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Modification of the existing maximum residue levels and setting of import tolerances for fluopyram in various crops

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer AG Crop Science Division submitted a request to the competent national authority in Italy to modify the existing maximum residue level (MRL) for the active substance fluopyram in kiwi. Additionally, the applicants Bayer Crop Science SA and Bayer SAS Crop Science Division submitted two applications to the competent national authority in Germany to modify the MRLs for fluopyram in certain stem vegetables, seed spices, apples and soyabeans based on intended EU uses as well as to lower the existing EU MRL in pome fruits and to raise the existing EU MRL in peanuts on the basis of authorised use of fluopyram in the USA. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all the crops under assessment except for palm hearts and bamboo shoots. Adequate analytical methods for enforcement are available to control the residues of fluopyram in commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term intake of residues resulting from the use of fluopyram according to the reported agricultural practices is unlikely to present a risk to consumer health. A long-term consumer intake concern is identified if the current MRL of 0.8 mg/kg in pome fruits is maintained and new MRLs for other commodities under consideration are supported, with apples being the highest contributing commodity to the diet for which exposure exceedances were noted. The chronic risk for consumers is unlikely if a lower MRL of 0.6 mg/kg in pome fruits proposed by the applicant is considered. Further risk manager considerations are required.

Keywords: fluopyram, various crops, honey, import tolerance, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer AG Crop Science Division submitted an application to the competent national authority in Italy (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance fluopyram in kiwi.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the EFSA Central Submission System on 4 January 2022. The appointed EMS Italy assessed the dossier and declared its admissibility on 28 February 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the 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, in order to identify whether other relevant scientific data or studies are available. The consultation run from 25 August 2022 to 15 September 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 30 September 2022. To accommodate for the intended use of fluopyram, the EMS proposed to raise the existing MRL in kiwi from the limit of quantification (LOQ) to 1.5 mg/kg. In order to assess whether the existing authorised EU uses of fluopyram would require modification of the existing EU MRL in honey, the applicant submitted residue trial data in honey. EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation.

Two further applications were submitted by the applicant Bayer (Crop Science SA and SAS, Crop Science Division) to the competent national authority in Germany (EMS) to modify the existing maximum residue levels (MRLs) for fluopyram in some stem vegetables, seed spices, apples and soyabeans and to set import tolerances in pome fruits and peanuts. The EMS Germany drafted two evaluation reports, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 30 February 2023. The EMS proposed to raise the existing MRLs for fluopyram in cardoon, Florence fennel and rhubarb from the LOQ to 8 mg/kg. For bamboo shoots and palm hearts, no data was available, and therefore, no MRL proposal was given. To support the intended use on seed spices, Germany proposed to raise the MRLs for fluopyram in all the seed spice group except for dill from the LOQ to 40 mg/kg. For soyabeans, the EMS proposed to raise the MRL of fluopyram from 0.2 to 0.3 mg/kg. Finally, the EMS proposed to establish maximum residue levels (MRLs) for pome fruits and peanuts imported from the USA at the level of 0.6 mg/kg and 0.2 mg/kg, respectively. EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification for both applications, which were requested from the EMSs. On 6 March 2023 and 22 March 2023, the EMS submitted the requested information in the form of revised 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 the EMSs in the framework of this application, the following conclusions are derived.

The metabolism of fluopyram in primary crops was investigated following foliar treatment in fruit crops (grapes), root crops (potato) and pulses and oilseeds crops (beans) and following drip irrigation in fruiting vegetables (pepper). The observed metabolism of fluopyram in rotational crops was considered similar to the metabolic pathway observed in primary crops.

Studies investigating the effect of processing on the nature of fluopyram (hydrolysis studies) demonstrated that the active substance and its benzamide metabolite (M25) are stable.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological relevance of metabolites, the residue definitions for plant products were proposed as 'fluopyram' for enforcement and as 'sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram' for risk assessment purposes. These residue definitions are applicable to primary crops, rotational crops and processed products. In the absence of specific metabolism studies on honey and considering the possible transfer of residues from floral nectar collected by honey bees from primary and rotational crops to honey, the same residue definitions as mentioned above is proposed.

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

Sufficiently validated analytical methods are available to quantify residues at the LOQ of 0.01 mg/kg in the crops and in honey assessed in this application according to the enforcement residue definition.

The available residue trials are sufficient to derive MRL proposals for fluopyram for all crops under consideration except for palm hearts and bamboo shoots. These two crops are not adequately supported by residue data. The lowering of the existing EU MRL of in pome fruit is proposed by the applicant and is sufficiently supported by residue data.

New specific studies investigating the magnitude of fluopyram residues in processed commodities were not submitted and are not required. The applicant assessed the distribution of residues in the peel and the pulp in four kiwi residue trials, allowing to derive a median peeling factor of 0.07 for kiwi.

The occurrence of fluopyram residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review, where MRLs for fluopyram in rotational crops were proposed. The intended EU primary crop uses under consideration are less critical than the primary crop use assessed by the MRL review for which the residues in rotational crops were assessed. Therefore, in the framework of the present assessment, a revision of residues in rotational crops was not performed.

Since apples, soyabean and/or their by-products are used as feed products, a potential carry-over of residues into the food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg DM for all relevant animal species. However, the contribution of fluopyram residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

Investigation of residues in honey is not required according to the data requirements applicable for the assessment of the submitted applications. However, the applicant provided four residue trials in honey, where fluopyram was applied on *Phacelia tanacetifolia* under semi-field conditions. The trials are considered sufficiently representative for the authorised EU uses reported under the MRL review and for the intended uses of fluopyram considered under the present assessment to conclude that residues above the LOQ of 0.01 mg/kg are not expected to occur in honey. Since validation data submitted for enforcement of fluopyram residues in honey indicate that a lower LOQ of 0.01 mg/kg is achievable, the risk managers could consider lowering the existing MRL in honey currently set at the LOQ of 0.05 mg/kg.

The toxicological profile of fluopyram was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.012 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw. The metabolites included in the residue definition are of similar toxicity as the parent active substance.

A comprehensive estimate of the dietary exposure of EU consumers was performed in the framework of the review of the existing MRLs for fluopyram according to Article 12 of Regulation (EC) No 396/2005; the calculated exposure for the current MRLs accounted for 99.99% of the ADI. EFSA now updated the exposure as calculated under option 2 of the MRL review with the risk assessment values derived from the residue trials on the crops under consideration. The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Since the applicant claims that the current MRL for pome fruits (0.8 mg/kg) is based on an out-to-date GAP and shall be lowered to 0.6 mg/kg and since a very narrow margin of safety was identified in the previous consumer exposure assessment, EFSA performed the risk assessment based on two different intake scenarios for pome fruits, where scenario 1 considered the situation when the existing EU MRL is maintained and the scenario 2 considered the lowering of the MRL in pome fruits.

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. EFSA concludes that acute consumer intake concerns are unlikely for the crops under consideration.

The outcome of the chronic risk assessment performed with scenario 1 presents a consumer intake concern as the ADI was exceeded (100.29% of the ADI, NL toddler diet). The highest contributing commodities to the exposure in NL toddler diet were milk (20.91% of the ADI), apples (17.97% of the ADI), bananas (8.55% of the ADI), table grapes (7.61% of the ADI) and pears (7.23% of the ADI). Scenario 2 did not result in an exceedance of the ADI (92.1% of the ADI, NL toddler diet) and the risk to consumers is considered unlikely. The contribution of residues in apples and pears to exposure in the NL toddler diet was reduced to 12.13% and 4.88% of the ADI, respectively. It should be noted that no specific consumption data are available for NL toddler for medlar, loquats, cardoon, rhubarb and seed spices. Therefore, the proposed MRLs for these crops do not affect the chronic exposure for the Dutch toddler diet in any of the two scenarios.

For the chronic exposure, when the existing EU MRL for pome fruits is considered along with new uses on other crops under consideration, the long-term consumer intake concerns cannot be excluded. Lowering the existing EU MRL in pome fruits from 0.8 mg/kg to 0.6 mg/kg would result in a lower long-term exposure for which no consumer health risks are identified.

Since there might be other EU authorisations in place requiring the existing EU MRL of 0.8 mg/kg in pome fruit and since the current MRL in the USA is still 0.8 mg/kg, further risk management consideration is required for the lowering of the existing EU MRL in pome fruits and raising the MRL in other commodities under consideration. Furthermore, it should be taken into account that the current CXL for fluopyram in pome fruits is 0.5 mg/kg. It is also noted that for some crops, the existing MRLs are set on a tentative basis following the outcome of the MRL review. Therefore, the conclusions reported in this reasoned opinion might need to be reconsidered after the assessment of the confirmatory data following the MRL review according to Article 12 of Regulation No 396/2005.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
130010	Apples	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the intended NEU and authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in apples is 12.13% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in apples to the NL toddler diet is 17.97% of the ADI.
130020	Pears	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in pear is 4.88% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in pears to the NL toddler diet is 7.23% of the ADI.
130030	Quinces	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in quinces is 0.01% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in quinces < 0.01% of the ADI for the NL toddler diet.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
130040	Medlars	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. However, as medlar and loquats do not contribute to the NL toddler diet for which chronic consumer intake concerns were identified, the existing MRL in these commodities is not associated with consumer exposure concerns.
130050	Loquats/ Japanese medlars	0.8		
0162010	Kiwi fruits (green, red, yellow)	0.01*	1.5 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 1.5 mg/kg for the SEU use. No acute intake concerns are identified. A long-term consumer intake concern for NL toddler diet is identified if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of the new MRL proposal in kiwi. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in kiwi account for 0.18% of the ADI for NL toddler diet, if the existing MRL is raised to 1.5 mg/kg.
0270020	Cardoons	0.01*	15	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use on cardoons. Risk for consumers from short-term intake of residues of fluopyram from cardoon is unlikely. Since cardoon does not contribute to the NL toddler diet for which chronic intake concerns were identified, the proposed MRL in this commodity is not associated with consumer exposure concerns.
0270040	Florence fennels	0.01*	15 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use. Risk for consumers from short-term intake of residues of fluopyram from Florence fennel is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of the new MRL proposal in Florence fennel. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in Florence fennel account for 0.02% of the ADI for the NL toddler diet if the existing MRL is raised to 15 mg/kg.
0270070	Rhubarbs	0.01*	15	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use on rhubarbs. Risk for consumers from short-term intake of residues of fluopyram is unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
				Since rhubarb does not contribute to the NL toddler diet for which chronic intake concerns were identified, the proposed MRL in this commodity is not associated with consumer exposure concerns.
0270080	Bamboo shoots	0.01*	No MRL proposal	The submitted data are not sufficient to derive an MRL proposal for the intended NEU/SEU use.
0270090	Palm hearts	0.01*	No MRL proposal	The submitted data are not sufficient to derive an MRL proposal for the intended NEU/SEU use.
0401020	Peanuts/ groundnuts	0.02	0.2 Further risk management considerations are required	The submitted data are sufficient to calculate an import tolerance (US GAP) of 0.2 mg/kg for peanuts. Risk for consumers from short-term intake of residues of fluopyram is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of the new MRL proposal in peanuts. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in peanuts account for 0.05% of the ADI for NL toddler diet if the existing MRL is raised to 0.2 mg/kg.
0401070	Soyabeans	0.2	0.3 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 0.3 mg/kg for the intended NEU use. Risk for consumers from short-term intake of residues of fluopyram from soyabeans is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of the new MRL proposal in soyabeans. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in soyabeans account for 0.08% of the ADI for NL toddler diet, if the existing MRL is raised to 0.3 mg/kg.
0810010	Anise/aniseed	0.05*	40	The submitted data are sufficient to derive an MRL proposal of 40 mg/kg in support of the intended NEU/SEU uses. Risk for consumers from short-term intake of residues of fluopyram is unlikely. However, as seed spices do not contribute to the NL toddler diet for which chronic consumer intake concerns were identified, the proposed MRL in these commodities is not associated with consumer exposure concerns.
0810020	Black caraway/black cumin			
0810030	Celery			
0810040	Coriander			
0810050	Cumin			
0810070	Fennel			
0810080	Fenugreek			
0810090	Nutmeg			
0810990	Other spices (seeds)			
1040000	Honey and other apiculture products	0.05*	0.01* Risk management consideration	Validation data submitted for the enforcement method of fluopyram residues in honey indicate that a lower LOQ of 0.01 mg/kg is achievable.

MRL: maximum residue level; NEU: northern Europe; SEU: southern European Union; ADI: acceptable daily intake; GAP: Good Agricultural Practice; LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received three applications to modify the existing maximum residue levels (MRLs) for fluopyram in apples, kiwi, some stem vegetables, seed spices and soyabeans and to set an import tolerance in pome fruits and peanuts. The detailed description of the intended European Union (EU) uses of fluopyram and the authorised uses of fluopyram in the United States of America (USA) on pome fruits and peanuts, which are the basis for the current MRL applications, are reported in Appendix A.

Fluopyram is the ISO common name for *N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-*o*-toluamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Fluopyram was evaluated in the framework of Directive 91/414/EEC[1] with Germany designated as rapporteur Member State (RMS); the representative uses assessed were foliar applications on grapes, tomatoes and strawberries. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013). Fluopyram was approved[2] for the use as fungicide on 1 February 2014. The process of renewal of the first approval has not yet been initiated.

