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REASONED OPINION

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

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ISK Biosciences Europe N.V. submitted two requests to the competent national authority in Finland and Belgium, respectively, to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in potatoes and in various crops. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for potatoes, lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs. Adequate analytical methods for enforcement are available to control the residues according to the residue definition as of the sum of flonicamid, TFNA and TFNG, expressed as flonicamid in the plant matrices under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg for each compound. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the uses of flonicamid according to the reported agricultural practices is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, Flonicamid, MRL, pesticide, potatoes, various crops

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, ISK Biosciences Europe N.V. submitted two applications to the competent national authority in Finland and Belgium (evaluating Member States, EMSs) respectively, to modify the existing maximum residue levels (MRLs) for the active substance flonicamid in potatoes and in lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs.

The first application for an MRL in potatoes, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 26 July 2022. The appointed EMS Finland assessed the dossier and declared its admissibility on 31 October 2022. The second application for MRLs in various crops, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 24 August 2022 and the appointed EMS Belgium declared its admissibility on 13 December 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential versions of the dossiers were published by EFSA, and a public consultation launched on each dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies, and other information part of, or supporting, the submitted application, to identify whether other relevant scientific data or studies are available. The two consultations run from 5 May 2023 to 26 May 2023. No additional data nor comments were submitted in the framework of these consultations.

At the end of the commenting period, each EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005. Both evaluation reports were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2023. To accommodate for the intended uses of flonicamid, the EMS Finland proposed to raise the existing MRLs for potatoes from 0.09 to 0.2 mg/kg; The EMS Belgium proposed to raise the existing MRLs as follows: from 0.07 to 0.6 mg/kg for lettuces and salad plants, from the limit of quantification (LOQ) of 0.03 to 0.6 mg/kg for spinaches and similar leaves, to 0.7 mg/kg for beans (without pods) and to 0.3 mg/kg for cardoons, celeries, Florence fennels and rhubarbs.

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification for both applications and requested the EMSs to address them. The applicant provided the requested information for each application in an updated IUCLID dossier. The additional information was then duly considered by the EMSs Belgium and Finland who submitted a revised evaluation report to EFSA on 1 September 2023 and 28 September 2023, respectively. These updated reports replaced the previously submitted evaluation reports.

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 each EMS in the framework of the two applications, the following conclusions are derived.

The metabolism of flonicamid following foliar spray applications was investigated in crops belonging to the groups of fruit crops (peaches, peppers), root crops (potatoes) and cereals/grass (wheat) has been investigated in the framework of the EU pesticides peer review and the MRL review. In the crops tested, the parent compound and the two metabolites 4-(trifluoromethyl)pyridine-3-carboxylic acid (TFNA) and N-[4-(trifluoromethyl)pyridine-3-carbonyl]glycine (TFNG), were found to be the main residues.

The crops under consideration in these applications may be grown in rotation. However, during the EU pesticides peer review it was concluded that the trigger value of 100 days was not exceeded because flonicamid and its metabolites TFNA and TFNG have short DT_{90} soil degradation values ranging from 1.5 to 8.7 days. Therefore, 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, TFNA and TFNG are stable under standard hydrolysis conditions. 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.

Based on the metabolic pattern identified in metabolism studies, the results of the hydrolysis studies, the toxicological relevance of metabolites and the capabilities of the enforcement analytical methods, the residue definitions for plant products were proposed as 'sum of flonicamid, TFNA and TFNG expressed as flonicamid' for both enforcement and risk assessment. These previously derived residue definitions are applicable to primary crops and processed commodities.

Sufficiently validated analytical methods based on high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) detection are available to quantify residues in the commodities assessed in these applications according to the enforcement residue definition. The methods enable quantification of residues at or above the individual LOQ of 0.01 mg/kg for each compound included in the residue definitions (combined LOQ of 0.03 mg/kg) in the crops assessed. Validation data of the QuEChERS method (BPL19-0032) proposed for enforcement purposes and its extraction efficiency in high-water content matrices were also provided in the context of these applications, whereby an independent laboratory validation (ILV) for high-acid commodities was not provided and would be required for rhubarb. Considering that a complete data package was not provided within the current applications, the suitability for enforcement of the Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) (QuEChERS) method should be further considered in the framework of the active substance renewal assessment.

As one of the crops under consideration, potatoes, and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. However, the intended uses on potatoes have no impact on the livestock dietary burdens obtained in a previous EFSA opinion, because those supervised trials median residue (STMR) and highest

residue (HR) values are still considered valid. Furthermore, the current EU MRLs for animal commodities are based on Codex MRLs (CXLs) derived from significantly higher livestock exposure calculations. Therefore, a modification of the existing EU MRLs for commodities of animal origin is considered unnecessary.

The available residue trials are sufficient to derive MRL proposals of 0.2 mg/kg for potatoes, of 0.6 mg/kg for lettuces and salad plants and for spinaches and similar leaves, of 0.7 mg/kg for beans (without pods) and of 0.3 mg/kg for cardoons, celeries, Florence fennels and rhubarbs. It shall be noted that in a previous assessment on flonicamid EFSA has already proposed an MRL of 0.2 mg/kg for potatoes and an MRL of 5 mg/kg for beans without pods. These MRL proposals are not yet implemented in the EU MRL legislation.

Processing factors (PF) for the crops under assessment were derived from processing studies provided and can be considered for inclusion in Annex VI of Regulation (EC) No 396/2005 as follows:

– Potato/wet peels:	0.38	– Potato/peeled potato:	1.46
– Potato /cooked potato:	1.37	– Potato/microwaved potato:	0.98
– Potato, French fries:	1.91	– Potato/crisps:	1.57
– Potato flakes:	2.98	–	–

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) and an acute reference dose (ARfD) of 0.025 mg/kg body weight (bw) (per day). 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 acute reference dose (ARfD); the highest acute exposure results among the commodities under assessment was calculated for beans without pods (based on the HR value derived for a higher MRL proposal of 5 mg/kg) with 92.8% ARfD, followed by potatoes (67.7%), escaroles/broad-leaved endives (54.6%) and lettuces (51.8%)). For the remaining crops, the exposure was less than 40%. No acute risk assessment for children or adults could be performed for land cress, baby leaf crops because no specific consumption data were available in the EFSA PRIMo rev. 3.1. However, EFSA assumes that these crops are covered by the risk assessment of other leafy crops like lettuces and escaroles, for which the same MRL proposal was derived and which are likely to be consumed in higher amounts. It is also noted that for certain commodities (pears and peaches) not included in the present assessment, an exceedance of the ARfD due to differences in the applied PRIMo versions was observed. Refinement options for the acute intake calculations could not be identified based on the available data and may be further investigated in future assessments.

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 applications, except for beans without pods. In this commodity, the median residue value derived for a higher MRL proposal in a previous EFSA opinion was used in the calculation. 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 1.28% of acceptable daily intake (ADI) for potatoes.

EFSA concluded that the proposed uses of flonicamid on potatoes (SEU uses), on the group of lettuces and salad plants (indoor use), on the group of spinaches and similar leaves (indoor use), on beans (without pods), cardoons, celeries, Florence fennels and rhubarbs will not result in a consumer exposure exceeding the toxicological reference values and are therefore 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 end points and the consumer risk assessment can be found in Appendices B–D.

Code[a]	Commodity	Existing/ Proposed EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Plant commodities **Enforcement residue definition:** Sum of flonicamid, TFNA and TFNG expressed as flonicamid				
0211000	Potatoes	0.09/0.2[b]	0.2	The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg for the SEU (8 trials) based on the intended critical outdoor SEU use with treatment at BBCH 51. The intended SEU use with treatment at BBCH 15 is also supported by residue data NEU uses at BBCH 15 and 51 are insufficiently supported by data (seven valid trials only) It is noted that an MRL proposal at the same level of 0.2 mg/kg was derived in a previous EFSA assessment. However, the MRL proposal has not yet been implemented in the MRL legislation Risk for consumers unlikely

Code[a]	Commodity	Existing/ Proposed EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0251010	Lamb's lettuce/corn lettuce	0.07	0.6	See lettuces (0251020)
0251020	Lettuces	0.07	0.6	The submitted data are sufficient to derive an MRL proposals for the intended indoor EU use (dip-treatment pre-transplanting at BBCH 11–16) whereas the intended NEU use is insufficiently supported by data (seven valid trials only) Extrapolation from indoor trials on lettuces to the whole group of lettuce and other salad plants (0251000) is possible. Risk for consumers unlikely
0251030	Escaroles/broad-leaved endives	0.07	0.6	See lettuces (0251020)
0251040	Cress and other sprouts and shoots	0.07	0.6	See lettuces (0251020)
0251050	Land cress	0.07	0.6	See lettuces (0251020)
0251060	Roman rocket/rucola	0.07	0.6	See lettuces (0251020)
0251070	Red mustards	0.07	0.6	See lettuces (0251020)
0251080	Baby leaf crops (including brassica)	0.07	0.6	See lettuces (0251020)
0251990	Other lettuce and other salad plants	0.07	0.6	See lettuces (0251020)
0252010	Spinaches	0.03*	0.6	See lettuces (0251010) Extrapolation of results from residue trials on lettuces to spinaches and similar leaves (0252000) is possible. Risk for consumers unlikely
0252020	Purslanes	0.03*	0.6	See spinaches (0252010)
0252030	Chards/beet leaves	0.03*	0.6	See spinaches (0252010)
0252990	Other spinach and similar	0.03*	0.6	See spinaches (0252010)
0260020	Beans (without pods)	0.03*/5[b]	0.7 or 5 Further risk management discussions recommended	The submitted data are sufficient to derive an MRL proposal for the intended NEU use of 0.7 mg/kg by extrapolation from seven GAP compliant residue trials on peas without pods It is noted that a higher MRL proposal of 5 mg/kg was derived in a previous EFSA assessment. However, the MRL proposal has not yet been implemented in the MRL legislation For both MRL proposals, a risk for consumers is unlikely. Further risk management discussion is required
0270020	Cardoons	0.03*	0.3	See celeries (0270030)
0270030	Celeries	0.03*	0.3	The submitted data on celeries are sufficient to derive a MRL proposal for the intended NEU use Extrapolation of results from residue trials on celeries to cardoons, Florence fennels and rhubarbs possible. Risk for consumers unlikely
0270040	Florence fennels	0.03*	0.3	See celeries (0270030)
0270070	Rhubarbs	0.03*	0.3	See celeries (0270030)

