0.03	0.06
0.2%	Horseradishes	0.3/0.15	0.06
0.2%	Brazil nuts	0.07/0.06	0.05
0.2%	Swine: Fat tissue	0.05/0.03	0.05
0.1%	Macadamia	0.07/0.06	0.03
0.1%	Laurel/bay leaves	6/3	0.03
0.08%	Pine nut kernels	0.07/0.06	0.02
0.06%	Cress and other sprouts	0.07/0.05	0.01
0.02%	Poultry: Fat tissue	0.05/0.04	0.00

3%	Rose hips	0.7/0.37	0.81
3%	Milk: Sheep	0.15/0.05	0.76
3%	Bovine: Muscle	0.15/0.12	0.68
3%	Bovine: Liver	0.2/0.17	0.68
3%	Other farmed animals:	0.15/0.12	0.67
3%	Lemons	0.15/0.07	0.63
2%	Lettuces	0.07/0.05	0.61
2%	Sage	6/3	0.60
2%	Swine: Muscle/meat	0.15/0.12	0.58
2%	Equine: Muscle/meat	0.15/0.12	0.58
2%	Sheep: Muscle/meat	0.15/0.12	0.57
2%	Bovine: Edible offals (other	0.2/0.17	0.56
2%	Cranberries	0.8/0.46	0.52
2%	Chives	6/3	0.51
2%	Pistachios	0.3/0.19	0.51
2%	Limes	0.15/0.07	0.49
2%	Sheep: Liver	0.2/0.17	0.48
2%	Swine: Edible offals (other	0.2/0.17	0.44
2%	Eggs: Chicken	0.15/0.1	0.43
2%	Poultry: Liver	0.1/0.09	0.42
1%	Swine: Kidney	0.2/0.17	0.37
1%	Basil and edible flowers	6/3	0.37
1%	Bovine: Kidney	0.2/0.17	0.36
1%	Rosemary	6/3	0.30
1%	Rosemary	6/3	0.30
1%	Rosemary	6/3	0.30
1%	Tarragon	6/3	0.30
1%	Chestnuts	0.07/0.06	0.27
1%	Red mustards	0.07/0.05	0.27
1.0%	Chervil	6/3	0.24
1.0%	Swine: Liver	0.2/0.17	0.24
0.7%	Goat: Muscle	0.15/0.12	0.19
0.6%	Eggs: Quail	0.15/0.1	0.14
0.5%	Pecans	0.07/0.06	0.14
0.5%	Walnuts	0.07/0.06	0.13
0.5%	Macadamia	0.07/0.06	0.13
0.5%	Sheep: Edible offals (other	0.2/0.17	0.12
0.5%	Poultry: Kidney	0.1/0.09	0.12
0.4%	Oat	0.4/0.17	0.11
0.4%	Cashew nuts	0.07/0.06	0.10
0.4%	Swine: Other products	0.03/0.03	0.10
0.4%	Lamb's lettuce/corn salads	0.07/0.05	0.09
0.3%	Almonds	0.07/0.06	0.09
0.3%	Bovine: Other products	0.04/0.04	0.08
0.3%	Hazelnuts/cobnuts	0.07/0.06	0.07
0.2%	Swine: Fat tissue	0.05/0.03	0.06
0.2%	Pine nut kernels	0.07/0.06	0.06
0.2%	Roman rocket/rucola	0.07/0.05	0.06
0.2%	Eggs: Goose	0.15/0.1	0.05
0.2%	Brazil nuts	0.07/0.06	0.04
0.1%	Bovine: Fat tissue	0.05/0.03	0.03
0.08%	Cress and other sprouts and	0.07/0.05	0.02
0.07%	Sheep: Kidney	0.2/0.17	0.02
0.05%	Poultry: Fat tissue	0.05/0.04	0.01