The EU MRLs for fluopyram are established in Annexes II and IIIA of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2020) and the proposed modifications have been implemented in recent MRL regulation.[4]

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[5], the applicant Bayer AG Crop Science Division submitted on 4 January 2022 an application to the competent national authority in Italy to modify the existing MRL for the active substance fluopyram in kiwi, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS, Italy, assessed the dossier and declared its admissibility on 28 February 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the 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, in order to identify whether other relevant scientific data or studies are available. The consultation run from 25 August 2022 to 15 September 2022. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report, in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 30 September 2022 (Italy, 2022). To accommodate for the intended SEU use of fluopyram, the EMS proposed to raise the existing MRL in kiwi fruits from the limit of quantification (LOQ) to 1.5 mg/kg. In order to assess whether the existing authorised EU uses of fluopyram would require modification of the existing EU MRL in honey, the applicant also submitted residue trial data in honey. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Two further applications were submitted by the applicant Bayer (Crop Science SA and SAS, Crop Science Division) to the competent national authority in Germany (EMS) to modify the existing MRLs for fluopyram in apples, cardoons, fennel, rhubarb, bamboo shoots, palm hearts, seed spices, pome fruits and soyabeans and to set import tolerances in pome fruits and peanuts. The EMS Germany

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.
[2] Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 225, 23.8.2013, p. 13–16.
[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances
[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.

drafted two evaluation reports, which were submitted to the European Commission and forwarded to EFSA on 30 February 2023. The EMS proposed to raise the existing MRLs for fluopyram in cardoon, Florence fennel and rhubarb from the LOQ to 8 mg/kg. For bamboo shoots and palm hearts, no data were available, and therefore, no MRL proposal was given. To support the intended use on seed spices, Germany proposed to raise the existing EU MRLs for fluopyram in all the seed spice group except for dill from the LOQ of 0.05 mg/kg to 40 mg/kg. For soyabeans, the EMS proposed to raise the MRL of fluopyram from 0.2 to 0.3 mg/kg. Finally, the EMS proposed to lower the existing EU maximum residue levels (MRLs) for pome fruits and to raise the existing EU MRL in peanuts based on authorised uses of fluopyram in the USA at the level of 0.6 mg/kg and 0.2 mg/kg, respectively. EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification for both applications, which were requested from the EMS. On 6 March 2023 and 22 March 2023, the EMS submitted the requested information in the form of revised evaluation reports (Germany, 2022, 2023).

For reasons of efficiency, all three MRL applications were assessed under one EFSA output.

EFSA based its assessment on the evaluation report submitted by the EMSs (Italy, 2022; Germany, 2022, 2023), the draft assessment report (DAR) and its addendum (Germany, 2011, 2012) prepared under Council Directive 91/414/EEC, the Commission review report on fluopyram (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram (EFSA, 2013), the JMPR reports (FAO, 2010, 2012, 2014, 2015, 2017) as well as the conclusions from previous EFSA opinions on fluopyram under Article 10 of Regulation (EC) No 396/2005 (EFSA, 2011, 2014, 2016, 2017, 2019a,c) and the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2020).

For the applications, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the applications to the EMSs are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017, 2018, 2020, 2021; OECD, 2011, 2013, 2018). 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 this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation reports submitted by the EMSs (Italy, 2022; Germany 2022, 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 fluopyram was investigated in the framework of the EU pesticides peer review (Germany, 2011; EFSA, 2013) following foliar application on root crops (potato), pulses and oilseeds crops (beans) and fruit crops (grapes) and following drip irrigation in pepper. In addition, a cell suspension study derived from apples was submitted and was considered as supporting information to help the identification of metabolites in plant and animal metabolism studies (Germany, 2011).

In grapes, fluopyram represented over 95% of the total radioactive residues (TRR) 18 days after the last treatment. In all foliar applications (grapes, potato and beans), very limited metabolism was observed in the leaves/foliage with the parent contributing to the range of 87–98% of the TRR. Fluopyram is, however, observed in lower proportions in potato tubers and beans (fresh and dry), where the residues are mostly composed of the metabolites resulting from the cleavage of the parent

[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-2022-00165; https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00099 https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00101

molecule: the fluopyram-benzamide (M25), fluopyram pyridyl-acetic acid (M40) and fluopyram pyridyl-carboxilic acid (M43). Similar metabolic profiles were observed in pepper.

It was concluded that the metabolic pathway of fluopyram is qualitatively similar throughout all crop groups and treatments. Nonetheless, quantitative differences were observed. Fluopyram remained unchanged after foliar application in fruit crops. Meanwhile, in pulses and after soil irrigation in fruits at longer periods after treatment, metabolism entailing cleavage between the phenyl and the pyridyl rings occurred, resulting in the formation of metabolites M25 (phenyl) and M40, M42, M43 (pyridyl moiety).

For the intended and authorised uses on the crops under consideration, the metabolic behaviour of fluopyram in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Fluopyram is highly persistent in soils (DT_{90} > 1,000 days), which also means that fluopyram is likely to accumulate in soils treated for several consecutive years (EFSA, 2013, 2020). Some of the intended uses are on crops that may be rotated with others and therefore the nature and magnitude of residues in rotational crops needs to be further investigated. The nature of residues in rotational crops was already investigated in the framework of the EU pesticides peer review of fluopyram (EFSA, 2013) and more recently in the MRL review (EFSA, 2020).

In soil, the primary metabolic pathway following microbial degradation was suggested to be via hydroxylation of fluopyram to fluopyram-7-hydroxy (M08) followed by cleavage to form metabolites M25 and M43, with M43 further metabolised to methyl-sulfoxide (M45) (Germany, 2011). None of the soil metabolites were highlighted as persistent during the EU pesticides peer review (EFSA, 2013).

Two confined rotational crop studies were assessed during the EU pesticides peer review, with fluopyram radiolabelled on either the phenyl or the pyridyl moiety (Germany, 2011; EFSA, 2013). Crops – leafy vegetables (Swiss chard), roots (turnips), and cereals (spring wheat) – were planted at nominal plant-back intervals (PBIs) of 30, 139 and 280 days after treatment (DAT). Residues in wheat straw, grain, Swiss chard and turnips declined over time, while residues in hay and forage remained at similar levels. However, significant residues were observed even at 280 DAT in all crops (up to 1.97 mg eq/kg in straw).

Parent fluopyram was the major component of the TRR (50–95% TRR) in all crops. However, in grains, metabolites M43 and M45 and in chards metabolite M08 were more prominent (up to 56%, 49% and 38.6% of the TRR, respectively). M08 and its conjugate were also observed in straw and hay at significant levels (up to 12.6% TRR). M08 and its conjugates were also observed in primary crops but at low levels. Like in primary crops, M25 was also identified in all crops at low levels, in the range of 2.8–11.7% TRR.

Overall, the metabolism and distribution of fluopyram in rotational crops is similar to the metabolic pathway observed in primary crops, involving hydroxylation followed by cleavage between the two rings (EFSA, 2013). Nonetheless, some metabolites may be specific to one metabolic pathway (M45 for rotational crops) and/or the relative proportions may vary, for example, hydroxylated parent compounds (M08) and their conjugates occur at much higher levels in rotational crops, whereas M25 is observed at higher levels in primary crops.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fluopyram was investigated in the framework of the EU pesticides peer review (Germany, 2011; EFSA, 2013). Studies were conducted with fluopyram and metabolites M08, M25, M40 and M43 radiolabelled on either the phenyl or the pyridyl moiety, simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).

Fluopyram, M08, M25 and M43 were stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (Germany, 2011; EFSA, 2013). Metabolite M40 ([3-chloro-5-(trifluoromethyl)12yridine-2-yl]acetic acid) almost completely degraded to fluopyram-picoline (3-chloro-2-methyl-5-(trifluoromethyl)pyridine) under all representative conditions. Nonetheless, based on the peer review, metabolite M40 is not expected to be present in significant levels in raw agricultural commodities (EFSA, 2013). Overall, it can be concluded that processing will not impact the nature of residues in processed commodities and is similar to that in primary crops.

1.1.4. Nature of residues in honey

Honey is a product produced by bees from sugary secretions of plants (floral nectar mainly). In the absence of specific metabolism studies with honey bees, the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions were used. Based on the available information, it is considered likely that the nature of residues in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops. Further information on whether enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues would be recommended (European Commission, 2018).

1.1.5. Analytical methods for enforcement purposes in plant commodities and honey

Analytical methods for the determination of fluopyram residues were assessed during the EU pesticides peer review (Germany, 2011; EFSA, 2013). An analytical method using gas chromatography with mass spectrometry (GC–MS) detection was concluded to be sufficiently validated for the determination of fluopyram. The method allows quantifying residues at the validated limit of quantification (LOQ) of 0.01 mg/kg in crops belonging to the group of high water content (lettuce), high oil content (oilseed rape), high acid content (orange) and dry matrices (wheat grain, peas seed). During the MRL review, it was concluded from the information provided by the EURL that fluopyram can be monitored using the QuEChERS method in high water content and high acid content commodities with an LOQ of 0.002 mg/kg and in high oil content and dry commodities with an LOQ of 0.01 mg/kg (EURL, 2018; EFSA, 2020). The methods are sufficiently validated for the determination of residues of fluopyram in the crops under consideration.

In the framework of the MRL review of fluopyram (EFSA, 2020), a minor deficiency was identified for the lack of analytical methods for difficult commodities such as hops and dill seeds.

In the current applications, two additional analytical methods were submitted (Italy, 2022; Germany, 2022). The first analytical method was validated for the determination of fluopyram in difficult matrices: hops (dried cone), coffee (green beans), black tea, cocoa (green beans) and coriander seeds (Germany, 2022). The method uses high-performance liquid chromatography coupled with tandem mass spectrometry (HPLC-MS/MS) combined with QuEChERS method. The second analytical method uses HPLC-MS/MS for the determination of fluopyram residues in honey (Italy, 2022). Both methods are considered adequately validated for the detection of fluopyram residues with an LOQ of 0.01 mg/kg in difficult matrices and honey in accordance with the EU guidance (European Commission, 2021). Furthermore, independent laboratory validation (ILV) studies were conducted on the same crop categories and submitted (Germany, 2022; Italy, 2022).

Studies on the extraction efficiency of the analytical enforcement method were submitted in the context of the EU pesticides peer review (Germany, 2011, 2023). Metabolism studies are available for the analytical groups of high acid (grapes) and high water (potato, bean and pepper) content commodities. It is noted that the high oil content analytical group, to which soyabeans and peanuts belong, is not present in the metabolism studies and therefore a cross-validation study considering the extraction efficiency of the methods and solvents used in the metabolism studies cannot be performed (Germany, 2023). Thus, the extraction efficiency on high oil content crops for the analytical methods used for enforcement and in the residue trials could not be assessed.

Regarding high water and high acid crops, EFSA notes that the justification provided on extraction efficiency for the analytical methods used for enforcement is not considered sufficient according to the requirements of the extraction efficiency Technical Guideline (European Commission, 2017). During the peer review, a cross-validation study was provided which compared the extraction solvent used in the metabolism studies (acetonitrile/water 4/1, v/v) with acetone. However, the solvent used in this study (acetone) was not the same as the one used in the enforcement method (acetone/water ratio of 2/1, v/v) which makes it unsuitable as a bridging study to prove the extraction efficiency of the method of enforcement (Germany, 2023).

EFSA concludes that the extraction efficiency of the analytical enforcement method cannot be demonstrated for the crop matrices under consideration according to the requirements of the extraction efficiency Technical Guideline (European Commission, 2017), thus introducing additional uncertainty for the present assessment. To satisfy the current criteria of the guidance, further investigation on this matter would be required. EFSA would therefore recommend reconsidering the identified uncertainties in this section by risk managers in future revisions of the guidance and in the

framework of the peer review for the renewal of approval of the active substance. For matrices that are difficult to analyse, an evaluation of the extraction efficiency would be needed, but it depends on the availability of radiolabelled sample material or samples with incurred residues (European Commission, 2017). It is also noted that the existing guidance document on extraction efficiency (European Commission, 2017) cannot be applied to the honey matrix.

1.1.6. Storage stability of residues in plants and honey

The storage stability of fluopyram and its metabolite M25 in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2013) and in a subsequent reasoned opinion on fluopyram (EFSA, 2014). Based on the available data, it was concluded that fluopyram residues are stable in high water content (lettuce, cabbage), high acid content (orange), high oil content (rapeseed) matrices and dry/high starch content (dry pea, wheat grain) commodities for a period of 36 months when stored at −18°C.

It is noted that no specific study is available for the storage stability in seed spices. However, as storage stability was investigated and demonstrated in the four main plant matrix groups for at least 36 months and considering that samples from these crops were stored for a maximum of 5 months at −18°C (Germany, 2022), a significant decline of residues in seed samples is not expected to have occurred. Therefore, no additional storage stability studies are required.

Information on the stability of fluopyram and its metabolite M25 in honey was submitted with the current application (Italy, 2022). It was demonstrated that residues were stable in honey for at least 6 months when stored at −18°C.

1.1.7. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological relevance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2013):

- residue definition for enforcement: 'fluopyram';
- residue definition for risk assessment: 'sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram'.

The same residue definitions are applicable to rotational crops and processed products.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical to the above-mentioned residue definition as well as the residue definitions proposed by the JMPR.