Abbreviations: BBCH, growth stages of mono- and dicotyledonous plants; GAP, Good Agricultural Practice; MRL, maximum residue level; NEU, northern Europe; SEU, southern Europe.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]MRL proposal based on an import tolerance request (US GAP) assessed by EFSA in the reasoned opinion on the setting of import tolerances for flonicamid in various crops and products of animal origin (EFSA Journal 2020;18(6):61369), not yet implemented into the MRL legislation.

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

ASSESSMENT

The European Food Safety Authority (EFSA) received two applications to modify the existing maximum residue levels (MRLs) for flonicamid respectively in potatoes and in various crops (lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs). The detailed description of the intended uses of flonicamid, which are the basis for the current MRL applications, 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); the representative uses assessed were foliar spray applications on potato, wheat, apple and pear in northern and southern EU and on peach in southern EU. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2010a). 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.

In accordance Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381,[5] the applicant ISK Biosciences Europe N.V. submitted two applications to the competent national authority in Finland and Belgium (EMSs) respectively, to modify the existing MRLs for the active substance flonicamid in potatoes and in lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs.

The first application for an MRL in potatoes, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 26 July 2022. The appointed EMS Finland assessed the dossier and declared its admissibility on 31 October 2022. The second application for MRLs in various crops, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 24 August 2022 and the appointed EMS Belgium declared its admissibility on 13 December 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential versions of the dossiers were published by EFSA, and a public consultation launched on each dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, to identify whether other relevant scientific data or studies are available. The two consultations run from 5 May 2023 to 26 May 2023. No additional data nor comments were submitted in the framework of these consultations.

At the end of the commenting period, each EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005. Both evaluation reports were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 1 June 2023.

EFSA assessed the applications and evaluation reports as required by Article 10 of the MRL regulation. For efficiency, the assessment was merged in a single reasoned opinion.

EFSA identified data gaps and points which needed further clarification for both applications and requested the EMSs to address them. The applicant provided the requested information for each application in an updated IUCLID dossier. The additional information was then duly considered by the EMSs Belgium and Finland who submitted a revised evaluation report to EFSA on 1 September 2023 and 28 September 2023, respectively. These updated reports replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation report submitted by each EMS (Belgium, 2023; Finland, 2023), the draft assessment report (DAR) and its addendum (France, 2005, 2009) prepared under 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, 2010a), as well as the conclusions from previous EFSA opinions on flonicamid (EFSA, 2010b, 2015, 2016a, 2017, 2018b, 2018c, 2018d, 2019b, 2020b, 2023), including the MRL review (EFSA, 2014) and the subsequent evaluation of the confirmatory data on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2020a). It is further noted that the proposals derived by EFSA in 2020 in the framework of an import tolerance application, included an MRL proposal for imported potatoes of 0.2 mg/kg and for imported beans without pods of 5 mg/kg (EFSA, 2020b). However, these proposals together with the MRL proposals derived in the recent EFSA opinion from 2023 (EFSA, 2023) are not yet implemented in EU Regulations.

[1]It should be noted that name flonicamid and its metabolites TFNA, TFNG, TFNA-AM, OH-TFNA-AM are identified as a pesticide active substance/metabolites that meet the definition of per- and polyfluoroalkyl substances (PFAS) based on its chemical structure (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, p. 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, p. 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, p. 1–16.

[5]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

For the current applications, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of each IUCLID MRL application are applicable (European Commission, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 1997a–1997g, 2000, 2010b, 2010c, 2020, 2021, 2022; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[7]

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

The evaluation reports submitted by the EMSs (Belgium, 2023; Finland, 2023) 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.[8]

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 (peaches, peppers), root crops (potatoes) and cereals/grass (wheat) following foliar application has been investigated in the framework of the EU pesticides peer review and the MRL review. In the crops tested, the parent compound and the two metabolites 4-(trifluoromethyl) pyridine-3-carboxylic acid (TFNA) and N-[4-(trifluoromethyl)pyridine-3-carbonyl]glycine (TFNG) were found to be the main residues (EFSA, 2010a, 2014).

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

1.1.2 | Nature of residues in rotational crops

Flonicamid is proposed to be used on crops that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the EU pesticides peer review, the DT_{90} value of flonicamid and its relevant metabolites, TFNA and TFNG, ranged from 1.5 to 8.7 days (EFSA, 2010a). The trigger value of 100 days was by far not exceeded for the parent and its two metabolites and therefore no studies investigating the nature of residues in rotational crops are required (European Commission, 1997c).

1.1.3 | Nature of residues in processed commodities

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

1.1.4 | Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of residues of flonicamid and its metabolites TFNG and TFNA in plant commodities were assessed during the EU pesticides peer review, the MRL review and, for hops, in the MRL review confirmatory data assessment (EFSA, 2010a, 2014).

Sufficiently validated analytical methods are available for the monitoring of residues of flonicamid and its metabolites TFNG and TFNA based on HPLC–MS/MS. The methods allow quantifying residues for each analyte included in the residue definition for enforcement 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, 2010a, 2014).

In the two MRL applications, a multiresidue QuEChERS HPLC–MS/MS analytical method is proposed for official control purposes for high-water, high-oil and high-acid content and dry commodities (Belgium, 2023) and for potato tubers, representative matrix of high-water content commodity (Finland, 2023). It is noted that this method has not been previously

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

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

[8]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-2023-00777 and https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00865.

evaluated by EFSA. Nonetheless, a summary of its validation data was provided, which is considered relevant for this assessment for high-water (potatoes, beans without pods, lettuces and salad plants, spinaches and similar leaves, celeries, Florence fennels) and high-acid (rhubarb) commodities (European Commission, 2022). However, since the EMS informed that a data package for validation of this method is also provided in the renewal assessment report, EFSA would recommend to further consider it in the broader framework of the active substance renewal assessment.

Validation data for the QuEChERS method (coded BPL19-0032) for flonicamid, TFNA and TFNG at the individual LOQ of 0.01 mg/kg are provided for the primary method in wheat grain and straw (dry commodities), in lettuce, sugar beet root (high-water content matrices), in rapeseeds (high-oil content matrix) and oranges whole fruits (high-acid content matrix). For all commodities tested two mass transitions were monitored except for metabolite TFNA in wheat grain, wheat straw, oil seed rape and lettuce where the same mass transition was monitored for quantification and confirmation. A confirmatory method was not provided however two different HPLC stationary phases were applied for lettuce for the purpose of confirmation (Belgium, 2023). An ILV was provided for wheat grain and lettuce for the parent and the metabolites TFNA and TFNG which monitored two different mass transitions for quantification and confirmation with exception of metabolite TFNA in wheat grain where the same mass transition was monitored however a different column was used (Belgium, 2023).

For high-acid commodities which is also relevant for this assessment (rhubarb), an ILV is not provided (Belgium, 2023; Finland, 2023).

Efficiency of the extraction procedures using methanol for the quantification of residues in high-water content commodities (method described in report n. A-22-00-02 and A-22-06-09) was demonstrated using incurred residues in lettuces (representative for high-water content commodities) 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) in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2022) in a previous EFSA opinion (EFSA, 2023).

The efficiency of the multiresidue method (BPL19-0032) based on QuEChERS extraction was assessed in the context of the current MRL applications (Belgium, 2023; Finland, 2023). The study was considered to sufficiently demonstrate efficiency of the extraction procedures using the solvent system used in the QuEChERS method (BPL19-0032) (extraction agent: 8 mL water and 10 mL acetonitrile with 1% formic acid (water/acetonitrile/formic acid (8:9.9:0.1, mL/mL/mL) which was calculated to: acetonitrile/water/formic acid (55/44.4/0.6, v/v/v) for the quantification of residues in high-water content commodities 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)), in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2022). The extracted amounts of flonicamid, TFNG and TFNA from lettuce samples with incurred residues of flonicamid using the two above solvent systems were comparable.