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)	2

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
71%	Beans (with pods)/boiled	3/1.41	18
50%	Pumpkins/boiled	0.4/0.14	12
48%	Courgettes/boiled	0.5/0.34	12
41%	Potatoes/fried	0.2/0.11	10
31%	Gherkins/pickled	0.5/0.34	7.8
31%	Peaches/canned	0.4/0.3	7.8
30%	Turnips/boiled	0.3/0.15	7.6
30%	Parsnips/boiled	0.3/0.15	7.6
27%	Beetroots/boiled	0.3/0.15	6.7
26%	Kales/boiled	0.5/0.24	6.6
26%	Currants (red, black and whit	0.8/0.23	6.6
18%	Peas (without pods)/canned	5/0.55	4.4
17%	Wheat/milling (flour)	2/0.35	4.2
17%	Raspberries/juice	1/0.36	4.2
15%	Salsifies/boiled	0.3/0.15	3.9

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
61%	Beans (without pods)/boiled	5/2.94	15
37%	Peas (without pods)/boiled	5/2.94	9.2
31%	Courgettes/boiled	0.5/0.34	7.8
31%	Pumpkins/boiled	0.4/0.14	7.7
28%	Peas (with pods)/boiled	3/2.03	6.9
23%	Beetroots/boiled	0.3/0.15	5.8
13%	Parsnips/boiled	0.3/0.15	3.2
12%	Currants (red, black and	0.8/0.23	2.9
11%	Turnips/boiled	0.3/0.15	2.9
11%	Beans/canned	2/0.39	2.8
11%	Celeriacs/boiled	0.3/0.15	2.7
10%	Peaches/canned	0.4/0.3	2.5
8%	Apples/juice	0.3/0.06	2.0
6%	Elderberries/juice	0.7/0.17	1.6
6%	Wheat/bread/pizza	2/0.35	1.5

Conclusion:
The estimated short-term intake (IESTI) exceeded the toxicological reference value for 2 commodities.

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

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[a]	Comment	Input value (mg/kg)[a]	Comment
Risk assessment residue definition: Sum of flonicamid and TFNA-AM, expressed as flonicamid				
Barley (straw)	0.05	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Beet, sugar (tops)	0.09	STMR (EFSA, 2017)	0.20	HR (EFSA, 2017)
Cabbage, heads (leaves)	0.14	STMR (EFSA, 2017)	0.23	HR (EFSA, 2017)
Oat (straw)	0.05	STMR (EFSA, 2015)	0.07	HR (EFSA, 2015)
Kale (leaves)	**0.15**	**STMR**	**0.24**	**HR**
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 (EFSA, 2018c)	0.29	HR (EFSA, 2018c)
Wheat (straw)	0.18	STMR (EFSA, 2014)	0.48	HR (EFSA, 2014)
Carrot (culls)	0.05	STMR (EFSA, 2018c)	0.15	HR (EFSA, 2018c)
Potato (culls)	0.06	STMR (EFSA, 2020b)	0.11	HR (EFSA, 2020b)
Swede (roots)	0.05	STMR (EFSA, 2018c)	0.15	HR (EFSA, 2018c)
Turnip (roots)	0.05	STMR (EFSA, 2018c)	0.15	HR (EFSA, 2018c)
Barley (grain)	0.14	STMR (EFSA, 2015)	0.14	STMR (EFSA, 2015)
Bean (seed, dry)	0.39	STMR (EFSA, 2020b)	0.39	STMR (EFSA, 2020b)
Cotton (undelinted seed)	0.04	STMR (EFSA, 2015)	0.04	STMR (EFSA, 2015)
Lupin (seed)	0.39	STMR (EFSA, 2020b)	0.39	STMR (EFSA, 2020b)
Oat (grain)	0.14	STMR (EFSA, 2015)	0.14	STMR (EFSA, 2015)
Pea (seed, dry)	0.39	STMR (EFSA, 2020b)	0.39	STMR (EFSA, 2020b)
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	0.06 STMR × 5 PF[b] (EFSA, 2014)	0.30	0.06 STMR × 5 PF[b] (EFSA, 2014)
Beet, sugar (dried pulp)	1.62	0.09 STMR × 18 PF[b] (EFSA, 2017)	1.62	0.09 STMR × 18 PF[b] (EFSA, 2017)
Beet, sugar (ensiled pulp)	0.27	0.09 STMR × 3 PF[b] (EFSA, 2017)	0.27	0.09 STMR × 3 PF[b] (EFSA, 2017)
Beet, sugar (molasses)	2.52	0.09 STMR × 28 PF[b] (EFSA, 2017)	2.52	0.09 STMR × 28 PF[b] (EFSA, 2017)
Brewer's grain	0.46	0.14 STMR × 3.3 PF[b] (EFSA, 2014)	0.46	0.14 STMR × 3.3 PF[b] (EFSA, 2014)
Citrus (dried pulp)	0.40	0.04 STMR × 10 PF[b] (EFSA, 2014)	0.40	0.04 STMR × 10 PF[b] (EFSA, 2014)
Cotton (meal)	0.05	0.04 STMR × 1.3 PF[b] (EFSA, 2015)	0.05	0.04 STMR × 1.3 PF[b] (EFSA, 2015)
Distiller's grain (dried)	1.16	0.35 STMR × 3.3 PF[b] (EFSA, 2014)	1.16	0.35 STMR × 3.3 PF[b] (EFSA, 2014)
Lupin seed (meal)	0.43	0.39 STMR × 1.1 PF[b] (EFSA, 2020b)	0.43	0.39 STMR × 1.1 PF[b] (EFSA, 2020b)
Potato (process waste)	1.20	0.06 STMR × 20 PF[b] (EFSA, 2020b)	1.20	0.06 STMR × 20 PF[b] (EFSA, 2020b)
Potato (dried pulp)	2.28	0.06 STMR × 38 PF[b] (EFSA, 2020b)	2.28	0.06 STMR × 38 PF[b] (EFSA, 2020b)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)[a]	Comment	Input value (mg/kg)[a]	Comment
Wheat gluten (meal)	0.63	0.35 STMR × 1.8 PF[b] (EFSA, 2014)	0.63	0.35 STMR × 1.8 PF[b] (EFSA, 2014)
Wheat (milled by-product)	2.45	0.35 STMR × 7 PF[b] (EFSA, 2014)	2.45	0.35 STMR × 7 PF[b] (EFSA, 2014)