EFSA concluded that these residue definitions are appropriate and applicable to the intended and authorised uses.

In the absence of specific metabolism studies on honey, the studies investigating the nature of residues in primary and rotational crops and studies investigating the degradation of the active substance during pasteurisation are considered to derive the residue definitions for honey; the same residue definitions as mentioned above are therefore proposed.

1.2. Magnitude of residues in plants and honey

1.2.1. Magnitude of residues in primary crops

To support the proposed good agricultural practices (GAPs), three separate applications were submitted and consolidated into this reasoned opinion. These applications included the following crops:

- Kiwi, including residue trials on honey, further reported in Section 1.2.3 (Italy, 2022);
- cardoon, celeries, Florence fennel, rhubarb, palm hearts, bamboo shoots, seed spices and herbal infusions from flowers, leaves and herbs (Germany, 2022);
- soyabean, peanuts and pome fruits (Germany, 2023).

To support the first application, the applicant submitted residue trials performed on kiwi (Italy, 2022).

For the second application, residue trials were conducted on celery, fennel seeds and chamomile flowers. It is noted that an MRL of 40 mg/kg for herbal infusions from leaves, herbs and flowers as well as MRLs of 70 mg/kg for dill seeds and 20 mg/kg for celeries stem have meanwhile been

implemented in the MRL regulation[9] based on a previous EFSA opinion (EFSA, 2019c) and the Article 12 assessment (EFSA, 2020). Thus, the MRL proposals for herbal infusions from flower, leaves and herbs, stem celery and dill seed are no longer necessary and the submitted data were not further evaluated by EFSA.

For the third application on soyabeans, peanuts and pome fruits, the applicant submitted residue trials performed on soyabeans, apples, pears and peanuts. Two different GAPs were provided for peanuts: one involving a combined soil and foliar treatment and another one with two foliar treatments. The EMS identified the GAP with a combined soil and foliar application to be the critical (Germany, 2023). Thus, EFSA limited the assessment only to the critical GAP for peanuts.

A detailed description of the uses evaluated is available in Appendix A.

The samples were analysed for the parent compound and the metabolite fluopyram-benzamide (M25), achieving an LOQ of 0.01 mg/kg per analyte. According to the EMS Italy and the EMS Germany, the methods of analysis used to analyse the residue trial samples were sufficiently validated and were fit for purpose (Italy, 2022; Germany, 2022, 2023). All samples of these residue trials prior to analysis were stored under conditions for which the integrity of the samples has been demonstrated.

Regarding the extraction efficiency of the analytical methods used in the residue trials for high water commodities (celery, apple and pear), the EMS Germany referred to metabolism studies provided in the context of the pesticides peer review and evaluated in the DAR. According to details reported in the DAR (Germany, 2011), the extraction of incurred residues in the metabolism studies was performed with acetonitrile/water (4/1, v/v). In the residue trials, the same extraction solvent system was used (acetonitrile/water 4/1, v/v). The extraction efficiency of the analytical methods for high water content crops used in metabolism studies demonstrated high extraction efficiency (> 89% of TRR) for all matrices. In the case of high acid content crops, an additional surface wash step with acetonitrile was done in the metabolism studies in grapes before the extraction with acetonitrile/water (4/1, v/v). However, in the analytical method used in the kiwi residue trials, the extraction solvent system acetonitrile/water (4/1, v/v) was used without a surface wash with acetonitrile. In the context of the peer review, a radio validation study was provided showing a comparable extraction of the TRR when only acetonitrile/water (4/1, v/v) was used without the surface wash step with acetonitrile (Germany, 2011). Based on the details reported in the DAR, the extraction efficiency in the residue trials of celery, apple, pear and kiwi is considered as being sufficiently proven. It should be noted that the above-mentioned studies were not re-submitted and re-evaluated during the current MRL applications. Therefore, this conclusion may need to be reconsidered in the framework of active substance renewal.

Since the analytical group high oil content is not represented in the metabolism studies, the extraction efficiency of the methods and solvents of the metabolism studies and the residue analytical method cannot be performed. Thus, the extraction efficiency on high oil content crops for the analytical methods used in the residue trials could not be assessed (Germany, 2023) and remains as additional uncertainty.

For matrices that are difficult to analyse, an evaluation of the extraction efficiency would be needed, but it depends on whether the radiolabelled sample material or samples with incurred residues are available (European Commission, 2017), which is not the case for fluopyram.

The results of the individual residue trials, the related risk assessment values (highest residue, median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

1.2.1.1. Pome fruits

An MRL of 0.8 mg/kg was derived for fluopyram in pome fruits during the EFSA review of MRLs according to Article 12 (EFSA, 2020), on the basis of import tolerance GAP in the USA (2 × 250 g/ha, PHI 0 days). This MRL has been implemented in the MRL legislation. Now the applicant applies for a lower MRL of 0.6 mg/kg based on an authorised use of fluopyram in the USA which replaces the previous authorisation for which an import tolerance MRL of 0.8 mg/kg has been derived. The new authorised GAP foresees a longer PHI interval (7 days instead of 0 days). The tolerance in place in the USA is still 0.8 mg/kg[10] and is set for the residue definition 'fluopyram'.

Authorised use in the USA on **pome fruits**: 2 × 250 g a.s./ha, PHI 7 days.

In support of the authorised US use of fluopyram on pome fruits, the applicant provided 23 GAP-compliant trials (17 trials on apples and 6 trials on pears) performed in the US. Two trials were not

[9] Regulation (EU) No 2021/618; Regulation (EU) No 2021/1807.
[10] https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.661

considered independent according to EU Technical guidelines (European Commission, 2020), as they were performed in the same location with dates of application less than 30 days apart. From these trials, the highest value was selected for the residue data set. The number of trials is considered sufficient to derive an MRL proposal of 0.6 mg/kg in support of the authorised GAP of fluopyram on pome fruits in the USA. It is noted that residues of the metabolite M25 were not determined and a conversion factor of 1 was used instead (Germany, 2023). This is not considered a major deficiency considering that:

- In the metabolism study performed with grapes (foliar application), fluopyram represented over 95% of the total radioactive residues (TRR) 18 days after the last treatment (see Section 1.1.1).
- Residues of the metabolite M25 were seen below the LOQ in all samples (< 0.01 mg/kg) of the residue trials performed with apples in Europe.
- The conversion factor for all the fruiting vegetables treated with foliar spray application was set as 1 in the MRL review (EFSA, 2020).

Intended SEU and NEU uses on **apples**: 3 × 150 g a.s./ha, BBCH 51–81, PHI 28 days:

To support the intended uses of fluopyram on apples in NEU and SEU, the applicant provided nine GAP-compliant residue trials on apples (5) and pears (4) from the NEU zone and 10 GAP-compliant residue trials on apples (6) and pears (4) from the SEU. According to EU Technical guidelines (European Commission, 2020), it is acceptable to have a mixed data set with minimum four apples trials and pears to derive an MRL proposal in apples. Overall, the provided data are sufficient to derive an MRL proposal of 0.6 mg/kg in apples for the intended NEU uses and of 0.4 mg/kg for the intended SEU uses. The residues of the metabolite M25 were seen below the LOQ in all samples (< 0.01 mg/kg).

1.2.1.2. Kiwi

In support of the intended SEU use of fluopyram on kiwi the applicant submitted 10 GAP-compliant residue trials performed in Southern Europe (Spain, Portugal, Italy, Southern France, Greece). In line with the decision of the EMS Italy, two trials performed in Portugal were not considered independent as the product was applied within 1 day difference in the same variety of kiwi with the same formulation and application pattern (Italy, 2022); from both trials only the highest value was selected for the residue data set. The number of trials is considered sufficient to derive an MRL proposal of 1.5 mg/kg in support of the intended SEU uses of fluopyram on kiwi. The residues of the metabolite M25 were seen below the LOQ in all samples (< 0.01 mg/kg) except for one where the metabolite was detected at 0.012 mg/kg.

1.2.1.3. Cardoon, rhubarb, Florence fennel, bamboo shoots, palm hearts, 'other' stem vegetables

For the intended indoor and NEU/SEU uses of fluopyram on cardoon, rhubarb, Florence fennel and in support of the intended NEU/SEU uses on bamboo shoots, palm hearts, the applicant submitted 10 GAP-compliant residue trials on celery performed in France (which belongs both to NEU and SEU zones). Three trials were performed in the northern zone of the country and three in the southern zone. The remaining four trials were performed under indoor conditions. The extrapolation of residue data on celery to cardoon, Florence fennel and rhubarb is proposed by the applicant and is considered acceptable in line with the EU technical guidelines (European Commission, 2020). However, the proposed extrapolation is not supported to bamboo shoots, palm hearts and non-specified 'other' stem vegetables, and therefore for these crops, no MRL proposal was derived by the EMS (Germany, 2022). EFSA agrees with the EMS Germany.

The fluopyram residues in the trials range from 0.046 to 0.52 mg/kg for SEU trials, 0.047–0.28 mg/kg for NEU trials and 0.036–5.6 mg/kg for indoor trials. It is noted that three trials per regulatory zone were submitted in support of each of the outdoor GAPs. This number is below the required minimum of four independent trials for minor crop set under Regulation (EU) No 544/2011. To overcome this deficiency, the EMS proposed to combine the three data sets from indoor and outdoor trials for a common MRL setting of 8 mg/kg (Germany, 2022). However, according to the Technical guidelines (European Commission, 2020), indoor and outdoor trials should not be combined, due to greater inherent variability. Sufficient number of trials were available to propose an MRL of 15 mg/kg based on the indoor uses for the residues of fluopyram in cardoon, rhubarb and Florence fennel. The residues of the metabolite M25 were seen below the LOQ in all samples (< 0.01 mg/kg).

1.2.1.4. Peanuts

In support of the authorised GAP of fluopyram in the USA which refers to split soil and foliar application of the active substance, the applicant submitted in total 10 GAP compliant supervised residue trials on peanuts which were performed in the USA. Two trials were not considered independent according to EU Technical guidelines (European Commission, 2020), as the distance between locations was < 20 km and the dates of application less than 30 days apart (Germany, 2023). The highest value among these trials was considered for the residue data set. The data are considered sufficient to derive an MRL proposal of 0.2 mg/kg for fluopyram in peanuts. Residues of the metabolite M25 were in a range between < 0.01 and 0.036 mg/kg. The tolerance for fluopyram in peanuts in the USA is also 0.2 mg/kg.[11]

1.2.1.5. Soyabeans

To support the intended uses in NEU, the applicant provided 12 GAP-compliant residue trials performed in northern Europe (northern France, Germany, Austria and Hungary) on soyabeans. Based on the available residue data, an MRL proposal of 0.3 mg/kg is derived. Residues of the metabolite M25 were seen below the LOQ in all samples (< 0.01 mg/kg). It was noted that the applicant also submitted 8 SEU trials (Germany, 2023), however, as the intended uses are reported only for the NEU zone and a completed data set is available for that region, the SEU trials were not further considered in the present assessment.

1.2.1.6. Seed spices (except dill)

The results of four GAP-compliant supervised residue trials conducted on fennel at various locations in southern France were submitted to support the intended uses in SEU and NEU France. No residue trials were provided for the northern zone (Germany, 2022). Nevertheless, it is noted that the intended uses in France are on minor crops not clearly attached to one zone, and therefore, a complete data set for either NEU or SEU are enough to set an MRL (European Commission, 2020). Furthermore, as proposed by the applicant, the extrapolation of residue data from any representative crop of the seed spice group to the whole group is acceptable based on the Technical guidelines (European Commission, 2020). Overall, the number of trials is considered sufficient to derive an MRL proposal of 40 mg/kg for the whole seed spices group except for dill seed for which a higher import tolerance has already been granted at 70 mg/kg (EFSA, 2020). Residues of benzamide-fluopyram (M25) were below the LOQ of 0.01 mg/kg in all the residue trials except for one trial at 0.016 mg/kg.

1.2.2. Magnitude of residues in rotational crops

The confined rotational crop study previously evaluated (EFSA, 2013) showed that residues of fluopyram cannot be excluded in rotational crops. Several residue field trials conducted in Europe, the USA and Canada were already provided in the framework of the peer review (Germany, 2011; EFSA, 2013) or submitted in the framework of an MRL application (EFSA, 2014). In all these trials, fluopyram was applied on bare soil, or early post-emergence applications on a primary crop at the dose rate of 500 g a.s./ha. Furthermore, an extensive investigation of the potential uptake of residues of fluopyram following multiannual use with rotational field studies was performed in the MRL review and MRL values for rotational crops were derived from the submitted residue trials for the worst-case scenario of crop failure (PBI of 30 days) (EFSA, 2020).

New rotational crop field studies were not submitted under the current MRL application and are not considered necessary. Since none of primary crop GAPs under assessment (on soyabean, cardoons, rhubarb, Florence fennel and seed spices) is more critical than the critical primary crop GAP on strawberries (2 × 250 g a.s./ha) which was evaluated in the MRL review to assess the residue carry-over in rotational crops and to propose MRLs in rotational crops (EFSA, 2020), EFSA does not see now the need to amend existing MRLs for rotational crops. Any contribution from soil uptake due to previous treatments is deemed properly covered (EFSA, 2020).