In the metabolism study on potatoes assessed in the EU pesticides peer review, potato tuber residues were extracted with acetonitrile (acetonitrile/water, 80/20) and two times with acetonitrile/water (50/50), whereas potato foliage residues were extracted with acetonitrile/water/acetic acid (60/40/0.1 v/v/v) which is the same extraction system used in the liquid chromatography–tandem mass spectrometry detector (LC–MS/MS) method (AGR/MOA/IKI220-1). As to whether the extraction procedure used for potato foliage can be extrapolated to potato tuber and sufficiently support extraction efficiency of the LC–MS/MS method (AGR/MOA/IKI220-1) as being in accordance with the EU Technical Guideline SANTE 2017/10632 on extraction efficiency (European Commission, 2022), should be further considered in the broader framework of the renewal assessment where a whole data package was reported to have been submitted.

With regards to high-acid commodities to which rhubarb included in this application belongs, a metabolism study covering this commodity group is not available and therefore for this specific commodity extraction efficiency could not be demonstrated by *cross*-validation according to the current guidance (European Commission, 2022). EMS proposed to address the gap by bridging between high-water content and 'slightly acidic matrices' as foreseen in the guidance (Belgium, 2023). Noting that rhubarb cannot be comfortably attributed to slight acid commodities considering its high acidity with a pH of around 3 and that a metabolism study on high-acid commodities or residue trials on rhubarb with incurred residues are not available, further considerations on a potential extrapolation is referred to the broader framework of the renewal assessment of the active substance.

EFSA concludes that sufficiently validated analytical methods for the enforcement of flonicamid residues in the crops under consideration in the present MRL application which belong to high-water content commodities (potatoes, lettuces and salad plants, spinaches and similar leaves, beans without pods, celeries, cardoons, Florence fennels) and high-acid (rhubarb) content commodities are available. Details on the analytical methods available are presented in Appendix B.1.1.1.

EFSA also recommends further considering the validation data in plant matrices of the QuEChERS method proposed for enforcement and its extraction efficiency in the framework of the peer review for the renewal of approval of the active substance, where a comprehensive data package was reported to have been provided (Belgium, 2023; Finland, 2023). Therefore, the conclusions from this assessment may need to be reviewed based on the outcome of the renewal assessment.

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, 2010a, 2015, 2018c, 2020b).

Storage stability of flonicamid and its metabolites TFNG and TFNA was demonstrated for a period of up to 23 months at −18°C in commodities with high-water content (apples, spinaches, tomatoes and potatoes) and for up to 6 months when stored at −18°C in high acid commodities (oranges).

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, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- Residue definition for risk assessment: sum of flonicamid, TFNA and TFNG expressed as flonicamid (EFSA, 2014).
- Residue definition for enforcement: sum of flonicamid, TFNA and TFNG expressed as flonicamid (EFSA, 2014).

The same residue definitions are applicable to processed products. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

For the proposed uses assessed in this application, EFSA concludes that these residue definitions are appropriate, and a modification is not required.

1.2 | Magnitude of residues in plants

1.2.1 | Magnitude of residues in primary crops

In support of these MRL applications, the applicant submitted residue trials performed in potatoes, lettuces, peas (without pods) and celeries. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Belgium, 2023; Finland, 2023). The samples were analysed for the parent compound and the two metabolites included in the residue definitions for enforcement and risk assessment. According to the assessments of the EMSs, the analytical methods used to analyse residues in the commodity samples were sufficiently validated and fit for purpose (Belgium, 2023; Finland, 2023).

To analyse the magnitude of residues in lettuces (studies 4 and 5) and for celeries (studies 1 and 2), the QuEChERS analytical method (BPL19-0032) based on LC–MS/MS was used. Extraction efficiency of the solvent system used in this analytical method BPL19-0032 (acetonitrile/water/formic acid (55/44.4/0.6, v/v/v) was proven via *cross*-validation in high-water content commodities (see Section 1.1.4.).

The residue trials on lettuces (studies 1–3) and peas without pods were analysed with the LC–MS/MS method (AGR/MOA/IKI220-1) which was validated for representative high-water content commodities in the study ISK/IKI/06001 (Belgium, 2023). The latter uses acetonitrile/water/acetic acid (60/40/0.1, v/v/v) for which extraction efficiency was not considered as proven in the provided cross-validation study previously assessed by EFSA (EFSA, 2023). It is however to be noted that in the metabolism study for potato foliage the same extraction solvent was used (see Section 1.1.4).

The HPLC-MS/MS analytical method used to determine the magnitude of residues in potatoes used acetonitrile/water/formic acid (55/44.4/0.6, v/v/v), for extraction of the samples (Finland, 2023). EFSA notes that equivalency of the extraction procedure used in this method and the extraction procedures performed in potato tubers in the metabolism studies should be further considered in the framework of the peer review for the renewal of approval of the active substance, where a comprehensive data package was reported to have been provided (Belgium, 2023; Finland, 2023). Therefore, the conclusions in this assessment may need to be reviewed based on the outcome of the renewal assessment.

Potatoes

Potatoes treated at BBCH 15

NEU outdoor GAP (foliar treatment): 1 × 80 g a.s./ha, BBCH 15, PHI n.a. (not applicable).

In support of the intended NEU outdoor foliar GAP (1 foliar application ×80 g a.s./ha, with latest application at BBCH 15), eight GAP compliant residue trials were submitted and performed on potatoes during the 2021 growing season in Austria, Germany, Northern France (two trials), the United Kingdom (UK), the Netherlands and Poland (two trials). The trials selected to support the intended NEU use were performed with an oil-based adjuvant mixed in the final formulation as foreseen in the intended GAP. Potatoes were harvest for analysis at maturity.

No residues were reported in untreated samples with exception of one residue trial (number NL06) where a mean residue of 0.041 mg/kg (as sum of flonicamid, TFNA and TFNG, expressed as flonicamid) was reported. Residues were also

quantified in untreated samples of the trial performed without the adjuvant. This trial was overdosed with twice the intended application rate. The EMS clarified that the source of contamination of trial NL06 is unknown. However, the study was overall well performed and well reported. In addition, the results of the trial NL06 were within the same range of magnitude as the results from the other trials of the study report. Therefore, the EMS did not reject the results from trial NL06 (Finland, 2023). EFSA considered this justification as not substantial enough to conclude this trial is valid. Since the intended NEU use is supported by seven GAP-complaint valid residue trials only, the number of trials is not enough to derive an MRL proposal.

SEU outdoor GAP (foliar treatment): 1 × 80 g a.s./ha, BBCH 15, PHI n.a.

In support of the intended SEU outdoor foliar GAP (1 foliar application ×80 g a.s./ha, with latest application at BBCH 15), eight GAP compliant residue trials were submitted and performed on potatoes during the 2021 growing season in Greece, Italy (two trials), Portugal, Southern France (two trials), Spain (two trials) (Finland, 2023). The trials selected to support the intended SEU use were performed with an oil-based adjuvant mixed in the final formulation as foreseen in the intended GAP. All eight trials were considered independent and of sufficient quality in support of the intended SEU GAP on potatoes.

EFSA concludes that the available trials are sufficient to derive an MRL proposal of 0.15 mg/kg for the intended SEU outdoor use. For an overview of the provided residue trials see Appendix B.1.2.1.

Potatoes treated at BBCH 51

NEU outdoor cGAP (foliar treatment): 1 × 80 g a.s./ha, BBCH 51, PHI n.a.

In support of the intended NEU outdoor foliar GAP (1 foliar application ×80 g a.s./ha, with latest application at BBCH 51), eight GAP compliant residue trials were submitted and performed on potatoes during the 2021 growing season in Austria, Germany, Northern France (two trials), UK, the Netherlands and Poland (two trials). The trials selected to support the NEU use were performed without adjuvant. Potatoes were harvest for analysis at maturity. No residues were reported in untreated samples with exception of one residue trial where a median residue of 0.041 mg/kg (as sum of flonicamid, TFNA and TFNG, expressed as flonicamid) was reported. This trial was overdosed with twice the application rate. The EMS clarified that the source of contamination of trial NL06 is unknown. However, the study was overall well performed and well reported. In addition, the results of the trial NL06 were within the same range of magnitude than the results from the other trials of the study report. Therefore, the EMS did not reject the results from trial NL06 (Finland, 2023). EFSA considered this justification as not substantial enough to maintain this trial. Since for the NEU use seven GAP-complaint valid residue trials only are available, the number of trials is not enough to derive an MRL proposal.

SEU outdoor cGAP (foliar treatment): 1 × 80 g a.s./ha, BBCH 51, PHI n.a.

In support of the intended SEU outdoor foliar GAP (1 foliar application ×80 g a.s./ha, with latest application at BBCH 51), eight GAP compliant residue trials were submitted and performed on potatoes during the 2021 growing season in Greece, Italy (two trials), Portugal, Southern France (two trials), Spain (two trials). The trials selected to support the intended SEU use were performed without adjuvant. Potatoes were harvest for analysis at maturity. For both trials in Southern France a higher residue level was reported at an earlier BBCH growth stage and these trials were selected as worse cases (Finland, 2023). All eight trials were considered independent and of sufficient quality to support the intended GAP. EFSA concludes that the available trials are sufficient to derive an MRL proposal of 0.2 mg/kg for the critical intended SEU use. For an overview of the provided residue trials see Appendix B.1.2.1.

Lettuces and salad plants, spinaches and similar leaves

NEU outdoor GAP (dip and drenching): 1 × 1 mg a.s./plant, BBCH 11–16 pre-transplant, PHI 49 days.