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

(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

(b): 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, 3.3, 10, 1.3, 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	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[a]	Comment[b]	Input value (mg/kg)[a]	Comment[b]
Risk assessment residue definition: sum of flonicamid, TFNG and TFNA, expressed as flonicamid						
Chinese cabbages/ pe-tsai	0.5	MRL proposal	0.15	STMR-RAC	0.24	HR-RAC
Kales	0.5	MRL proposal	0.15	STMR-RAC	0.24	HR-RAC
Kohlrabies	0.15	MRL proposal	0.05	STMR-RAC	0.06	HR-RAC
Citrus fruits	0.15	EFSA (2020a)	0.04	STMR-RAC (EFSA, 2014)	0.07	HR-RAC
Tree nuts (except pistachios and coconuts)	0.07	EFSA (2020b)[d]	0.03	STMR-RAC	0.06	HR-RAC
Pistachios	0.3	EFSA (2020b)[d]	0.03	STMR-RAC	0.19	HR-RAC
Pome fruits	0.3	EFSA (2014)	0.06	STMR-RAC	0.19	HR-RAC
Apricots	0.3	EFSA (2017)	0.10	STMR-RAC	0.13	HR-RAC
Cherries (sweet)	0.4	EFSA (2020a)	0.13	STMR-RAC	0.18	HR-RAC
Peaches	0.4	EFSA (2014)	0.08	STMR-RAC	0.3	HR-RAC
Plums	0.3	EFSA (2020a)	0.06	STMR-RAC	0.13	HR-RAC
Strawberries	0.7	EFSA (2019a,b)	0.14	STMR-RAC	0.45	HR-RAC
Blackberries, Raspberries (red and yellow)	1	EFSA (2018a)	0.36	STMR-RAC	0.48	HR-RAC
Blueberries, Cranberries, Currants (red, black and white), Gooseberries (green, red and yellow)	0.8	EFSA (2019a,b)	0.23	STMR-RAC	0.46	HR-RAC
Rose hips, Mulberries (black and white), Azarole/ Mediterranean medlar, Elderberries, Other small fruit & berries	0.7	EFSA (2018a)	0.17	STMR-RAC	0.37	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[a]	Comment[b]	Input value (mg/kg)[a]	Comment[b]
Potatoes	0.2	EFSA (2020b)[d]	0.06	STMR-RAC	0.11	HR-RAC
Other root and tuber vegetables (except sugar beet and radishes)	0.3	EFSA (2018b)	0.05	STMR-RAC	0.15	HR-RAC
Radishes	0.6	EFSA (2018a)	0.22	STMR-RAC	0.29	HR-RAC
Tomatoes	0.5	EFSA (2020a)	0.11	STMR-RAC	0.34	HR-RAC
Sweet peppers/bell peppers	0.3	EFSA (2015)	0.06	STMR-RAC	0.15	HR-RAC
Aubergines/egg plants	0.5	EFSA (2020a)	0.11	STMR-RAC	0.34	HR-RAC
Cucurbits with edible peel (except courgettes)	0.5	EFSA (2014)	0.15	STMR-RAC	0.34	HR-RAC
Courgettes	0.5	EFSA (2020a)	0.15	STMR-RAC	0.34	HR-RAC
Cucurbits with inedible peel	0.4	EFSA (2020a)	0.06	STMR-RAC[c]	0.14	HR-RAC[c]
Brussels sprouts	0.6	EFSA (2016b)	0.07	STMR-RAC	0.32	HR-RAC