1.2.3. Magnitude of residues in honey

Investigation of residues in honey is not required according to the data requirements applicable for the assessment of the submitted MRL applications. However, in the context of the MRL application of

[11] https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.661

fluopyram in kiwi, the applicant submitted four independent residue trials performed in northern and southern Europe under semi-field conditions to investigate the residue carry-over from plants to honey. The active substance was applied on *Phacelia tanacetifolia* (treated plot) in two foliar applications at a rate of 250 g a.s./ha with a 7-day interval during the flowering phase. The critical GAP selected by the applicant considered all the EU uses assessed in the MRL review and covers the uses under assessment. The trials are considered valid. Residue data indicate that residues of fluopyram and its metabolites M25, M40, M43, M08 and M45 will not occur above the LOQ of 0.01 mg/kg in honey. The existing EU MRL is set at the default LOQ of 0.05 mg/kg and could potentially be lowered to a lower analytically achievable LOQ of 0.01 mg/kg.

According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. It is noted that the existing guidance document on extraction efficiency (European Commission, 2017) cannot be applied to the honey matrix.

It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/62[12].

1.2.4. Magnitude of residues in processed commodities

Fluopyram and fluopyram-benzamide (M25) were stable under standard hydrolysis conditions simulating pasteurisation, boiling/baking and sterilisation (see Section 1.1.3). The effect of industrial processing and/or household preparation on residue levels in processed commodities was assessed on studies conducted on oranges, grapes, strawberries, tomato, melon, apple, banana, oilseed, potato, sugar beet, peanuts (Germany, 2011; EFSA, 2013). Robust processing factors (fully supported by data) could be derived for grapes (washed grapes, juice, dry and wet pomace, must, wine, and dried raisins) strawberries (jam), tomatoes (peeled and canned fruits, juice), melons (peeled), apples (washed fruits, juice, dry and wet pomace, and sauce), bananas (peeled) and rapeseeds (crude oil, refined oil and meal/press cake). Furthermore, tentative processing factors are available for citrus (pulp, dried pulp and juice), potato tuber (peeled), sugar beet (refined sugar, molasses, dried pulp) and for peanut (meal/pressed cake and refined oil) based on only one study (EFSA, 2020).

Furthermore, in the current applications, the applicant assessed the distribution of residues in the peel and the pulp in four kiwi residue trials (Italy, 2022). The number and quality of the studies is sufficient to derive a robust median peeling factor of 0.07 for kiwi. Given the wide range of crops on which the processing studies are available, further processing studies were not required for the crops under consideration.

An overview of all available processing factors is available in Appendix B.1.2.3.

1.2.5. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation, except for the bamboo shoots and palm hearts (see Appendix B.1.2.1). For honey, the residue trials data indicate that residues above the LOQ of 0.01 mg/kg will not occur, and therefore, risk managers might consider lowering the existing EU MRL, currently set at the default LOQ of 0.05 mg/kg, to a lower analytically achievable limit.

With regard to pome fruits, it is noted that the existing EU MRL (0.8 mg/kg) is higher than the MRL proposal of 0.6 mg/kg derived for apples from the intended NEU use and for pome fruits as derived from the authorised use in the USA. The applicant proposes lowering of the existing EU MRL in the whole group of pome fruits to accommodate a new, less critical authorisation of fluopyram on these crops in the USA. The lowering could be supported, provided that there are no other EU authorisations in place requiring the maintaining of the existing EU MRL. Moreover, the tolerance in place in the USA is 0.8 mg/kg. Further risk management considerations are therefore required (see Appendix B.4).

In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses and the uses authorised in US are likely to pose a consumer health risk.

[12] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

2. Residues in livestock

Apples and soyabeans and their by-products may be used for feed purposes. A livestock dietary burden calculation according to OECD guidance (OECD, 2013) was performed during the MRL review considering the authorised uses in primary crops and the residue contribution from rotational crops (EFSA, 2020). The MRL review calculation was now updated with the new supervised trials media residue (STMR) values derived in the context of this application, to estimate whether the intended use of fluopyram on apples and soyabeans and resulting residues in these feed commodities would have an impact on the residues expected in food of animal origin.

The input values for the exposure calculations for livestock are presented in Appendix D.1.

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.10 mg/kg dry matter (DM) with the main contributors being potato (for cattle, sheep and swine diet) and swede (for poultry diet). The calculated dietary burden was then compared with the intakes which were previously considered by the MRL review to derive the current MRLs for animal commodities (see Appendix B.2). Comparing the results, it is evident that the residues in apple pomace and soyabean meal, seed and hulls have a negligible impact on the existing livestock exposure, and therefore, the modification of the MRLs set for animal commodities is currently not required.

3. Consumer risk assessment

A comprehensive estimate of the dietary exposure of EU consumers was performed in the framework of the review of the existing MRLs for fluopyram according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2020). As fluopyram is a persistent substance that may accumulate in soil following multiannual uses two options were considered in the consumer risk assessment of the MRL review. Option 1 assumed that adequate risk mitigation measures are in place to avoid significant residues in crops grown in rotation with crops treated with fluopyram. On the other hand, option 2 assumed that no risk mitigation measurements were implemented and therefore considered the residues from rotational crops.

The MRLs implemented in the current regulation are based on option 2 of the MRL review (EFSA, 2020). It should be highlighted that the chronic exposure estimated during the MRL review based on option 2 was very close to an ADI of 100% (99.99% of the ADI NL toddler diet) and that a safe scenario could not be concluded by considering Codex maximum residue limits (CXLs) higher than the derived EU MRLs and therefore CXLs were disregarded. Furthermore, for option 2, the major contributors to the chronic exposure were milk (20%), apples (18%) and banana (9%).

The exposure as calculated under option 2 of the MRL review was now updated with the risk assessment values derived from the residue trials on the crops under consideration using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019b). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for fluopyram used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2013). The metabolites included in the risk assessment residue definition were considered not more toxic than the parent compound.

It is noted that the applicant claims that the current MRL for pome fruits (0.8 mg/kg) is based on an out-to-date GAP in the USA and provided new data to propose a lower MRL of 0.6 mg/kg in support of a less critical authorised GAP in the USA. Since there might be other authorised uses on pome fruits in EU requiring maintenance of the existing EU MRL and since the exposure calculations performed by the MRL review identify a very narrow margin of safety, EFSA performed the risk assessment based on two different scenarios for pome fruits:

- Scenario 1: keeping the existing MRL of 0.8 mg/kg (STMR and HR values based on the import tolerance US GAP submitted during the MRL review).
- Scenario 2: lowering of the existing EU MRL to 0.6 mg/kg (STMR and HR values based on a new less critical US use).

The input values used in the exposure calculations are summarised in Appendix D.1.

Short-term (acute) dietary risk assessment

The short-term exposure was performed only for the crops under consideration using the highest residue value as derived from the submitted residue trials. Where necessary, for some crops, the conversion factor (CF) for risk assessment was applied. For honey, the input value was the HR as derived from the residue trials. For kiwi, the peeling factor as derived from the data submitted under the current application was applied. The crops for which the MRL proposal could not be derived, bamboo shoots and palm hearts, were excluded from the calculation. For pome fruits in exposure scenario 1, the input value was the highest residue (0.6 mg/kg; EFSA, 2020) supporting the existing EU MRL of 0.8 mg/kg. In exposure scenario 2, the input value for pome fruit was the highest residue value (0.495 mg/kg) supporting a lower MRL proposal of 0.6 mg/kg as derived on the basis of submitted residue data. The calculated exposure did not exceed the ARfD for any of the crops assessed in this application.

The highest acute consumer exposure for the crops under assessment was calculated for rhubarbs (42% of ARfD) for both scenarios (see Appendix B.3).

Long-term (chronic) dietary risk assessment

Scenario 1: For this scenario, the median residue value (0.2 mg/kg; EFSA, 2020) supporting the existing EU MRL of 0.8 mg/kg in pome fruits was used as an input value. For the remaining crops under consideration and honey, for which the MRL proposals could be made, the STMR values as derived from the submitted residue trials were used as input values. Where necessary, for some crops, the conversion factor (CF) for risk assessment was applied. In addition, peeling factors were applied for kiwi, bananas and melon. The crops on which no uses were reported in the MRL review were excluded from the chronic exposure calculation. A long-term consumer intake concern was identified for the Dutch toddler diet. The total calculated intake accounted for a maximum of 100.29% of the ADI. The major contributors to the chronic exposure in the NL toddler diet were milk (20.91%), apples (17.97%), banana (8.55%), table grapes (7.61%) and pears (7.23%) (see Appendix B.3).

Scenario 2: For this scenario, the median residue value (0.15 mg/kg) supporting a lower MRL proposal of 0.6 mg/kg was used as the input value for pome fruits. For the remaining crops under consideration and honey, for which the MRL proposals could be made, the STMR values as derived from the submitted residue trials were used as input values. Where necessary, for some crops, the conversion factor (CF) for risk assessment was applied. In addition, peeling factors were applied to kiwi, bananas and melon. The crops on which no uses were reported in the MRL review were excluded from the chronic exposure calculation. The highest estimated long-term dietary intake accounted for 92.1% of the ADI (NL toddler diet). The major contributors to the chronic exposure were milk (20.91%), apples (12.13%) and banana (8.55%) (see Appendix B.3).

A detailed description of the contribution of the crops under assessment to the Dutch toddler diet (The highest estimated long-term dietary intake) is presented in Appendix B.3.1. It should be noted that specific consumption data are not available for NL toddler for medlar, loquats, cardoon, rhubarb and seed spices. Therefore, the residues in these crops do not affect the chronic exposure for the Dutch toddler diet.

Based on the outcome of the chronic risk assessment performed with both scenarios, it can be concluded that scenario 1 presents a consumer intake concern as the ADI was exceeded (100.29% of the ADI NL toddler). Nevertheless, scenario 2 did not result in an exceedance of the ADI (92.1% of the ADI NL toddler), and therefore, it is considered that the risk to consumers is unlikely.

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

4. Conclusion and recommendations

The data submitted in support of these MRL applications were found to be sufficient to derive an MRL proposal for the commodities under evaluation, except for bamboo shoots and palm hearts. For honey, the residue trials data indicate that residues above the LOQ of 0.01 mg/kg will not occur, and therefore, risk managers might consider lowering the existing EU MRL, currently set at the default LOQ of 0.05 mg/kg, to a lower analytically achievable limit.

With regard to pome fruits, it is noted that the applicant proposes to lower the current MRL of 0.8 mg/kg to 0.6 mg/kg. The applicant claims that the authorised US GAP supporting the existing EU MRL of 0.8 mg/kg is no longer in use and has been replaced by a less critical authorised GAP, for which residue data indicate that a lower MRL of 0.6 mg/kg would be sufficient. Since there might be

other uses authorised in the EU that require maintaining of the existing EU MRL in pome fruits and since a very narrow margin of safety was identified in the chronic exposure calculated by the MRL review with a high contribution of apples, EFSA performed the consumer risk assessment following two different scenarios. In scenario 1, the existing EU MRL in pome fruit remained whereas in scenario 2, the existing MRL in pome fruits was lowered to 0.6 mg/kg as proposed by the applicant and supported by submitted residue data under the present assessment.

EFSA concludes that acute consumer intake concerns are unlikely for the crops under consideration. For the chronic exposure, when the existing EU MRL for pome fruits along with the new MRL proposals for other commodities are considered, the long-term consumer intake concerns cannot be excluded for NL toddler diet. Lowering of the existing EU MRL in pome fruits from 0.8 mg/kg to 0.6 mg/kg would result in a lower long-term exposure for which no consumer health risks are identified for the NL toddler diet. No specific consumption data is available for NL toddlers for medlar, loquats, cardoon, rhubarb and seed spices, and therefore, these crops do not affect the chronic exposure in any of the two scenarios.

As there might be other EU authorisations in place requiring the existing EU MRL of 0.8 mg/kg in pome fruits and the current MRL in the USA is still 0.8 mg/kg, further risk management consideration is required to lower the existing EU MRL in pome fruits. Furthermore, it should be taken into account that the current CXL for fluopyram in pome fruits is 0.5 mg/kg[13] (FAO, 2012), which is lower than the MRL current implemented in the EU regulation and the MRL proposed in this application. It is also noted that for some crops, the existing MRLs are set on a tentative basis following the outcome of the MRL review. Therefore, the conclusions reported in this reasoned opinion might need to be reconsidered after the assessment of the confirmatory data following the MRL review according to Article 12 of Regulation No 396/2005.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
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
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	pre-harvest interval
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
SC	suspension concentrate
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – Summary of intended and authorised GAPs triggering the amendment of existing EU MRLs

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages and 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		
Apples	NEU	F	*Venturia inaequalis, Podosphaera leucotricha*	WG	50	Foliar application	51–81	1–3	7–12	10–30	300–1,500	150	g a.s./ha	28	For SDHI resistance management, it is recommended to alternate products. The interval between application might be longer in field.
Apples	SEU	F	*Venturia inaequalis, Podosphaera leucotricha*	WG	50	Foliar application	51–81	1–3	7–12	10–30	300–1,500	150	g a.s./ha	28	For SDHI resistance management, it is recommended to alternate products. The interval between application might be longer in field.
Apples	NEU (NL)	F	*Venturia inaequalis, Podosphaera leucotricha*	WG	50	Foliar application	71–81	1–2	7–12	10–30	300–1,500	150	g a.s./ha	28	For SDHI resistance management, it is recommended to alternate products. The interval between application might be longer in field.
Apples	USA	F	*Podosphaera leucotricha*	SC	500	Foliar application	81–87	1–2	7–14		500–2,800	87.5–250	g a.s./ha	7	US Label rate: 2.4 to 6.84 fl oz/acre. Do not apply more than 13.7 fl oz of LUNA PRIVILEGE (0.446 lbs Fluopyram) per acre per year, regardless of formulation or method of application.
Pears	USA	F	*Podosphaera leucotricha*	SC	500	Foliar application	81–87	1–2	7–14		500–2,800	87.5–250	g a.s./ha	7	US Label rate: 2.4 to 6.84 fl oz/acre. Do not apply more than 13.7 fl oz of LUNA PRIVILEGE (0.446 lbs Fluopyram) per acre per year, regardless of formulation or method of application.
Quinces	USA	F	*Podosphaera leucotricha*	SC	500	Foliar application	81–87	1–2	7–14		500–2,800	87.5–250	g a.s./ha	7	US Label rate: 2.4 to 6.84 fl oz/acre. Do not apply more than 13.7 fl oz of LUNA PRIVILEGE (0.446 lbs Fluopyram) per acre per year, regardless of formulation or method of application.