In support of the intended NEU outdoor GAP, eight trials (including four decline trials) were submitted. Trials were performed on lettuce during the 2019 growing season in Germany (two trials), Northern France, Poland, UK (two trials) and in The Netherlands (two trials) (Belgium, 2023). In untreated control samples, residues of the parent and of the metabolites TFNA and TFNG were below the LOQ, except in one control sample, where at a PHI of 49 days residues of TFNA and TFNG slightly exceeded the LOQ (TFNA: 0.02–0.03 mg/kg; TFNG: 0.01 mg/kg). EFSA disregarded this trial because of the positive result of the control sample, although the EMS considered the deficiency of the trial of minor relevance, since in the treated sample, residues for each analyte included in the residue definitions were below LOQ of 0.01 mg/kg at the PHI of 49 days (Finland, 2023). Consequently, for the NEU EFSA concluded that only seven valid GAP-complaint residue trials only are available and therefore an MRL proposal could not be derived. For an overview of the provided residue trials see Appendix B.1.2.1.

EFSA concludes that the available trials are insufficient to derive an MRL proposal on lettuce for the intended NEU use.

EU indoor GAP (dip and drenching): 1 mg a.s./plant, BBCH 11–16 pre-transplant, PHI 49 days.

In support of the intended EU indoor GAP, nine trials (including seven decline trials) were submitted and performed on lettuces (four trials on open leaf and five on head forming varieties) under greenhouse conditions during the 2012 (in Italy, two trials),

2013 (in Southern France, one trial), 2014 (in Italy, two trials) and 2019 (in Germany, Northern France, UK and The Netherlands, one trial in each country) growing seasons (Belgium, 2023). For an overview of the provided residue trials see Appendix B.1.2.1.

EFSA concluded that the available trials are sufficient to derive an MRL proposal of 0.6 mg/kg on lettuce for the intended EU indoor use.

The MRL proposal of 0.6 mg/kg can be extrapolated to the whole group of lettuces and salad plants and as well to spinaches and similar leaves.[9]

Beans without pods

NEU outdoor GAP (foliar treatment): 1 × 70 g a.s./ha, BBCH 11–75, PHI 14 days.

In support of the intended NEU outdoor GAP on beans without pods, eight trials on peas without pods were submitted. Trials were performed on peas without pods during the years 2007 (two trials performed in Northern France), 2008 (four trials performed in Northern France), 2010 (two trials performed in Belgium) growing seasons (Belgium, 2023). Six of the eight trials performed in Northern France were assessed by EFSA previously (EFSA, 2010b) and considered later with additional two trials to derive an MRL proposal of 0.7 mg/kg for peas without pods (EFSA, 2015). For an overview of the provided residue trials see Appendix B.1.2.1.

It is to be noted that two trials performed during the 2007 growing season are in locations approximately 20 km apart so they can be considered as independent in accordance with the guidelines SANTE/2019/12752 (European Commission, 2020).

Two other trials performed during the 2008 growing season are performed at trial locations in two different villages which are less than 10 km apart. The application date of these two trials was also only 6 days apart, however the residues were significantly different (0.17 vs. 0.37 mg/kg) and the EMS considered these two trials as valid. EFSA notes that their independency could be questioned. Therefore, noting that beans without pods are classified as minor crops (European Commission, 2020) in the EU, seven residue trials deem sufficient for extrapolation and the two trials in question were considered as duplicates. The highest residue of 0.37 mg/kg was selected.

EFSA concludes that the available trials are sufficient to derive an MRL proposal of 0.7 mg/kg on beans without pods for the intended NEU outdoor use.

Celeries, cardoons, Florence fennel, rhubarbs

NEU outdoor GAP (foliar treatment): 1 × 70 g a.s./ha, BBCH 11–49, PHI 21 days.

In support of the intended NEU outdoor GAP on celeries, cardoon, Florence fennel and rhubarbs, seven residue trials (representing decline trials) were submitted which were performed on celeries during the 2019 (one trial performed in Germany and two trials performed in the United Kingdom) and 2020 (two trials performed in Germany and two trials in Belgium) growing seasons (Belgium, 2023). An extrapolation to cardoons, Florence fennel and rhubarbs is possible (European Commission, 2020). For an overview of the provided residue trials see Appendix B.1.2.1.

EFSA concludes that the available trials are sufficient to derive an MRL proposal of 0.3 mg/kg on celeries, cardoons, Florence fennels and rhubarbs for the intended NEU outdoor use.

1.2.2 | Magnitude of residues in rotational crops

Studies investigating the magnitude of residues in rotational crops were not provided and are not required, since significant residues are not expected in rotational crops grown in soil treated with flonicamid according to the intended uses (see Point 1.1.2.).

1.2.3 | Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of residues of flonicamid and its metabolites in processed commodities were assessed in the framework of the EU pesticides peer review and the MRL review and in a previous EFSA opinion (EFSA, 2010a, 2014, 2010b).

Additional data from studies on processed potatoes were submitted by the applicant for the current assessment together with a balance study on potatoes including potato wet peel, potato crisps and potato flakes already assessed by EFSA in the framework of a previous MRL application (EFSA, 2020b; Finland, 2023).

[9]Although some of the trials were performed in head-forming lettuce varieties, EFSA accepted the extrapolation to other leafy crops, because the phenological development and the morphological characteristics are the same for head-forming and non-head forming lettuces at the BBCH of 11 to 16 relevant for intended GAP. Based on this argument, the proposed extrapolation has already been accepted in a previous EFSA assessment (EFSA, 2018c). Furthermore, it is noted that the trials performed with a dipping irrigation application at pre-planting are considered representative for the GAP where clods are dipped in or drenched followed by irrigation pre-transplanting.

The previously submitted study investigated the effects of processing on the magnitude of residues of flonicamid and its metabolites TFNA and TFNG in potato wet peels, potato chips and potato flakes. (EFSA, 2020b).

New studies on potato processing were provided in the framework of the related MRL application. A total of four processing trials (1 balance trial / 3 follow-up trials) were performed on potatoes after two foliar applications of 80 g a.s./ha at latest BBCH 70–71. A balance trial for potato processing including potatoes, wet peel and washed and peeled potatoes and three follow-up processing trials for six processed commodities (potato crisps/chips, potato flakes, potatoes (peeled), microwaved potatoes, cooked potatoes and French fries) was provided and assessed in the framework of the current application. Before processing, potatoes were washed and peeled. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Finland, 2023).

With regards to extraction efficiency, the method used to analyse processed commodities uses the solvent system for the residue trials (Section 1.2.1.), whereas in the method of analysis for dry processed commodities, the solvent acetonitrile/water/formic acid (49.5/50/0.5 (v/v/v))is used, which is considered within the tolerance provided for in the guidance of the extraction procedure used in the QuEChERS method (Section 1.1.4.; Finland, 2023). Extraction efficiency is nevertheless recommended to be further considered in the framework of the renewal assessment for the active substance flonicamid.

An overview of the processing studies on potatoes and derived processing factors is presented in Appendix B.1.2.3.

Processing studies in potatoes demonstrated that their processing leads to a reduction in potato wet peels and microwaved potatoes, whereas for potatoes peeled, potatoes cooked, French fries, potato crisps and flakes a concentration of the residue was observed (Finland, 2023). The number and quality of the processing studies is sufficient to derive robust processing factors for potato peel by considering the available two balance trials as sufficient, potato crisps/chips, potato flakes, potatoes (peeled), microwaved potatoes, cooked potatoes and French fries which are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

For the remaining commodities under assessment, no new studies investigating the magnitude of flonicamid residues in processed commodities were 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 (see Appendix B.3; European Commission, 1997d).

1.2.4 | Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for potatoes, lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs (see Appendix B.1.2.1).

It shall be noted that in a previous assessment on flonicamid, EFSA has already proposed an MRL of 0.2 mg/kg for potatoes and a higher MRL of 5 mg/kg for beans without pods (EFSA, 2020b). These MRL proposals are still to be considered for implementation in the EU MRL regulation.

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

Potatoes may be used for feed purposes. However, since the input values on potatoes for the livestock dietary burden calculations derived in this opinion are identical to those previously derived for the import tolerance proposal for potatoes[10] and the most recent dietary burden assessment is still valid (EFSA, 2020b). It was therefore not necessary to update the animal dietary burden calculations and to perform further considerations on the animal dietary burden.

Anyway, the current EU MRLs for flonicamid in animal commodities which are based on Codex MRLs implemented in Regulation (EU) 2018/687[11] were derived from significantly higher dietary burden calculations for livestock (EFSA, 2016b) then those calculated based on the EU uses, a modification of the existing EU MRLs for commodities of animal origin is considered unnecessary.

It is noted that studies on extraction efficiency were included within the current MRL application in the updated evaluation report by the EMS (Finland, 2023). Noting that a change of the existing MRLs in products of animal origin is not required in this assessment, EFSA would recommend considering the extraction efficiency of the analytical methods to quantify residues of flonicamid in animal matrices in the broader context of the upcoming renewal assessment, where a comprehensive data package, including a new monitoring analytical method for milk with its ILV, should be included.

[10]Input values for the dietary burden derived from the GAP on potatoes under this assessment: STMR 0.06 mg/kg, HR 0.11 mg/kg. Input values derived for the (US) GAP assessed previously (EFSA, 2020b): STMR 0.06 mg/kg, HR 0.11 mg/kg.