Head cabbages	0.5	EFSA (2017)	0.14	STMR-RAC	0.23	HR-RAC
Lettuce and other salad plants including Brassicaceae	0.07	EFSA (2018a)	0.03	STMR-RAC	0.05	HR-RAC
Herbs and edible flowers (except basil and edible flowers)	6	EFSA (2016a)	0.71	STMR-RAC	3	HR-RAC
Basil and edible flowers	6	EFSA (2016a)	2.11	STMR-RAC (EFSA, 2020b)	3	HR-RAC
Beans (with pods)	3	EFSA (2020b)[d]	0.85	STMR-RAC	1.41	HR-RAC
Beans (without pods)	5	EFSA (2020b)[d]	0.55	STMR-RAC	2.94	HR-RAC
Peas (with pods)	3	EFSA (2020b)[d]	0.85	STMR-RAC	2.03	HR-RAC
Peas (without pods)	5	EFSA (2020b)[d]	0.55	STMR-RAC	2.94	HR-RAC
Beans, lentils, peas and lupins	2	EFSA (2020b)[d]	0.39	STMR-RAC	0.39	STMR-RAC
Other pulses	0.8	EFSA (2018a)	0.16	STMR-RAC	–	–
Cotton seeds	0.2	EFSA (2015)	0.04	STMR-RAC	0.04	STMR-RAC
Barley	0.4	EFSA (2015)	0.17	STMR-RAC	0.17	STMR-RAC
Oat	0.4	EFSA (2015)	0.17	STMR-RAC	0.17	STMR-RAC
Rye	2	EFSA (2020a)	0.35	STMR-RAC (EFSA, 2014)	0.35	STMR-RAC
Wheat	2	EFSA (2020a)	0.35	STMR-RAC (EFSA, 2014)	0.35	STMR-RAC
HOPS (dried)	20	EFSA (2020b)[d]	2.52	STMR-RAC	10.13	HR-RAC
Sugar beet roots	0.03	EFSA (2017)	0.03	STMR-RAC	0.03	HR-RAC
Risk assessment residue definition: sum of flonicamid and TFNA-AM, expressed as flonicamid						
Muscle/meat (mammals)	0.15	FAO (2016b)	0.06	STMR-RAC	0.12	HR-RAC
Fat tissue (mammals)	0.05	FAO (2016b)	0.02	STMR-RAC	0.03	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)[a]	Comment[b]	Input value (mg/kg)[a]	Comment[b]
Liver (mammals)	0.2	FAO (2016b)	0.1	STMR-RAC	0.17	HR-RAC
Kidney (mammals)	0.2	FAO (2016b)	0.1	STMR-RAC	0.17	HR-RAC
Edible offals, other than liver and kidney (mammals)	0.2	FAO (2016b)	0.1	STMR-RAC	0.17	HR-RAC
Other products (swine)	0.03	EFSA (2014)	0.03	MRL	0.03	MRL
Other products (mammals except swine)	0.04	EFSA (2014)	0.04	MRL	0.04	MRL
Muscle/meat (poultry)	0.1	FAO (2016b)	0.04	STMR-RAC	0.08	HR-RAC
Fat tissue (poultry)	0.05	FAO (2016b)	0.04	STMR-RAC	0.04	HR-RAC
Liver (poultry)	0.1	FAO (2016b)	0.04	STMR-RAC	0.09	HR-RAC
Kidney (poultry)	0.1	FAO (2016b)	0.04	STMR-RAC	0.09	HR-RAC
Edible offals, other than liver and kidney (poultry)	0.1	FAO (2016b)	0.04	STMR-RAC	0.09	HR-RAC
Other products (poultry)	0.03	EFSA (2014)	0.03	MRL	–	–
Milk	0.15	FAO (2016b)	0.05	STMR-RAC	0.05	STMR-RAC
Eggs	0.15	FAO (2016b)	0.08	STMR-RAC (EFSA, 2017)	0.1	HR-RAC (EFSA, 2017)