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages and 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		
Medlar	USA	F	*Podosphaera leucotricha*	SC	500	Foliar application	81–87	1–2	7–14		500–2,800	87.5–250	g a.s./ha	7	US Label rate: 2.4 to 6.84 fl oz/acre. Do not apply more than 13.7 fl oz of LUNA PRIVILEGE (0.446 lbs Fluopyram) per acre per year, regardless of formulation or method of application.
Loquats/ Japanese medlars	USA	F	*Podosphaera leucotricha*	SC	500	Foliar application	81–87	1–2	7–14		500–2,800	87.5–250	g a.s./ha	7	US Label rate: 2.4 to 6.84 fl oz/acre. Do not apply more than 13.7 fl oz of LUNA PRIVILEGE (0.446 lbs Fluopyram) per acre per year, regardless of formulation or method of application.
Kiwi	SEU (FR, IT, EL)	F	B1: *Botrytis cinerea* (BOTRCI) *Pseudomonas syringae actinidiae – PSA* (PSDMAK) B2: *Botrytis cinerea* (BOTRCI)	WG	50 (Fluopyram)	Foliar spraying	B1: 51–75 B2: 80–87	B1: 2 B2: 1 Total per season:3	B1: 14 B2: 60–120 after B1	15–60	250–1,000	150	g a.s./ha	7	Application per crop/ season: 450 g/ha
Cardoons	NEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Cardoons	SEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Cardoons	EU (FR)	G	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Celeries	NEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	An MRL of 20 mg/kg for celeries was already implemented in the MRL regulation based on the MRL review (EFSA, 2020). An MRL proposal is no longer necessary (Germany, 2022).
Celeries	SEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Celeries	EU (FR)	G	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Florence fennels	NEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Florence fennels	SEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Florence fennels	EU (FR)	G	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages and 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		
Rhubarbs	NEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Rhubarbs	SEU (FR)	F	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Rhubarbs	EU (FR)	G	Fungi	SC	250	Foliar spraying	41–49	1				125–150	g a.s./ha	7	
Bamboo shoots	NEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	7	
Bamboo shoots	SEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	7	
Palm hearts	NEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	7	
Palm hearts	SEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	7	
Peanuts/ groundnuts	USA	F	Early leaf spot (*Cercospora arachidicola*) Late leaf spot (*Cercosporidium personatum*)	SC	500	Soil application+ Foliar (broadcast, aerial)	00/85–89	1–2	120–150		30–50 (soil) + 100–200 (foliar)	200–250	g a.s./ha	7	US Label rate: 5.6 to 6.84 fl oz/acre (foliar); 4.0 to 6.84 fl oz/acre (soil). Max 13.7 fl oz/acre/year (500 g a.i./ha) Soil application 250 g a.s./ha: treated seeds or in furrow or band application. GAP selected by the EMS as the more critical GAP for peanuts among the GAPs to be tested (Germany, 2023).
Peanuts/ groundnuts	USA	F	Early leaf spot (*Cercospora arachidicola*) Late leaf spot (*Cercosporidium personatum*)	SC	500	Foliar application	85–89	1–2	14		100–200	200–250	g a.s./ha	7	5.6 to 6.84 fl oz/acre (foliar) Maximum total per year for all uses is 13.7 fl oz/acre (0.50 kg a.s./ha).
Soyabeans	NEU	F	*Sclerotinia sclerotiorum Diaporthe phaseolorum*	SE	125	Foliar application	51–79	1–2	14	30–60	200–400	125	g a.s./ha	28	Registration pending the current MRL modification claim.
Anise/ aniseed	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Anise/ aniseed	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment				PHI (days)[d]	Remarks
				Type[b]	Conc. a.s. (g/kg)	Method kind	Range of growth stages and 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		
Black caraway/ Black cumin	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Black caraway/ black cumin	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Coriander seed	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Coriander seed	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Celery seed	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Celery seed	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Cumin seed	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Cumin seed	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Fennel seed	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Fennel seed	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Fenugreek	NEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Fenugreek	SEU (FR)	F	Fungi	SC	250	Foliar spraying	31–89	1				125–150	g a.s./ha	3	
Herbal infusions from (a) flowers (b) leaves and herbs	NEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	14	An MRL of 40 mg/kg for herbal infusions from flowers, leaves and herbs was already implemented in the MRL regulation based on a previous EFSA opinion (EFSA, 2019c). An MRL proposal is no longer necessary (Germany, 2022).
Herbal infusions from (a) flowers (b) leaves and herbs	SEU (FR)	F	Fungi	SC	250	Foliar spraying		1				125–150	g a.s./ha	14	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water dispersible granule; SC: suspension concentrate; SE: suspension emulsion; SDHI: succinate dehydrogenase inhibitor.

(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 preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Grapes	Foliar, 1 × 100 + 2 × 200 g a.s./ha	18–19	Radiolabelled active substance: Phenyl-UL-14C and Pyridyl-2,6-14C (Germany, 2011; EFSA, 2013)
		Peppers	Drip irrigation, 5 and 20 mg/plant	55–97	
	Root crops	Potatoes	Foliar, 3 × 167 g a.s./ha	51	
	Pulses/ oilseeds	Beans	Foliar, 2 × 250 g a.s./ha	4–29	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnips	Bare soil, 534 or 514 g a.s./ha	30, 139, 280	Phenyl-UL-14C and Pyridyl-2,6-14C (Germany, 2011; EFSA, 2013). Rotational crop study on cereals surrogate for primary seed treatment.
	Leafy crops	Swiss chards	Bare soil, 534 or 514 g a.s./ha	30, 139, 280	
	Cereal (small grain)	Spring wheat	Bare soil, 534 or 514 g a.s./ha	30, 139, 280	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Fluopyram, M08, M25 and M43 are stable. M40 is not stable, but not expected in the RAC in significant levels (Germany, 2011; EFSA, 2013).
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		
	Sterilisation (20 min, 120°C, pH 6)		Yes		

Can a general residue definition be proposed for primary crops?	Yes	Also covering seed treatment and local treatment (pre-forcing for witloof) (EFSA, 2020).
Rotational crop and primary crop metabolism similar?	Yes	The metabolic pathway is similar in all primary as well as rotational crops. Fluopyram is the major constituent of the residue. Some metabolites were only found in rotational crops (M45) and others were observed in higher proportions than in primary crops (M08) (EFSA, 2013).

Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	–
Plant residue definition for monitoring (RD-Mo)	Fluopyram	
Plant residue definition for risk assessment (RD-RA)	Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content (lettuce), high oil content (oilseed rape), high acid content (orange) and dry matrices (wheat grain, peas seed): • DFG S19 (EN 12393) method, GC-MS, LOQ 0.01 mg/kg. Confirmatory method and ILV available (EFSA, 2013). • QuEChERS method in high water and high acid content commodities with an LOQ of 0.002 mg/kg and in high oil content and dry commodities with an LOQ of 0.01 mg/kg (EFSA, 2020). Difficult matrix: hops (dried cone), coffee (green beans), black tea, cocoa (green beans) and coriander seeds. • HPLC–MS/MS, method 01584 according to the QuEChERS procedure, LOQ 0.01 mg/kg. Confirmatory method and ILV available (Germany, 2022). Honey • HPLC–MS/MS method 01594, LOQ 0.01 mg/kg. Confirmatory method and ILV available (Italy, 2022).	

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; RAC: raw agricultural commodity; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry.

B.1.1.2. Stability of residues in plants and honey

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Lettuce, cabbage	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
		Lettuce	−18°C	34	Months	M40, M43, M08, M45	EFSA (2013)
	High oil content	Rapeseed	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
		Rapeseed	−18°C	24	Months	M40, M43	EFSA (2013)
	High protein content	Dry pea, wheat grain	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
		Wheat grain, dry pea	−18°C	24	Months	M40, M43, M08, M45	EFSA (2013)
	High acid content	Orange	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
		Orange, grapes	−18°C	6	Months	M40, M43	EFSA (2013)
Products of animal origin (available studies)	–	Honey	−18°C	6	Months	Fluopyram, M25	Italy (2022)

B.1.2. Magnitude of residues in plants

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

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Apples	NEU	**Mo:** 0.07; 0.07; 0.01; 0.10; 0.11; 0.12; 0.14; 0.24; 0.40 **RA:** 0.08; 0.08; 0.11; 0.11; 0.12; 0.13; 0.15; 0.25; 0.41	Residue trials on apples and pears compliant with GAP were merged (Germany, 2023). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials. Residue results of trials on pears are underlined.	0.6	**Mo:** 0.40 **RA:** 0.41	**Mo:** 0.11 **RA:** 0.12	1
	SEU	**Mo:** 0.06; 0.07; 0.07; 0.08; 0.09; 0.11; 0.13; 2 × 0.16; 0.17 **RA:** 0.07; 0.08; 0.08; 0.09; 0.10; 0.12; 0.14; 2 × 0.17; 0.18	Residue trials on apples and pears compliant with GAP were merged (Germany, 2023). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials. Residue results of trials on pears are underlined.	0.4	**Mo:** 0.17 **RA:** 0.18	**Mo:** 0.10 **RA:** 0.11	1
Pome fruits	US	**Mo:** 0.06; 0.06; 4 × 0.07; 0.09; 0.11[e]; 0.12; 0.13; 0.13; 0.14; 0.16; 2 × 0.17; 0.19; 0.20; 0.20; 0.21; 0.23; 0.25; 0.50 **RA:** –	Residue trials on apples and pears compliant with the authorised GAP were merged (Germany, 2023). Only residues of parent fluopyram were determined. To express residues in for risk assessment, a CF of 1 was used. Residue results of trials on pears are underlined. Extrapolation of residue data on apples and pears to the whole group of pome fruit is acceptable (European Commission, 2020).	0.6	**Mo:** 0.50 **RA:** 0.50	**Mo:** 0.14 **RA:** 0.14	1
Kiwi	SEU	**Mo:** 0.19; 0.23; 0.29; 2 × 0.33; 0.4; 0.43[e]; 0.46; 0.49; 0.52 **RA:** 0.20; 0.24; 0.30; 2 × 0.34; 0.41; 0.44[e]; 0.47; 0.50; 0.53	Residue trials on kiwi compliant with intended GAP (Italy, 2022). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials.	1.5	**Mo:** 0.52 **RA:** 0.53	**Mo:** 0.33 **RA:** 0.34	1
Cardoon, Florence fennel, rhubarb, palm hearts, bamboo shoots	NEU	**Mo:** 0.047; 0.12; 0.28 **RA:** 0.057; 0.13; 0.29	Residue trials on celery compliant with the intended GAPs (Germany, 2022). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials. The extrapolation of residue data on celery is acceptable to cardoon, Florence fennel and rhubarb. Extrapolation to palm hearts and bamboo shoots is not acceptable (European Commission, 2020).	0.7[f]	**Mo:** 0.28[f] **RA:** 0.29[f]	**Mo:** 0.12[f] **RA:** 0.13[f]	1
	SEU	**Mo:** 0.046; 0.094; 0.52 **RA:** 0.056; 0.10; 0.53		1.5[f]	**Mo:** 0.52[f] **RA:** 0.53[f]	**Mo:** 0.094[f] **RA:** 0.10[f]	1