[11]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, p. 63–104.

3 | CONSUMER RISK ASSESSMENT

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a; EFSA, 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). The metabolites included in the risk assessment residue definition were considered less toxic than the parent compound (EFSA, 2010a).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in these applications 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 applications, except for beans with pods. For this commodity, the HR derived in a previous EFSA opinion (EFSA, 2020b) was used as input value since higher than the HR derived based on the intended use under assessment. The list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any the crops assessed in this application (see Appendix B.3). The highest acute exposure results among the commodities under assessment was calculated for beans without pods (based on the higher MRL proposal of 5 mg/kg) with 92.8% ARfD, potatoes (67.7%), escaroles/broad-leaved endives (54.6%) and lettuces (51.8%). For the remaining crops, the exposure was less than 40%. It is noted that for some of the minor crops under assessment (i.e. land cresses and baby leave crops), no specific consumption data were available in the EFSA PRIMo rev. 3.1. However, EFSA assumes that these crops are covered by the risk assessment of other leafy crops like lettuces and escaroles, for which the same MRL proposal was derived and which are likely to be consumed in higher amounts.

Regarding commodities not included in the present MRL applications, it should be noted that the short-term exposure was found to exceed the ARfD for pears and peaches (105% and 114% of ARfD, respectively) as already identified in previous assessments (EFSA, 2019b; EFSA, 2020a, 2020b, 2023). This exceedance is due to differences in the revised PRIMo versions compared to the version used in the MRL review[12] (EFSA, 2014). Further refinement following the use of unrounded HR values of the residue trials reported in the MRL review (EFSA, 2014) still leads to a slight exceedance of the ARfD for pears and peaches (102% and 113% of ARfD, respectively). For pears and peaches where the exposure calculation exceeds the ARfD with PRIMo 3.1, options for further refinement of the risk assessment shall be explored, e.g. in the process of the renewal of the approval or under a specific mandate or to consider lowering the existing MRLs for pears (0.3 mg/kg) and peaches (0.4 mg/kg) to the LOQ.

Long-term (chronic) dietary risk assessment

The comprehensive long-term exposure assessment performed in the framework of the MRL review was revised in previous EFSA assessments of MRL applications issued after the MRL review and considering acceptable Codex MRLs (CXLs) (EFSA, 2014, 2015, 2016a, 2016b, 2017a, 2017b, 2018b, 2018c, 2018d). EFSA updated the previous calculation by including the STMR values as derived for potatoes (identical to the STMR derived in a previous EFSA opinion issued in 2020), the group of lettuces and salad plants, the group of spinaches and similar leaves, cardoons, celeries, rhubarbs, Florence fennels and rhubarbs. For beans without pods, the STMR derived in a previous EFSA opinion (EFSA, 2020b) was used as input value since higher than the STMR derived based on the intended uses under assessment. The contributions of commodities for which no GAP was supported in the framework of the MRL review and in the EFSA opinions issued after the MRL review were not included in the calculation. The input values used in the exposure calculations are summarised in Appendix D.1.

No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The total calculated intake accounted for a maximum of 31%[13] of the ADI (NL toddler diet) (see also Appendix B.3). The contribution of residues expected in potatoes with 1.28% of the ADI (PT general) was highest. Beans without pods (based on the higher MRL proposal of 5 mg/kg, EFSA, 2020b) contributed with 0.62% of ADI (GEMS/Food G11). In the group of lettuces and salad plants the expected contribution was highest for lettuces (0.21% of ADI (ES adult)), for the group of spinaches and similar leaves it was highest for spinaches (0.29% of ADI (NL toddlers)), followed by celeries (0.03% of ADI (GEMS/Food G11)) and rhubarbs (0.03% of ADI (IE adult), Florence fennels (0.01% of ADI (IT adult)) and cardoons (0.01% of ADI (GEMS/Food G08)).

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.

[12]The MRLs for these commodities were established when previous versions of EFSA PRIMo were used for risk assessment (EFSA, 2014). The higher exposure results derived with PRIMo 3.1 compared to PRIMo 3/PRIMo 2 can be explained by the higher consumption data and/or different unit weight data which triggers the IESTI case implemented in PRIMo 3.1.

[13]Provided that MRL proposals assessed recently by EFSA (EFSA, 2020b, 2023) for flonicamid will be adopted in the EU MRL legislation.

4 | CONCLUSION AND RECOMMENDATIONS

The data submitted in support of these MRL applications were found to be sufficient to derive an MRL proposal for potatoes, lettuces and other salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs.

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

EFSA concluded that the proposed use of flonicamid on potatoes, lettuces and other salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

In addition, although not related to the food commodities assessed within the present MRL applications, the short-term exposure was found to exceed the ARfD for pears and peaches. Possible short-term intake concerns for some food commodities were already identified in previous EFSA assessments and are due to the use of a new version of PRIMo. Refinement options for the acute intake calculations could not be identified based on the available data for the current assessment and may be further investigated in future assessments.

The MRL recommendations are summarised in Appendix B.4.

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
cGAP	critical GAP
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
GLP	Good Laboratory Practice
GS	growth stage
HPLC	high performance liquid chromatography
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 Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
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
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment

RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
WG	water-dispersible granule
WHO	World Health Organization

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CONFLICT 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.

REQUESTOR

European Commission

QUESTION NUMBERS

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APPENDIX A

Summary of intended GAP triggering the amendment of existing EU MRLs

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	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	PHI (days)[d]	Remarks
Potatoes	NEU	F	Potato aphid (*Macrosiphum euphorbiae*) Green peach aphid (*Myzus persicae*) Buckthorn aphid (*Aphis nasturtii*)	WG	495.1	Foliar spray	BBCH 51	1	–	26	200–500	80	g a.s./ha	–	cGAP
Potatoes	SEU	F	Potato aphid (*Macrosiphum euphorbiae*) Green peach aphid (*Myzus persicae*) Buckthorn aphid (*Aphis nasturtii*)	WG	495.1	Foliar spray	BBCH 51	1	–	26	200–500	80	g a.s./ha	–	cGAP
Potatoes	NEU	F	Potato aphid (*Macrosiphum euphorbiae*) Green peach aphid (*Myzus persicae*) Buckthorn aphid (*Aphis nasturtii*)	WG	495.1	Foliar spray	BBCH 15	1	–	26	200–500	80	g a.s./ha	–	Potato Adjuvant: Not mandatory. Mixing tank with oil-based adjuvants is possible
Potatoes	SEU	F	Potato aphid (*Macrosiphum euphorbiae*) Green peach aphid (*Myzus persicae*) Buckthorn aphid (*Aphis nasturtii*)	WG	495.1	Foliar spray	BBCH 15	1	–	26	200–500	80	g a.s./ha	–	Potato Adjuvant: Not mandatory. Mixing tank with oil-based adjuvants is possible

(Continues)

(Continued)

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	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	PHI (days)[d]	Remarks
Lamb's lettuce	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	Pre-transplant, maximum 1 day before the transplant. Clods are dipped in or drenched with the application solution
Lettuces	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Escaroles/broad-leaved endives	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Cress and other sprouts and shoots	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Land cress	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Roman rocket/rucola	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Red mustards	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Baby leaf crops (including brassica)	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Other lettuce and other salad plants	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	

(Continued)

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	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	PHI (days)[d]	Remarks
Lamb's lettuce,	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	Pre-transplant, maximum 1 day before the transplant. Clods are dipped in or drenched with the application solution
Lettuces	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	-	-	-	1	mg a.s./plant	49	
Escaroles/broad-leaved endives,	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Cress and other sprouts and shoots	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Land cress	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Roman rocket/rucola	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Red mustards	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Baby leaf crops (including brassica)	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Other lettuce and other salad plants	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	

(Continues)

(Continued)

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	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	PHI (days)[d]	Remarks
Spinaches	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	Pre-transplant, maximum 1 day before the transplant. Clods are dipped in or drenched with the application solution
Purslanes	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Chards/beet leaves	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Other spinach and similar	NEU	F	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Spinaches	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	Pre-transplant, maximum 1 day before the transplant. Clods are dipped in or drenched with the application solution
Purslanes	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Chards/beet leaves	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Other spinach and similar	EU	G	Aphids	WG	500	Dip and drenching followed by irrigation	BBCH 11–16	1	–	–	–	1	mg a.s./plant	49	
Beans (without pods)	NEU	F	Aphids	WG	500	Foliar spray	BBCH 11–75	1	–	14–35	150–500	70	g a.s./ha	14	–
Cardoons	NEU	F	Aphids	WG	500	Foliar spray	BBCH 11–49	1	–	14–35	200–500	70	g a.s./ha	21	–

(Continued)

				Preparation		Application				Application rate per treatment					
Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	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	PHI (days)[d]	Remarks
Celeries	NEU	F	Aphids	WG	500	Foliar spray	BBCH 11–49	1	–	14–35	200–500	70	g a.s./ha	21	–
Florence fennels	NEU	F	Aphids	WG	500	Foliar spray	BBCH 11–49	1	–	14–35	200–500	70	g a.s./ha	21	–
Rhubarbs	NEU	F	Aphids	WG	500	Foliar spray	BBCH 11–49	1	–	14–35	200–500	70	g a.s./ha	21	–