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

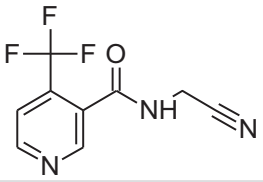
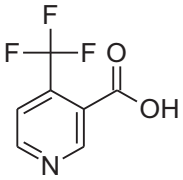
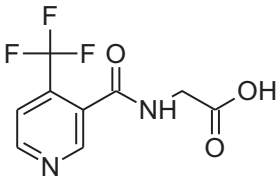
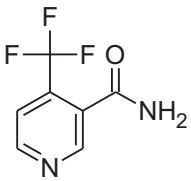
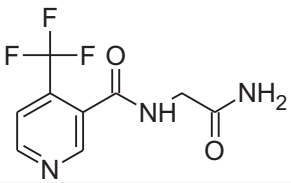
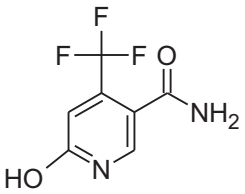
(a): Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

(c): For cucurbits with inedible peel, STMR and HR values were derived based on residues measured in melon pulp (EFSA, 2020a).

(d): MRLs not yet implemented by Regulation.

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChiKey[a]	Structural formula[b]
flonicamid	*N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide O=C(NCC#N)c1cnccc1C(F)(F)F RLQJEEJISHYWON-UHFFFAOYSA-N	
TFNA	4-(trifluoromethyl)nicotinic acid or 4-(trifluoromethyl)pyridine-3-carboxylic acid OC(=O)c1cnccc1C(F)(F)F LMRJHNFECNKDKH-UHFFFAOYSA-N	
TFNG	*N*-[4-(trifluoromethyl)nicotinoyl]glycine or *N*-[4-(trifluoromethyl)pyridine-3-carbonyl]glycine O=C(NCC(=O)O)c1cnccc1C(F)(F)F AXMBYGGSBXWTEY-UHFFFAOYSA-N	
TFNA-AM	4-(trifluoromethyl)pyridine-3-carboxamide or 4-(trifluoromethyl)nicotinamide O=C(N)c1cnccc1C(F)(F)F JUIWZYBJXUPIKF-UHFFFAOYSA-N	
TFNG-AM	*N*-(2-amino-2-oxoethyl)-4-(trifluoromethyl)pyridine-3-carboxamide O=C(NCC(N)=O)c1cnccc1C(F)(F)F FZAQQBPOTJCLJM-UHFFFAOYSA-N	
OH-TFNA-AM	6-oxo-4-(trifluoromethyl)-1,6-dihydropyridine-3-carboxamide or 6-hydroxy-4-(trifluoromethyl)nicotinamide FC(F)(F)c1cc(O)ncc1C(N)=O JZASIHOQMPWGMF-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).
(b): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).