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Cardoon, Florence fennel, rhubarb	EU	**Mo:** 0.036; 0.14; 0.55; 5.6 **RA:** 0.046; 0.15; 0.56; 5.6	Residue trials on celery compliant with the intended GAPs (Germany, 2022). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials. The extrapolation of residue data on celery is acceptable to cardoon, Florence fennel and rhubarb.	15	**Mo:** 5.6 **RA:** 5.6	**Mo:** 0.35 **RA:** 0.36	1
Peanuts/groundnuts	US	**Mo:** 0.012; 0.015[e]; 2 × 0.032; 0.033; 0.042; 0.043; 0.047; 0.052; 0.13 **RA:** 0.022; 0.025[e]; 2 × 0.042; 0.043; 0.044; 0.052; 0.053; 0.059; 0.17	Residue trials on peanuts compliant with the authorised GAP (Germany, 2023). Residues of the metabolite benzamide-fluopyram (M25) were in a range between < 0.01 and 0.036 mg/kg.	0.2	**Mo:** 0.13 **RA:** 0.17	**Mo:** 0.033 **RA:** 0.043	1.3
Soyabean	NEU	**Mo:** < 0.01; 0.012; 0.015; 0.026; 0.035; 0.042; 0.054; 0.057; 0.062; 0.064; 0.091; 0.18 **RA:** < 0.02; 0.022; 0.025; 0.036; 0.045; 0.052; 0.064; 0.067; 0.072; 0.074; 0.1; 0.19	Residue trials on soyabean compliant with the intended GAP (Germany, 2023). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials.	0.3	**Mo:** 0.18 **RA:** 0.19	**Mo:** 0.048 **RA:** 0.058	1
Seed spices (except dill)	NEU	No data	Residue trials on fennel compliant with intended GAP (Germany, 2022). Residues of benzamide-fluopyram (M25) were below the LOQ in all the residue trials except for one trial at 0.016 mg/kg. The extrapolation of residue data in fennel seed to the whole group of seed spices is acceptable. The intended uses in France are on minor crops not clearly reattached to one zone and therefore a complete data set for either NEU or SEU are enough to set an MRL (European Commission, 2020).	40	**Mo:** 13.2 **RA:** 13.2	**Mo:** 6.8 **RA:** 6.8	1
	SEU	**Mo:** 1.8; 1.9; 11.7; 13.2 **RA:** 1.8; 1.9; 11.7; 13.2					

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Honey	EU	**Mo:** 4 × < 0.01 **RA:** 4 × < 0.02	Northern and southern Europe semi-field trials on *Phacelia tanacetifolia* treated with 2 × 250 g a.s./ha with a 7-day interval during the flowering phase via foliar application. The number of trials is sufficient to derive an MRL in honey	0.01*	**Mo:** 0.01 **RA:** 0.02	**Mo:** 0.01 **RA:** 0.02	1

MRL: maximum residue level; GAP: Good Agricultural Practice; LOQ: limit of quantification; Mo: monitoring; RA: risk assessment.
*: Indicates that the value is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor EU trials, 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.
(e): Maximum residue value taken from two non-independent trials.
(f): The number of trials is below the required minimum of four independent trials for minor crop set under regulation 544/2011. MRL, HR and STMR values are only indicative.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	Residues in wheat grain, straw, hay and forage, Swiss chard and turnips cannot be excluded. Significant residues were observed even at 280 DAT in all crops (up to 1.97 mg eq/kg in straw) following ~500 g a.s./ha bare soil application, which based on PEC soil, is 1.2N compared the NEU critical GAP on strawberries (foliar, 2 × 250g/ha) (EFSA, 2020).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes	Yes, unless appropriate risk mitigation measures are implemented at national level residues above 0.01 mg/kg in the edible part of crops cannot be excluded; In cereal straw and forage even after 286 days residues may still be expected, however, the contribution of residues compared to primary uses is limited (< 25% of residues from primary uses) (EFSA, 2020).

DAT: days after treatment; eq: residue expressed as a.s. equivalent; a.s.: active substance; PEC: predicted environmental concentrations; NEU: northern European Union;
GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/ Source
		Individual values	Median PF		
Orange, pulp	1	0.16	0.16	–	Tentative[c] (EFSA, 2011)
Orange, juice	1	0.01	0.01	–	Tentative[c] (EFSA, 2011)
Orange, dried pulp	1	0.93	0.93	–	Tentative[c] (EFSA, 2011)
Grape, washed berries	4	0.5; 0.59; 0.66; 0.74	0.62	1.05	EFSA (2011)
Wine grapes, juice	4	0.1; 0.12; 0.14; 0.16; 0.54	0.14	1.2	EFSA (2011), Germany (2011)
Wine grapes, dry pomace	4	4.83; 5.88; 7.24; 7.50	6.56	1	Germany (2011)
Wine grapes, wet pomace	4	2.24; 3.14; 3.62; 3.89	3.38	1	EFSA (2011); Germany (2011)
Wine grapes, must	6	0.21; 2x 0.22; 0.31; 0.68, 1.08	0.26	1.1	Germany (2011)
Wine grapes, red wine (unheated)	4	0.14; 0.17; 0.19; 0.20	0.18	1.2	Germany (2011)
Wine grapes, white wine	2	0.64; 0.74	0.69	1	Germany (2011)
Table grapes, dried (raisins)	4	2; 2.44; 2.88; 3.2; 6.56	3.04	1	Germany (2011)
Strawberries, jam	4	0.28; 0.58; 0.63; 0.64	0.61	1.1	Germany (2011)

Processed commodity	Number of valid studies[a]	Processing Factor (PF)		CF_P[b]	Comment/ Source
		Individual values	Median PF		
Tomatoes, peeled and canned	5	0.07; 0.18; 0.21; 0.25; 0.33	0.21	1.3	Germany (2011)
Tomatoes, juice	5	0.09; 0.27; 0.42; 0.44; 0.56	0.42	1.15	Germany (2011)
Melons, peeled	18	0.03; 0.05; 2x 0.06; 0.08, 0.09; 2x 0.11; 4x 0.13; 0.17; 0.20; 2x 0.25; 0.50	0.13	1	EFSA (2011)
Apples, washed	5	0.36; 0.43; 0.55; 0.7; 1.38	0.55	1	EFSA (2011)
Apples, juice	5	0.05; 2x 0.09; 0.13; 0.44	0.09	1.00	EFSA (2011)
Apples, dry pomace	4	5.45; 5.71; 7.64; 11.88	6.68	1.01	EFSA (2011)
Apples, wet pomace	5	1.73; 1.24; 2.26; 4.13; 2.45;	2.26	1.05	EFSA (2011)
Apples, sauce	5	0.01; 0.24; 2x 0.36; 0.63	0.36	1.30	EFSA (2011)
Bananas, peeled	4	0.82; 1.47; 0.44; 1.15	0.98	1.2	EFSA (2011)
Rapeseeds, crude oil	4	1.00; 1.25; 1.27; 2.14	1.26	1.12	EFSA (2011)
Rapeseeds, refined oil	4	0.64; 0.83; 1.00; 1.71	0.92	1.17	EFSA (2011)
Rapeseeds, meal/ press cake	4	0.67; 0.71; 0.75; 1.27	0.73	1.29	EFSA (2011)
Potato tuber, peeled	1	0.67	0.67	–	Tentative[c] (EFSA, 2011)
Sugar beet, refined sugar	1	1.27	1.27	–	Tentative[c] (EFSA, 2011)
Sugar beet, molasses	1	0.92	0.92	–	Tentative[c] (EFSA, 2011)
Sugar beet, pulp (dried)	1	1.27	1.27	–	Tentative[c] (EFSA, 2011)
Peanut, meal/ press cake	1	0.19	0.19	–	Tentative[c] (EFSA, 2011)
Peanut, refined oil	1	0.24	0.24	–	Tentative[c] (EFSA, 2011)
Kiwi, peeled	4	0.05; 0.05; 0.08; 0.13	0.07	–	Italy (2022)

PF: Processing factor (= Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).
CFp: Conversion factor for risk assessment in processed commodity (= Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo).
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Median of the individual conversion factors for each processing residues trial.
(c): A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N) 0.1 mg/kg DM	Previous Assessment (EFSA, 2020)
	mg/kg bw per day		mg/kg DM					Max burden
	Median	Maximum	Median	Maximum				mg/kg DM
Cattle (all)	0.074	0.092	2.48	3.13	Dairy cattle	Potato, process waste	Yes	3.13
Cattle (dairy only)	0.074	0.092	1.93	2.39	Dairy cattle	Potato, process waste	Yes	2.39
Sheep (all)	0.083	0.101	2.50	3.04	Ram/Ewe	Potato, process waste	Yes	3.04
Sheep (ewe only)	0.083	0.101	2.50	3.04	Ram/Ewe	Potato, process waste	Yes	3.04
Swine (all)	0.037	0.051	1.61	2.21	Swine (breeding)	Potato, process waste	Yes	2.21
Poultry (all)	0.049	0.061	0.72	0.90	Poultry layer	Swede, roots	Yes	0.90
Poultry (layer only)	0.049	0.061	0.72	0.90	Poultry layer	Swede, roots	Yes	0.90

bw: body weight; DM: dry matter.

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

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

B.3. Consumer risk assessment

ARfD	0.5 mg/kg bw (European Commission, 2013)
Highest IESTI, according to EFSA PRIMo	**Scenario 1 without risk mitigation measures:** Rhubarbs: 42% of ARfD Florence fennels: 18% of ARfD Pears: 17% of ARfD Apples: 13% of ARfD Quinces: 3% of ARfD Medlar: 2% of ARfD Fennel seed: 2% of ARfD Other commodities under consideration: exposure individually less than 1% of the ARfD **Scenario 2 with risk mitigation measures:** Rhubarbs: 42% of ARfD Florence fennels: 18% of ARfD Pears: 14% of ARfD Apples: 11% of ARfD Quinces: 2% of ARfD Fennel seed: 2% of ARfD Other commodities under consideration: exposure individually less than 1% of the ARfD
Assumptions made for the calculations	**Scenario 1:** The short-term exposure was performed only for the crops under consideration, and honey, using the highest residue value as derived from the submitted residue trials. Where necessary, for some crops the conversion factor (CF) for risk assessment was applied. For kiwi the peeling factor as derived from the data submitted under the current application was applied. The crops for which the MRL proposal could not be derived, bamboo shoots and palm hearts, were excluded from the calculation. No acute exposure calculation could be performed for "other" seed spices as specific consumption data are not available. For pome fruit the input value used in scenario 1 was the highest residue (0.6 mg/kg; EFSA, 2020) supporting the existing EU MRL of 0.8 mg/kg. **Scenario 2:** The short-term exposure was performed only for the crops under consideration using the highest residue value as derived from the submitted residue trials. Where necessary, for some crops the conversion factor (CF) for risk assessment was applied. For kiwi the peeling factor as derived from the data submitted under the current application was applied. The crops for which the MRL proposal could not be derived, bamboo shoots and palm hearts, were excluded from the calculation. No acute exposure calculation could be performed for "other" seed spices as specific consumption data are not available. For pome fruit in exposure scenario 2 the input value was the highest residue value (0.5 mg/kg) supporting a lower MRL proposal of 0.6 mg/kg as derived with the submitted residue data. Calculations performed with PRIMo revision 3.1

ADI	0.012 mg/kg bw (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	**Scenario 1 without risk mitigation measures:** 100.29% ADI (NL toddler diet) Highest contribution of crops assessed: Apples: 20.8% of ADI (DE child) Pears: 7.23% of ADI (NL toddler) Soyabeans: 1.79% of ADI (GEMS/Food G11) Rhubarbs: 0.73% of ADI (IE adult) Coriander seed: 0.57% of ADI (DE child) Celery seed: 0.57% of ADI (DE child) Fennel seed: 0.57% of ADI (DE child) Anise/aniseed: 0.57% of ADI (DE child) Nutmeg: 0.57% of ADI (DE child) Cumin seed: 0.57% of ADI (DE child) Other spices (seeds): 0.36% of ADI (FR toddler 2 3 yr) Florence fennels: 0.29% of ADI (IT adult) Kiwi: 0.18% of ADI (NL toddler) Cardoons: 0.17% of ADI (GEMS/Food G08) Medlar: 0.14% of ADI (GEMS/Food G15) Loquats/Japanese medlars: 0.11% of ADI (GEMS/Food G10) Peanuts/groundnuts: 0.10% of ADI (NL child) Quinces: 0.06% of ADI (RO general) Black caraway/black cumin: 0.03% of ADI (DE women) Fenugreek: <0.01% of ADI (DE women) **Scenario 2 with risk mitigation measures:** 92.1% ADI (NL toddler diet) Highest contribution of crops assessed: Apples: 14.04% of ADI (DE child) Pears: 4.88% of ADI (NL toddler) Soyabeans: 1.79% of ADI (GEMS/Food G11) Rhubarbs: 0.73% of ADI (IE adult) Coriander seed: 0.57% of ADI (DE child) Celery seed: 0.57% of ADI (DE child) Fennel seed: 0.57% of ADI (DE child) Anise/aniseed: 0.57% of ADI (DE child) Nutmeg: 0.57% of ADI (DE child) Cumin seed: 0.57% of ADI (DE child) Other spices (seeds): 0.36% of ADI (FR toddler 2 3 yr) Florence fennels: 0.29% of ADI (IT adult) Kiwi: 0.18% of ADI (NL toddler) Cardoons: 0.17% of ADI (GEMS/Food G08) Peanuts/groundnuts: 0.10% of ADI (NL child) Medlar: 0.09% of ADI (GEMS/Food G15) Loquats/Japanese medlars: 0.07% of ADI (GEMS/Food G10) Quinces: 0.04% of ADI (RO general) Black caraway/black cumin: 0.03% of ADI (DE women) Fenugreek: <0.01% of ADI (DE women)
Assumptions made for the calculations	**Scenario 1:** The long-term exposure assessment was calculated by updating the risk assessment of the recent comprehensive MRL review (EFSA, 2020). For pome fruits in scenario 1, the STMR value (0.2 mg/kg; EFSA, 2020) supporting the existing EU MRL of 0.8 mg/kg was

used as an input value. For the remaining crops under consideration, and for honey, for which the MRL proposals could be made, the STMR values as derived from the submitted residue trials were used. Where necessary, for some crops the conversion factor (CF) for risk assessment was applied. In addition, peeling factors were applied for kiwi, bananas and melon. The crops on which no uses were reported in the MRL review were excluded from the chronic exposure calculation.