Abbreviations: a.s., active substance; GAP, good agricultural practice; MRL, maximum residue level; MS, member state; NEU, Northern European Union; SEU, southern European Union; 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**	**Crops**	**Applications**	**Sampling (DAT/ DALA)**	**Comment/sSource**
	Fruit crops	Peaches	Foliar: 2 × 100 g/ha, 14 days interval	21	Radiolabelled active substance: 3-^{14}C-phenyl
			Foliar: 2 × 500 g/ha, 14 days interval	21	(EFSA, 2010a, 2014)
		Peppers	Foliar: 1 × 100 g/ha	7, 14	
	Root crops	Potatoes	Foliar: 2 × 100 g/ha, 14 days interval	14	
			Foliar: 2 × 500 g/ha, 14 days interval	14	
	Cereals/grass	Wheat	Foliar: 1 × 100 g/ha	21	
			Foliar: 1 × 500 g/ha	21	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	–	–	–	–	EFSA, 2010a
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Parent flonicamid (EFSA, 2010a); TFNG and TFNA (EFSA, 2018c)
	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 (2010a)
Rotational crop and primary crop metabolism similar?	Not triggered	EFSA (2010a)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2010a); EFSA (2018c)
Plant residue definition for monitoring (RD-Mo)	Flonicamid (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 oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg individual for flonicamid, TFNG and TFNA (combined LOQ of 0.03 mg/kg) (EFSA, 2010a, 2014). Extraction efficiency proven in high water content matrices (EFSA, 2023) QuEChERS (BPL19-0032) HPLC–MS/MS, LOQ 0.01 mg/kg individual for flonicamid, TFNG and TFNA (combined LOQ of 0.03 mg/kg). Confirmation by monitoring an additional SRM transition for all commodities tested, except for TFNA in high water content matrices (lettuces), dry matrices (wheat grain and straw) and high-oil matrices (oilseed rape) where confirmation was done with the same mass transition as quantification, ILV available for high water matrices (lettuces) and dry commodities (wheat grain) for two mass transitions for both matrices and parent and metabolites with exception of TFNA in wheat grain where the same mass transition was monitored twice and for confirmation a different column was used. ILV for high-acid commodities missing. Extraction efficiency (solvent acetonitrile/water/formic acid 55/44.4/0.6, v/v/v) proven in high water content matrices (lettuces) (Belgium, 2023; Finland, 2023) <u>Hops:</u> <u>Fresh hops</u>: HPLC–MS/MS, LOQ 0.01 mg/kg individually for flonicamid, TFNG and TFNA (combined LOQ of 0.03 mg/kg). <u>Dried hops</u>: 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; 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 | Stability of residues in plants

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

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]
Potatoes (BBCH 15)	NEU	**Mo/RA:** 5 × < 0.030; 0.036; 0.038	Residue trials on potatoes GAP compliant. One additional overdosed trial (scaled to the application rate of the GAP of 0.047 mg/kg) was rejected, because of positive results in the untreated control sample. Number of trials insufficient to derive an MRL proposal.	–	–	–	–
	SEU	**Mo/RA:** 3 × <0.030; 0.035; 0.045; 0.048; 0.058; 0.100	Residue trials on potatoes GAP compliant.	0.15	0.1	0.04	1
Potatoes (BBCH 51)	NEU	**Mo/RA:** 2 × <0.030; 0.031; 0.033; 0.034; 0.051; 0.055	Residue trials on potatoes GAP compliant. One additional overdosed trial (scaled to the application rate of the GAP of 0.039 mg/kg) was rejected, because of positive results in the untreated control sample. Number of trials insufficient to derive an MRL proposal.	–	–	–	–
	SEU	**Mo/RA:** 0.031; 0.037; 0.046; 0.051; 0.068; 0.084; 2 × 0.110	Residue trials on potatoes GAP compliant.	**0.2**	**0.11**	**0.06**	1
Lettuces and salad plant	NEU	**Mo/RA:** 2 × ≤ 0.03; 0.04; 0.05; 0.09; 0.12; 0.20	Residue trials on lettuces (open leaf varieties underlined where identifiable) compliant with GAP. All trials performed with dipping irrigation application.	–	–	–	–
Spinaches and similar leaves			One additional trial (< 0.03 mg/kg) was rejected, because of positive results in the untreated control sample. Number of trials is insufficient to derive an MRL proposal and to extrapolate results to the whole group of lettuces and salad plants and of spinaches and similar leaves.				
	Indoor	**Mo/RA:** <0.03; 0.03; 2 × 0.05; 0.10; 0.11; 0.17; 0.22; 0.34	Residue trials on lettuces (open leaf varieties underlined where identifiable) compliant with GAP. All trials performed with dipping irrigation application. Extrapolation to the whole group of lettuces and salad plants and spinaches and similar leaves is acceptable based on the proposed pre-transplanting application at very early stage of plant development for which the salad varieties is considered as irrelevant and already accepted in a previous assessment (EFSA, 2018a).	**0.6**	0.34	0.1	1
Beans (without pods)	NEU	**Mo/RA:** NEU: 0.104; 0.11; 0.18; 0.214; 0.28; 0.37; 0.43	Residue trials on peas without pods compliant with GAP on beans without pods) already assessed by EFSA (2010b, 2015). Extrapolation to beans without pods is acceptable.	**0.7**	0.43	0.21	1

(Continues)

(Continued)

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]
Celeries, cardoons, Florence fennels, rhubarbs	NEU	**Mo/RA:** NEU: 3 × < 0.03; 0.03; 0.06; 0.08; 0.14	Residue trials on celeries compliant with GAP. Extrapolation to cardoons, Florence fennels and rhubarbs is acceptable:	**0.3**	0.14	0.03	1

Abbreviations: GAP, good agricultural practice; Mo, monitoring; MRL, maximum residue level; RA, risk assessment.

[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	EFSA (2010a) 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
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	EFSA (2010a)

B.1.2.3 | Processing factors

Processed commodity	Number of valid studies[a]	Processing factor (PF)			
		Individual values	Mean/ median PF	CF_P[b]	Comment/source
Potato, wet peels	2	< 0.428 (mean of < 0.428; < 0.428; < 0.428; < 0.428; < 0.428)	0.38	–	Balance study with five experimental replicates. Residues in wet peel < LOQ (Finland, 2023)
		0.334[c] (mean of 0.335; 0.333)[c]			Balance study with two experimental replicates (EFSA, 2020b)
Potato, peeled	4	1.142; 1.777; 0.666; 1.90	1.46	–	Balance study (1st) and three follow-up studies (Finland, 2023)
Potato, washed and peeled	1	1.199 (mean of 1.428; 1.285; 1.285; 0.714; 1.285)	1.199	–	Tentative[d] (Finland, 2023)
Potato, cooked (peeled)	4	1.142 (mean of 1.285; 1.0); 2.0, 0.833, 1.60	1.37	–	Balance study (1st) and three follow-up studies (Finland, 2023)
Potato, microwaved (peeled)	4	0.857; 1.333; 0.416; 1.10	0.98	–	Balance study (1st) and three follow-up studies (Finland, 2023)
Potato, French fries (peeled)	4	1.571; 2.888; 1.00; 2.250	1.91	–	Balance study (1st) and three follow-up studies (Finland, 2023)
Potato, crisps (peeled)	5	1.285; 3.333; 1.250; 3.10	1.57	–	Balance study (1st) and three follow-up studies (Finland, 2023)
		1.569 (mean of 1.516; 1.622[c])			Balance study with two experimental replicates (EFSA, 2020b)
Potato, flakes	5	3.428; 5.00; 2.916; 2.80	2.98	–	Balance study (1st) and three follow-up studies (Finland, 2023)
		2.980 (mean of 2.849, 3.111)			Balance study with two experimental replicates (EFSA, 2020b)

Abbreviation: PF, processing factor.

[a]Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

[b]Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

[c]It is noted the presence of a typo in EFSA (2020b) where the PFs were erroneously reported as 0.033 and 0.034. The values are here correctly reported, and they should be considered as superseding those of the previous output EFSA (2020b).

[d]A tentative PF is derived based on a limited data set: results on potatoes based on one study only).

B.2 | RESIDUES IN LIVESTOCK

No update of the previous dietary burden calculation required.

B.3 | CONSUMER RISK ASSESSMENT

ARfD	0.025 mg/kg bw (European Commicion, 2010)
Highest IESTI, according to EFSA PRIMo	Potatoes: 67.7% of ARfD (UK infant) Lamb's lettuce: 3.8% of ARfD (BE toddlers) Lettuces: 51.8% of ARfD (NL child) Escaroles/broad-leaved endives: 54.6 % of ARfD (BE toddlers) Cress and other shoots and sprouts: 0.5% of ARfD (UK vegetarian) Land cress: no acute risk assessments for children and adults possible because of unavailable consumption data Roman rocket/rucola: 3.7% of ARfD (DE child) Red mustard: 7.2% of ARfD (NL general) Baby leaf crops: no consumption data available for acute risk assessment. Spinaches: 30.7% ARfD (BE toddlers) Purslanes: 2.6% of ARfD (adults: DE woman 14-50 years) Chards/beet leaves: 25.7% of ARfD (adults: NL general) Beans without pods (based on the higher MRL proposal of 5 mg/kg, EFSA, 2020b): 92.8% of ARfD (IE child) Cardoons: 5.8% of ARfD (IT adult) Celeries: 21.0% of ARfD (BE toddler) Florence fennels: 10.4% of ARfD (UK vegetarian) Rhubarbs: 20.8% of ARfD (UK toddler)
Assumptions made for the calculations	The calculation is based on the highest residue levels (HR values) expected in raw agricultural commodities under assessment, expressed as flonicamid equivalents, except for beans without pods, for which the higher HR values derived by EFSA (2020b) was used in the risk assessment. For certain commodities (pears and peaches) not included in the present MRL application, a slight exceedance of the ARfD due to differences in the applied PRIMo versions is observed (pears 102% and peaches 113% of the ARfD). Refinement options for the acute intake calculations could not be identified based on the available data and may be further investigated in future assessments. Calculations performed with PRIMo revision 3.1

ADI	0.025 mg/kg bw per day (European Commisio, 2010)
Highest IEDI, according to EFSA PRIMo	31% ADI (NL toddler)

	Contribution of crops assessed: Potatoes: 1.28% of ADI (PT general) Lamb's lettuce: 0.03% of ADI (GEMS/Food G11) Lettuces: 0.21% of ADI (ES adult) Escaroles/broad-leaved endives: 0.10 % of ADI (NL toddler) Cress and other shoots and sprouts: 0.03% of ADI (GEMS/Food G10) Land cress: no chronic consumption data available Roman rocket/rucola: 0.01% of ADI (GEMS/Food G6) Red mustard: 0.001% of ADI (GEMS/Food G6) Baby leaf crops: no chronic consumption data available Other lettuces and other salad plants: 0.06% of ADI (IT adult) Spinaches: 0.29% ADI (NL toddler) Purslanes: 0.002% of ADI (PL general) Chards/beet leaves: 0.03% of ADI (ES adult) Other spinach and similar: 0.03% of ADI (IT adult) Beans without pods (based on the higher MRL proposal of 5 mg/kg, EFSA, 2020b): 0.62% of ADI (GEMS/Food G11) Cardoons: 0.01% of ADI (GEMS/Food G08) Celeries: 0.03% of ADI (GEMS/Food G11) Florence fennels: 0.01% of ADI (IT adult) Rhubarbs: 0.03% of ADI (IE adult)
Assumptions made for the calculations	The calculation is based on the median residue levels (STMR values) derived for the raw agricultural commodities under assessment, except for beans with pods. For this crop, the STMR previously derived (EFSA, 2020b) since higher and covering intended use. For the remaining commodities, the input values as derived in the MRL review and in subsequent EFSA assessments and, where considered acceptable by EFSA, the Codex MRLs (CXLs) derived by JMPR (EFSA, 2014, 2015, 2016a,b, 2017a,b 2018b,c,d, 2019b, 2020a,b, 2023, 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 EFSA assessments were not included in the calculation. Calculations performed with PRIMo revision 3.1

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/ proposed EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Plant commodities **Enforcement residue definition:** Sum of flonicamid, TFNA and TFNG expressed as flonicamid				
0211000	Potatoes	0.09/0.2[b]	0.2	The submitted data are sufficient to derive an MRL proposal of 0.2 mg/kg for the SEU (eight trials) based on the intended critical outdoor SEU use with treatment at BBCH 51. The intended SEU use with treatment at BBCH 15 is also supported by residue data. NEU uses at BBCH 15 and 51 are insufficiently supported by data (seven valid trials only) It is noted that an MRL proposal at the same level of 0.2 mg/kg was derived in a previous EFSA assessment. However, the MRL proposal has not yet been implemented in the MRL legislation Risk for consumers unlikely
0251010	Lamb's lettuce/ corn lettuce	0.07	0.6	See lettuces (0251020)
0251020	Lettuces	0.07	0.6	The submitted data are sufficient to derive an MRL proposals for the intended indoor EU use (dip-treatment pre-transplanting at BBCH 11–16) whereas the intended NEU use is insufficiently supported by data (seven valid trials only) Extrapolation from indoor trials on lettuces to the whole group of lettuce and other salad plants (0251000) is possible. Risk for consumers unlikely
0251030	Escaroles/ broad-leaved endives	0.07	0.6	See lettuces (0251020)
0251040	Cress and other sprouts and shoots	0.07	0.6	See lettuces (0251020)
0251050	Land cress	0.07	0.6	See lettuces (0251020)
0251060	Roman rocket/ rucola	0.07	0.6	See lettuces (0251020)
0251070	Red mustards	0.07	0.6	See lettuces (0251020)
0251080	Baby leaf crops (including brassica)	0.07	0.6	See lettuces (0251020)
0251990	Other lettuce and other salad plants	0.07	0.6	See lettuces (0251020)
0252010	Spinaches	0.03*	0.6	See lettuces (0251010) Extrapolation of results from residue trials on lettuces to spinaches and similar leaves (0252000) is possible. Risk for consumers unlikely
0252020	Purslanes	0.03*	0.6	See spinaches (0252010)
0252030	Chards/beet leaves	0.03*	0.6	See spinaches (0252010)
0252990	Other spinach and similar	0.03*	0.6	See spinaches (0252010)
0260020	Beans (without pods)	0.03*/5[b]	0.7 or 5 Further risk management discussions recommended	The submitted data are sufficient to derive an MRL proposal for the intended NEU use of 0.7 mg/kg by extrapolation from seven GAP compliant residue trials on peas without pods It is noted that a higher MRL proposal of 5 mg/kg was derived in a previous EFSA assessment. However, the MRL proposal has not yet been implemented in the MRL legislation For both MRL proposals, a risk for consumers is unlikely. Further risk management discussion is required
0270020	Cardoons	0.03*	0.3	See celeries (0270030)

(Continued)

Code[a]	Commodity	Existing/ proposed EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0270030	Celeries	0.03*	0.3	The submitted data on celeries are sufficient to derive a MRL proposal for the intended NEU use Extrapolation of results from residue trials on celeries to cardoons, Florence fennels and rhubarbs possible. Risk for consumers unlikely
0270040	Florence fennels	0.03*	0.3	See celeries (0270030)
0270070	Rhubarbs	0.03*	0.3	See celeries (0270030)

Abbreviations: BBCH, growth stages of mono- and dicotyledonous plants; GAP, good agricultural practice; MRL, maximum residue level; NEU, Northern Europe; SEU: southern Europe.

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]MRL proposal based on an import tolerance request (US GAP) assessed by EFSA in the reasoned opinion on the setting of import tolerances for flonicamid in various crops and products of animal origin (EFSA Journal 2020;18(6):61369), not yet implemented into the MRL legislation.

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

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Flonicamid

LOQs (mg/kg) range from:	0.02	to:	0.50
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 : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	31%	NL toddler	7.69	12%	Milk: Cattle	6%	Wheat	3%	Beans (with pods)		31%
	21%	DK child	5.25	8%	Rye	6%	Wheat	3%	Milk: Cattle		21%
	20%	DE child	4.88	6%	Wheat	4%	Milk: Cattle	3%	Apples		20%
	19%	NL child	4.65	6%	Wheat	5%	Milk: Cattle	1%	Apples		19%
	18%	FR child 3 15 yr	4.52	6%	Wheat	5%	Milk: Cattle	2%	Beans (with pods)		18%
	17%	FR toddler 2 3 yr	4.31	6%	Milk: Cattle	4%	Wheat	3%	Beans (with pods)		17%
	17%	UK infant	4.21	8%	Milk: Cattle	4%	Wheat	1%	Peas (without pods)		17%
	17%	GEMS/Food G06	4.16	10%	Wheat	2%	Tomatoes	0.5%	Milk: Cattle		17%
	15%	UK toddler	3.77	5%	Wheat	4%	Milk: Cattle	1%	Beans		15%
	14%	RO general	3.59	7%	Wheat	2%	Milk: Cattle	0.9%	Tomatoes		14%
	14%	ES child	3.43	6%	Wheat	2%	Milk: Cattle	0.8%	Beans (with pods)		14%
	13%	GEMS/Food G15	3.36	6%	Wheat	1%	Milk: Cattle	0.6%	Potatoes		13%
	13%	SE general	3.25	4%	Wheat	2%	Milk: Cattle	1%	Bovine: Muscle/meat		13%
	13%	GEMS/Food G08	3.21	6%	Wheat	1%	Milk: Cattle	0.8%	Rye		13%
	13%	GEMS/Food G07	3.15	6%	Wheat	1%	Milk: Cattle	0.6%	Potatoes		13%
	12%	IT toddler	3.03	9%	Wheat	0.6%	Tomatoes	0.3%	Beans (with pods)		12%
	12%	GEMS/Food G10	3.01	5%	Wheat	1%	Milk: Cattle	0.6%	Tomatoes		12%
	12%	GEMS/Food G11	2.89	5%	Wheat	2%	Milk: Cattle	0.7%	Potatoes		12%
	11%	IE adult	2.70	3%	Wheat	0.9%	Milk: Cattle	0.6%	Beans (with pods)		11%
	10%	DE women 14-50 yr	2.55	3%	Wheat	2%	Milk: Cattle	0.7%	Rye		10%
	10%	DE general	2.52	3%	Wheat	2%	Milk: Cattle	0.8%	Rye		10%
	9%	PT general	2.33	5%	Wheat	0.9%	Potatoes	0.6%	Beans (without pods)		9%
	9%	NL general	2.18	3%	Wheat	2%	Milk: Cattle	0.8%	Beans (with pods)		9%
	9%	IT adult	2.13	6%	Wheat	0.5%	Beans (with pods)	0.5%	Tomatoes		9%
	9%	FR infant	2.13	3%	Milk: Cattle	2%	Beans (with pods)	1%	Wheat		9%
	8%	ES adult	2.06	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%
	6%	LT adult	1.60	2%	Rye	1%	Wheat	0.8%	Milk: Cattle		6%
	6%	FI 3 yr	1.60	2%	Wheat	0.9%	Rye	0.8%	Potatoes		6%
	6%	UK vegetarian	1.54	3%	Wheat	0.7%	Milk: Cattle	0.6%	Beans		6%
	6%	DK adult	1.38	2%	Wheat	1%	Milk: Cattle	0.7%	Rye		6%
	5%	FI 6 yr	1.31	1%	Wheat	0.9%	Rye	0.7%	Potatoes		5%
	5%	UK adult	1.28	2%	Wheat	0.6%	Milk: Cattle	0.3%	Beans		5%
	3%	IE child	0.78	2%	Wheat	0.7%	Milk: Cattle	0.2%	Beans (without pods)		3%
	3%	FI adult	0.75	1.0%	Rye	0.4%	Wheat	0.2%	Tomatoes		3%
	2%	PL general	0.60	0.6%	Potatoes	0.5%	Apples	0.4%	Tomatoes		2%