Scenario 2:

The long-term exposure assessment was calculated by updating the risk assessment values derived in the recent comprehensive MRL review (EFSA, 2020). For pome fruits in scenario 1, the STMR value (0.14 mg/kg) supporting a lower MRL proposal of 0.6 mg/kg were used as input value. For the remaining crops under consideration, and for honey, for which the MRL proposals could be made, the STMR values as derived from the submitted residue trials were used. Where necessary, for some crops the conversion factor (CF) for risk assessment was applied. In addition, peeling factors were applied for kiwi, bananas and melon. The crops on which no uses were reported in the MRL review were excluded from the chronic exposure 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.

B.3.1. Contribution of the crops under assessment to the Dutch toddler diet

Crop	Scenario 1: % ADI, NL toddler diet	Scenario 2: % ADI, NL toddler diet
Apples	17.97	12.13
Pears	7.23	4.88
Quinces	0.01	–
Medlars	No consumption data	No consumption data
Loquats/Japanese medlars	No consumption data	No consumption data
Soyabeans	0.08	0.08
Peanuts	0.05	0.05
Cardoons	No consumption data	No consumption data
Rhubarbs	No consumption data	No consumption data
Florence fennels	0.02	0.02
Seed spices (except dill)	No consumption data	No consumption data
Kiwis	0.18	0.18

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
130010	Apples	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the intended NEU and authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in apples is 12.13% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in apples to the NL toddler diet is 17.97% of the ADI.
130020	Pears	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in pear is 4.88% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in pears to the NL toddler diet is 7.23% of the ADI.
130030	Quinces	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. Under this MRL scenario, the contribution of residues in quinces is 0.01% of the ADI for the NL toddler diet. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. Under this MRL scenario, the contribution of residues in quinces $<$ 0.01% of the ADI for the NL toddler diet.
130040	Medlar	0.8	0.6 or 0.8 Further risk management considerations are required	The submitted data are sufficient to support the proposal of the applicant to lower the existing EU MRL to 0.6 mg/kg in support of the authorised US uses. Acute and chronic risk for consumers is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of new MRL proposals for the crops under consideration in this assessment. However, as medlar and loquats do not contribute to the NL toddler diet for which chronic consumer intake concerns were identified, the existing MRL in these commodities is not associated with consumer exposure concerns.
130050	Loquats/ Japanese medlars	0.8		

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
0162010	Kiwi	0.01*	1.5 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 1.5 mg/kg for the SEU use. No acute intake concerns are identified. A long-term consumer intake concern for NL toddler diet is identified if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of the new MRL proposal in kiwi. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in kiwi account for 0.18% of the ADI for NL toddler diet, if the existing MRL is raised to 1.5 mg/kg.
270020	Cardoons	0.01*	15	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use on cardoons. Risk for consumers from short-term intake of residues of fluopyram from cardoon is unlikely. Since cardoon does not contribute to the NL toddler diet for which chronic intake concerns were identified, the proposed MRL in this commodity is not associated with consumer exposure concerns.
270040	Florence fennels	0.01*	15 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use. Risk for consumers from short-term intake of residues of fluopyram from Florence fennel is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg in pome fruits is maintained along with the implementation of the new MRL proposal in Florence fennel. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg the chronic risk for consumers is considered unlikely. The residues in Florence fennel account for 0.02% of the ADI for the NL toddler diet if the existing MRL is raised to 15 mg/kg.
270070	Rhubarbs	0.01*	15	The submitted data are sufficient to derive an MRL proposal of 15 mg/kg based on the intended indoor use on rhubarbs. Risk for consumers from short-term intake of residues of fluopyram is unlikely. Since rhubarb does not contribute to the NL toddler diet for which chronic intake concerns were identified, the proposed MRL in this commodity is not associated with consumer exposure concerns.
270080	Bamboo shoots	0.01*	No MRL proposal	The submitted data are not sufficient to derive an MRL proposal for the intended NEU/SEU use.
270090	Palm hearts	0.01*	No MRL proposal	The submitted data are not sufficient to derive an MRL proposal for the intended NEU/SEU use.
401020	Peanuts/ groundnuts	0.02	0.2 Further risk management considerations are required	The submitted data are sufficient to calculate an import tolerance (US GAP) of 0.2 mg/kg for peanuts. Risk for consumers from short-term intake of residues of fluopyram is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of the new MRL proposal in peanuts. If

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
				the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in peanuts account for 0.05% of the ADI for NL toddler diet if the existing MRL is raised to 0.2 mg/kg.
401070	Soyabeans	0.2	0.3 Further risk management considerations are required	The submitted data are sufficient to derive an MRL proposal of 0.3 mg/kg for the intended NEU use. Risk for consumers from short-term intake of residues of fluopyram from soyabeans is unlikely. A long-term consumer intake concern is identified for the NL toddler diet if the current MRL of 0.8 mg/kg of pome fruits is maintained along with the implementation of the new MRL proposal in soyabeans. If the existing EU MRL in pome fruits is lowered to 0.6 mg/kg, the chronic risk for consumers is considered unlikely. The residues in soyabeans account for 0.08% of the ADI for NL toddler diet, if the existing MRL is raised to 0.3 mg/kg.
0810010	Anise/aniseed	0.05*	40	The submitted data are sufficient to derive an MRL proposal of 40 mg/kg in support of the intended NEU/ SEU uses. Risk for consumers from short-term intake of residues of fluopyram is unlikely. However, as seed spices do not contribute to the NL toddler diet for which chronic consumer intake concerns were identified, the proposed MRL in these commodities is not associated with consumer exposure concerns.
0810020	Black caraway/ black cumin			
0810030	Celery			
0810040	Coriander			
0810050	Cumin			
0810070	Fennel			
0810080	Fenugreek			
0810090	Nutmeg			
0810990	Other spices (seeds)			
1040000	Honey and other apiculture products	0.05*	0.01* Risk management consideration	Validation data submitted for the enforcement method of fluopyram residues in honey indicate that a lower LOQ of 0.01 mg/kg is achievable.

MRL: maximum residue level; NEU: northern Europe; SEU: southern European Union; ADI: acceptable daily intake; GAP: Good Agricultural Practice; LOQ: limit of quantification.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

- scenario 1

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

LOQs (mg/kg) range from: 0.01 to: 40.0

Toxicological reference values

ADI (mg/kg bw per day):	0.012	ARfD (mg/kg bw):	0.5
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2013	Year of evaluation:	2013

Input values

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

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

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : 1

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	100%	NL toddler	12.04	21%	Milk: Cattle	18%	Apples	9%	Bananas		100%
	73%	DE child	8.72	21%	Apples	7%	Milk: Cattle	7%	Table grapes		73%
	57%	NL child	6.84	10%	Apples	9%	Milk: Cattle	7%	Wheat		57%
	43%	GEMS/Food G07	5.17	7%	Wheat	6%	Wine grapes	3%	Celeries		43%
	43%	IE adult	5.15	5%	Basil and edible flowers	5%	Wine grapes	4%	Wheat		43%
	41%	GEMS/Food G06	4.96	11%	Wheat	5%	Table grapes	4%	Tomatoes		41%
	41%	GEMS/Food G11	4.88	7%	Celeries	6%	Wheat	4%	Wine grapes		41%
	39%	FR child 3 15 yr	4.70	8%	Milk: Cattle	7%	Wheat	3%	Oranges		39%
	37%	FR toddler 2 3 yr	4.43	10%	Milk: Cattle	5%	Apples	5%	Wheat		37%
	37%	GEMS/Food G08	4.38	6%	Wheat	4%	Wine grapes	2%	Lettuces		37%
	36%	GEMS/Food G15	4.34	7%	Wheat	4%	Wine grapes	2%	Milk: Cattle		36%
	36%	GEMS/Food G10	4.32	6%	Wheat	4%	Lettuces	2%	Milk: Cattle		36%
	34%	SE general	4.11	5%	Wheat	5%	Lettuces	4%	Milk: Cattle		34%
	33%	UK infant	4.02	14%	Milk: Cattle	4%	Wheat	3%	Apples		33%
	33%	RO general	3.95	8%	Wheat	6%	Wine grapes	4%	Milk: Cattle		33%
	32%	ES child	3.88	7%	Wheat	5%	Lettuces	4%	Milk: Cattle		32%
	32%	UK toddler	3.86	7%	Milk: Cattle	6%	Wheat	3%	Apples		32%
	31%	DK child	3.67	7%	Wheat	4%	Milk: Cattle	4%	Apples		31%
	30%	DE women 14-50 yr	3.65	4%	Milk: Cattle	4%	Apples	3%	Wheat		30%
	29%	DE general	3.43	4%	Milk: Cattle	4%	Apples	3%	Wine grapes		29%
	28%	PT general	3.35	10%	Wine grapes	6%	Wheat	2%	Apples		28%
	26%	IT toddler	3.11	11%	Wheat	4%	Lettuces	2%	Tomatoes		26%
	25%	ES adult	3.00	7%	Lettuces	4%	Wheat	2%	Milk: Cattle		25%
	24%	NL general	2.92	3%	Wheat	3%	Milk: Cattle	2%	Apples		24%
	24%	FR adult	2.88	9%	Wine grapes	4%	Wheat	2%	Milk: Cattle		24%
	22%	IT adult	2.63	7%	Wheat	5%	Lettuces	1%	Tomatoes		22%
	20%	FR infant	2.35	6%	Milk: Cattle	3%	Apples	2%	Beans (with pods)		20%
	18%	FI 3 yr	2.17	2%	Bananas	2%	Wheat	2%	Raspberries (red and yellow)		18%
	18%	UK vegetarian	2.16	3%	Wheat	3%	Wine grapes	2%	Lettuces		18%
	17%	DK adult	2.01	4%	Wine grapes	2%	Milk: Cattle	2%	Wheat		17%
	16%	UK adult	1.96	4%	Wine grapes	3%	Wheat	1%	Lettuces		16%
	14%	FI 6 yr	1.68	2%	Wheat	1%	Raspberries (red and yellow)	1%	Bananas		14%
	12%	LT adult	1.38	3%	Apples	2%	Wheat	1%	Milk: Cattle		12%
	11%	PL general	1.27	3%	Apples	2%	Table grapes	1%	Tomatoes		11%
	10%	FI adult	1.16	2%	Lettuces	1%	Wine grapes	1.0%	Apples		10%
	6%	IE child	0.72	2%	Wheat	1%	Milk: Cattle	0.5%	Apples		6%

Conclusion:
The estimated TMDI/NEDI/IEDI was in the range of 0 % to 100.3 % of the ADI.
For 1 diet(s) the ADI is exceeded.
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 of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
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)
76%	Lettuces	15/10	381
73%	Celeries	20/9.74	364
42%	Rhubarbs	15/5.6	208
18%	Florence fennels	15/5.6	91
18%	Peaches	1.5/0.95	90
17%	Pears	0.8/0.6	83
15%	Sweet peppers/bell peppers	2/1.23	73
15%	Table grapes	2/1	73
13%	Apples	0.8/0.6	65
10%	Bananas	0.8/0.52	50
8%	Oranges	0.5/0.32	42
8%	Escaroles/broad-leaved	2/0.98	39
7%	Apricots	1.5/0.95	33
6%	Lamb's lettuce/corn salads	20/10	28
5%	Chinese cabbages/pe-tsai	2/0.84	27

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)
31%	Celeries	20/9.74	156
24%	Lettuces	15/10	121
21%	Florence fennels	15/5.6	104
12%	Cardoons	15/5.6	58
10%	Rhubarbs	15/5.6	52
8%	Blueberries	7/4.33	39
7%	Table grapes	2/1	34
5%	Wine grapes	1.5/0.95	23
4%	Chinese cabbages/pe-tsai	2/0.84	21
4%	Sweet peppers/bell peppers	2/1.23	20
4%	Escaroles/broad-leaved	2/0.98	20
4%	Blackberries	5/2.39	20
4%	Purslanes	20/10	19
4%	Lamb's lettuce/corn salads	20/10	19
4%	Chards/beet leaves	2/0.98	19

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

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)
51%	Florence fennels/boiled	15/5.6	254
42%	Rhubarbs/sauce/puree	15/5.6	209
13%	Escaroles/broad-leaved endiv	2/0.98	65
6%	Chards/beet leaves/boiled	2/0.98	30
5%	Peaches/canned	1.5/0.95	25
4%	Currants (red, black and white	4/0.78	22
4%	Beans (with pods)/boiled	3/1.65	21
4%	Leeks/boiled	0.8/0.32	18
4%	Broccoli/boiled	0.5/0.23	18
3%	Spinaches/frozen; boiled	2/0.98	14
3%	Raspberries/juice	5/1.12	13
2%	Elderberries/juice	4/0.78	12
2%	Witloofs/boiled	0.3/0.14	12
2%	Pumpkins/boiled	0.4/0.12	11
2%	Courgettes/boiled	0.6/0.3	11