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.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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)
113%	Peaches	0.4 / 0.3	28
102%	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
80%	Apples	0.3 / 0.19	20
79%	Tomatoes	0.5 / 0.34	20
68%	Watermelons	0.4 / 0.14	17
67%	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
55%	Escaroles/broad-leaved endives	0.6 / 0.34	14
52%	Lettuces	0.6 / 0.34	13

Expand/collapse list

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
27%	Escaroles/broad-leaved endives	0.6 / 0.34	6.9
26%	Chards/beet leaves	0.6 / 0.34	6.4
24%	Chinese cabbages/pe-tsai	0.5 / 0.24	6.1
23%	Watermelons	0.4 / 0.14	5.7
23%	Pears	0.3 / 0.19	5.7
22%	Peaches	0.4 / 0.3	5.6
22%	Melons	0.4 / 0.14	5.5

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)
90%	Escaroles/broad-leaved endives / boiled	0.6 / 0.34	23
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
42%	Chards/beet leaves / boiled	0.6 / 0.34	11
41%	Potatoes / fried	0.2 / 0.11	10
31%	Gherkins / pickled	0.5 / 0.34	7.8
31%	Peaches / canned	0.4 / 0.3	7.7
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 white) / juice	0.8 / 0.23	6.6
25%	Florence fennels / boiled	0.3 / 0.14	6.3
21%	Rhubarbs / sauce/puree	0.3 / 0.14	5.2

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%	Escaroles/broad-leaved endives / boiled	0.6 / 0.34	6.9
28%	Peas (with pods) / boiled	3 / 2.03	6.9
23%	Beetroots / boiled	0.3 / 0.15	5.8
19%	Celeries / boiled	0.3 / 0.14	4.7
17%	Chards/beet leaves / boiled	0.6 / 0.34	4.3
13%	Parsnips / boiled	0.3 / 0.15	3.2
12%	Currants (red, black and white) / juice	0.8 / 0.23	2.9
11%	Turnips / boiled	0.3 / 0.15	2.9
11%	Spinaches / frozen; boiled	0.6 / 0.34	2.8
11%	Beans / canned	2 / 0.39	2.8
11%	Celeriacs / boiled	0.3 / 0.15	2.7

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 | CONSUMER RISK ASSESSMENT

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
Risk assessment residue definition: sum of flonicamid, TFNG and TFNA, expressed as flonicamid						
Potatoes	0.2	**MRL proposal** EFSA (2020b)	0.06	STMR-RAC	0.11	HR-RAC
Lettuce and other salad plants (including Brassicaceae)	0.6	**MRL proposal**	0.100	STMR-RAC	0.340	HR-RAC
Spinach and similar leaves	0.6	**MRL proposal**	0.100	STMR-RAC	0.340	HR-RAC
Beans without pods	5[c]	EFSA (2020b)	0.55	STMR-RAC	2.94	HR-RAC
Cardoons	0.3	**MRL proposal**	0.03	STMR-RAC	0.14	HR-RAC
Celeries	0.3	**MRL proposal**	0.03	STMR-RAC	0.14	HR-RAC
Florence fennels	0.3	**MRL proposal**	0.03	STMR-RAC	0.14	HR-RAC
Rhubarbs	0.3	**MRL proposal**	0.03	STMR-RAC	0.14	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[c]	EFSA (2020b)	0.03	STMR-RAC	0.06	HR-RAC
Pistachios	0.3[c]	EFSA (2020b)	0.03	STMR-RAC	0.19	HR-RAC
Pome fruits	0.3	EFSA (2014)	0.06	STMR-RAC	0.185	HR-RAC
Apricots	0.3	EFSA (2017a)	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	0.298	HR-RAC
Plums	0.3	EFSA (2020a)	0.06	STMR-RAC	0.13	HR-RAC
Strawberries	0.7	EFSA (2019b)	0.14	STMR-RAC	0.45	HR-RAC
Blackberries, Raspberries (red and yellow)	1	EFSA (2018c)	0.36	STMR-RAC	0.48	HR-RAC
Blueberries, Cranberries, Currants (red, black and white), Gooseberries (green, red and yellow)	0.8	EFSA (2019b)	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 (2018c)	0.17	STMR-RAC	0.37	HR-RAC
Other root and tuber vegetables (except sugar beet and radishes)	0.3	EFSA (2018d)	0.05	STMR-RAC	0.15	HR-RAC
Radishes	0.6	EFSA (2018c)	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[b]	0.14	HR-RAC[b]
Brussels sprouts	0.6	EFSA (2016b)	0.07	STMR-RAC	0.32	HR-RAC
Head cabbages	0.5	EFSA (2017a)	0.14	STMR-RAC	0.23	HR-RAC
Chinese cabbages/pe-tsai	0.5[c]	EFSA (2023)	0.15	STMR-RAC	0.24	HR-RAC
Kales	0.5[c]	EFSA (2023)	0.15	STMR-RAC	0.24	HR-RAC
Kohlrabies	0.15[c]	EFSA (2023)	0.05	STMR-RAC	0.06	HR-RAC

(Continued)

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment[a]
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[c]	EFSA (2020b)	0.85	STMR-RAC	1.41	HR-RAC
Peas (with pods)	3[c]	EFSA (2020b)	0.85	STMR-RAC	2.03	HR-RAC
Peas (without pods)	5[c]	EFSA (2020b)	0.55	STMR-RAC	2.94	HR-RAC
Pulses: Beans, lentils, peas and lupins	2[c]	EFSA (2020b)	0.39	STMR-RAC	0.39	STMR-RAC
Other pulses	0.8	EFSA (2018c)	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[c]	EFSA (2020b)	2.52	STMR-RAC	10.13	HR-RAC
Sugar beet roots	0.03	EFSA (2017a)	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
Liver (mammals)	0.2	FAO (2016b)	0.10	STMR-RAC	0.17	HR-RAC
Kidney (mammals)	0.2	FAO (2016b)	0.10	STMR-RAC	0.17	HR-RAC
Edible offal, other than liver and kidney (mammals)	0.2	FAO (2016b)	0.10	STMR-RAC	0.17	HR-RAC
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 offal, other than liver and kidney (poultry)	0.1	FAO (2016b)	0.04	STMR-RAC	0.09	HR-RAC
Milk	0.15	FAO (2016b)	0.05	STMR-RAC	0.05	STMR-RAC
Eggs	0.15	FAO (2016b)	0.06	STMR-RAC	0.12	HR-RAC

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

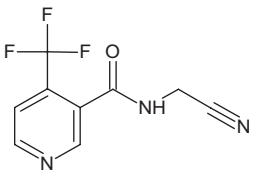
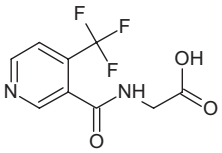
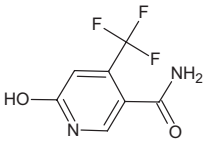
[a]Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

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

[c]MRLs not yet implemented by Regulation.

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Flonicamid	*N*-(cyanomethyl)-4-(trifluoromethyl)pyridine-3-carboxamide O=C(NCC#N)c1cnccc1C(F)(F)F RLQJEEJISHYWON-UHFFFAOYSA-N	
TFNA	4-(trifluoromethyl)pyridine-3-carboxylic acid OC(=O)c1cnccc1C(F)(F)F LMRJHNFECNKDKH-UHFFFAOYSA-N	
TFNG	*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 O=C(N)c1cnccc1C(F)(F)F JUIWZYBJXUPIKF-UHFFFAOYSA-N	
OH-TFNA-AM	6-hydroxy-4-(trifluoromethyl)pyridine-3-carboxamide FC(F)(F)c1cc(O)ncc1C(N) = O JZASIHOQMPWGMF-UHFFFAOYSA-N	

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

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123,232, 7 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123,835, 28 August 2021).