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)
66%	Celeries/boiled	20/9.74	329
22%	Florence fennels/boiled	15/5.6	109
16%	Rhubarbs/sauce/puree	15/5.6	82
14%	Cardoons/boiled	15/5.6	68
8%	Purslanes/boiled	20/10	41
4%	Escaroles/broad-leaved	2/0.98	20
2%	Chards/beet leaves/boiled	2/0.98	12
2%	Currants (red, black and	4/0.78	9.9
2%	Spinaches/frozen; boiled	2/0.98	8.1
2%	Peaches/canned	1.5/0.95	7.8
1%	Elderberries/juice	4/0.78	7.2
1%	Courgettes/boiled	0.6/0.3	6.9
1%	Pumpkins/boiled	0.4/0.12	6.6
1%	Wine grapes/wine	1.5/0.67	6.3
1%	Cauliflowers/boiled	0.3/0.14	5.8

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fluopyram is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- scenario 2

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Fluopyram

LOQs (mg/kg) range from: 0.01 to: 40.0

Toxicological reference values

ADI (mg/kg bw per day):	0.012	ARfD (mg/kg bw):	0.5
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2013	Year of evaluation:	2013

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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	92%	NL toddler	11.05	21%	Milk: Cattle	12%	Apples	9%	Bananas		92%
	66%	DE child	7.88	14%	Apples	7%	Milk: Cattle	7%	Table grapes		66%
	53%	NL child	6.38	9%	Milk: Cattle	7%	Wheat	7%	Apples		53%
	42%	GEMS/Food G07	5.09	7%	Wheat	6%	Wine grapes	3%	Celeries		42%
	42%	IE adult	5.07	5%	Basil and edible flowers	5%	Wine grapes	4%	Wheat		42%
	41%	GEMS/Food G06	4.89	11%	Wheat	5%	Table grapes	4%	Tomatoes		41%
	40%	GEMS/Food G11	4.77	7%	Celeries	6%	Wheat	4%	Wine grapes		40%
	38%	FR child 3 15 yr	4.57	8%	Milk: Cattle	7%	Wheat	3%	Oranges		38%
	36%	GEMS/Food G08	4.29	6%	Wheat	4%	Wine grapes	2%	Lettuces		36%
	35%	GEMS/Food G10	4.26	6%	Wheat	4%	Lettuces	2%	Milk: Cattle		35%
	35%	GEMS/Food G15	4.26	7%	Wheat	4%	Wine grapes	2%	Milk: Cattle		35%
	35%	FR toddler 2 3 yr	4.20	10%	Milk: Cattle	5%	Wheat	4%	Apples		35%
	33%	SE general	4.02	5%	Wheat	5%	Lettuces	4%	Milk: Cattle		33%
	33%	UK infant	3.90	14%	Milk: Cattle	4%	Wheat	2%	Bananas		33%
	32%	RO general	3.85	8%	Wheat	6%	Wine grapes	4%	Milk: Cattle		32%
	31%	ES child	3.78	7%	Wheat	5%	Lettuces	4%	Milk: Cattle		31%
	31%	UK toddler	3.74	7%	Milk: Cattle	6%	Wheat	2%	Oranges		31%
	29%	DE women 14-50 yr	3.48	4%	Milk: Cattle	3%	Wheat	3%	Wine grapes		29%
	29%	DK child	3.47	7%	Wheat	4%	Milk: Cattle	3%	Apples		29%
	27%	DE general	3.26	4%	Milk: Cattle	3%	Wine grapes	3%	Wheat		27%
	27%	PT general	3.25	10%	Wine grapes	6%	Wheat	1%	Table grapes		27%
	25%	IT toddler	3.03	11%	Wheat	4%	Lettuces	2%	Tomatoes		25%
	24%	ES adult	2.93	7%	Lettuces	4%	Wheat	2%	Milk: Cattle		24%
	23%	FR adult	2.82	9%	Wine grapes	4%	Wheat	2%	Milk: Cattle		23%
	23%	NL general	2.82	3%	Wheat	3%	Milk: Cattle	2%	Wine grapes		23%
	21%	IT adult	2.56	7%	Wheat	5%	Lettuces	1%	Tomatoes		21%
	19%	FR infant	2.23	6%	Milk: Cattle	2%	Apples	2%	Beans (with pods)		19%
	18%	UK vegetarian	2.12	3%	Wheat	3%	Wine grapes	2%	Lettuces		18%
	17%	FI 3 yr	2.10	2%	Bananas	2%	Wheat	2%	Raspberries (red and yellow)		17%
	16%	UK adult	1.93	4%	Wine grapes	3%	Wheat	1%	Lettuces		16%
	16%	DK adult	1.92	4%	Wine grapes	2%	Milk: Cattle	2%	Wheat		16%
	14%	FI 6 yr	1.63	2%	Wheat	1%	Raspberries (red and yellow)	1%	Bananas		14%
	10%	LT adult	1.25	2%	Apples	2%	Wheat	1%	Milk: Cattle		10%
	9%	PL general	1.12	2%	Apples	2%	Table grapes	1%	Tomatoes		9%
	9%	FI adult	1.12	2%	Lettuces	1%	Wine grapes	0.7%	Tomatoes		9%
	6%	IE child	0.70	2%	Wheat	1%	Milk: Cattle	0.4%	Apples		6%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Fluopyram 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 of IESTI calculation only for crops with GAPs under assessment

Unprocessed commodities

Results for children
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)
76%	Lettuces	15/10	381
73%	Celeries	20/9.74	364
42%	Rhubarbs	15/5.6	208
18%	Florence fennels	15/5.6	91
18%	Peaches	1.5/0.95	90
15%	Sweet peppers/bell peppers	2/1.23	73
15%	Table grapes	2/1	73
14%	Pears	0.6/0.5	69
11%	Apples	0.6/0.5	53
10%	Bananas	0.8/0.52	50
8%	Oranges	0.5/0.32	42
8%	Escaroles/broad-leaved	2/0.98	39
7%	Apricots	1.5/0.95	33
6%	Lamb's lettuce/corn salads	20/10	28
5%	Chinese cabbages/pe-tsai	2/0.84	27

Expand/collapse list

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

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)
31%	Celeries	20/9.74	156
24%	Lettuces	15/10	121
21%	Florence fennels	15/5.6	104
12%	Cardoons	15/5.6	58
10%	Rhubarbs	15/5.6	52
8%	Blueberries	7/4.33	39
7%	Table grapes	2/1	34
5%	Wine grapes	1.5/0.95	23
4%	Chinese cabbages/pe-tsai	2/0.84	21
4%	Sweet peppers/bell peppers	2/1.23	20
4%	Escaroles/broad-leaved	2/0.98	20
4%	Blackberries	5/2.39	20
4%	Purslanes	20/10	19
4%	Lamb's lettuce/corn salads	20/10	19
4%	Chards/beet leaves	2/0.98	19

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)
51%	Florence fennels/boiled	15/5.6	254
42%	Rhubarbs/sauce/puree	15/5.6	209
13%	Escaroles/broad-leaved endiv	2/0.98	65
6%	Chards/beet leaves/boiled	2/0.98	30
5%	Peaches/canned	1.5/0.95	25
4%	Currants (red, black and white	4/0.78	22
4%	Beans (with pods)/boiled	3/1.65	21
4%	Leeks/boiled	0.8/0.32	18
4%	Broccoli/boiled	0.5/0.23	18
3%	Spinaches/frozen; boiled	2/0.98	14
3%	Raspberries/juice	5/1.12	13
2%	Elderberries/juice	4/0.78	12
2%	Witloofs/boiled	0.3/0.14	12
2%	Pumpkins/boiled	0.4/0.12	11
2%	Courgettes/boiled	0.6/0.3	11

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)
66%	Celeries/boiled	20/9.74	329
22%	Florence fennels/boiled	15/5.6	109
16%	Rhubarbs/sauce/puree	15/5.6	82
14%	Cardoons/boiled	15/5.6	68
8%	Purslanes/boiled	20/10	41
4%	Escaroles/broad-leaved	2/0.98	20
2%	Chards/beet leaves/boiled	2/0.98	12
2%	Currants (red, black and	4/0.78	9.9
2%	Spinaches/frozen; boiled	2/0.98	8.1
2%	Peaches/canned	1.5/0.95	7.8
1%	Elderberries/juice	4/0.78	7.2
1%	Courgettes/boiled	0.6/0.3	6.9
1%	Pumpkins/boiled	0.4/0.12	6.6
1%	Wine grapes/wine	1.5/0.67	6.3
1%	Cauliflowers/boiled	0.3/0.14	5.8

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Fluopyram is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram				
Grapefruits, dried pulp	0.12	STMR × PF (0.93) × CF (1.1)[a]	0.12	STMR × PF (0.93) × CF (1.1)[a]
Oranges, dried pulp	0.12	STMR × PF (0.93) × CF (1.1)[a]	0.12	STMR × PF (0.93) × CF (1.1)[a]
Lemons, dried pulp	0.30	STMR × PF (0.93) × CF (1.1)[a]	0.30	STMR × PF (0.93) × CF (1.1)[a]
Mandarins, dried pulp	0.30	STMR × PF (0.93) × CF (1.1)[a]	0.30	STMR × PF (0.93) × CF (1.1)[a]
Apple, pomace, wet	0.32	STMR[d] × PF (2.26)	0.32	STMR[d] × PF (2.26) × CF (1.05)
Potato, culls	0.03	STMR[b]	0.07	HR[b]
Potato, process waste	0.60	STMR[b] × default PF (20)	0.60	STMR[b] × default PF (20)
Potato, dried pulp	1.14	STMR[b] × default PF (38)	1.14	STMR[b] × default PF (38)
Cassava/tapioca, roots	0.02	STMR[b]	0.02	HR[b]
Carrot, culls	0.10	STMR[b]	0.18	HR[b]
Swede, roots	0.10	STMR[b]	0.18	HR[b]
Turnip, roots	0.10	STMR[b]	0.18	HR[b]
Cabbage, heads, leaves	0.01	STMR[b]	0.08	HR[b]
Kale, leaves (forage)	0.03	STMR[b]	0.09	HR[b]
Bean, seed (dry)	0.04	STMR × CF (1.3)	0.04	STMR × CF (1.3)
Cowpea, seed	0.04	STMR × CF (1.3)	0.04	STMR × CF (1.3)
Pea (Field pea), seed (dry)	0.04	STMR × CF (1.3)	0.04	STMR × CF (1.3)
Lupin, seed	0.04	STMR × CF (1.3)	0.04	STMR × CF (1.3)
Lupin seed, meal	0.05	STMR × default PF (1.1) × CF (1.3)	0.05	STMR × default PF (1.1) × CF (1.3)
Peanut, meal	0.02	STMR × default PF (2) × CF (1.2)	0.02	STMR × default PF (2) × CF (1.2)
Sunflower, meal	0.15	STMR × default PF (2)	0.15	STMR × default PF (2)
Canola (Rape seed), meal	0.32	STMR × PF (0.73) × CF (1.29)	0.32	STMR × PF (0.73) × CF (1.29)
Rape, meal	0.32	STMR × PF (0.73) × CF (1.29)	0.32	STMR × PF (0.73) × CF (1.29)
Soyabean, seed	0.045	STMR[d]	0.045	STMR[d]
Soyabean, meal	< 0.01	STMR[d] × PF (0.047)	< 0.01	STMR[d] × PF (0.047)
Soyabean, hulls	0.06	STMR[d] × PF (1.31)	0.02	STMR[d] × PF (1.31)
Cotton, undelinted seed	0.07	STMR × CF (1.2)	0.07	STMR × CF (1.2)
Cotton, meal	0.09	STMR × default PF (1.25) × CF (1.2)	0.09	STMR × default PF (1.25) × CF (1.2)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley, grain	0.02	STMR	0.02	STMR
Brewer's grain, dried	0.07	STMR × default PF (3.3)	0.07	STMR × default PF (3.3)
Corn, field (Maize), grain	0.01*	STMR	0.01*	STMR
Corn, pop, grain	0.01*	STMR	0.01*	STMR
Corn, field, milled by-pdts	0.01*	STMR[(c)]	0.01*	STMR[(c)]
Corn, field, hominy meal	0.01*	STMR[(c)]	0.01*	STMR[(c)]
Corn, field, distiller's grain (dry)	0.01*	STMR[(c)]	0.01*	STMR[(c)]
Corn, field, gluten feed	0.01*	STMR[(c)]	0.01*	STMR[(c)]
Corn, field, gluten, meal	0.01*	STMR[(c)]	0.01*	STMR[(c)]
Millet, grain	0.01	STMR	0.01	STMR
Oat, grain	0.02	STMR	0.02	STMR
Rye, grain	0.01	STMR	0.01	STMR
Sorghum, grain	0.36	STMR	0.36	STMR
Triticale, grain	0.19	STMR	0.19	STMR
Wheat, grain	0.19	STMR	0.19	STMR
Wheat, distiller's grain (dry)	0.63	STMR × default PF (3.3)	0.63	STMR × default PF (3.3)
Wheat gluten, meal	0.34	STMR × default PF (1.8)	0.34	STMR × default PF (1.8)
Wheat, milled by-pdts	1.33	STMR × default PF (7)	1.33	STMR × default PF (7)
Beet, sugar, dried pulp	0.18	STMR[(b)] × default PF (18)	0.18	STMR[(b)] × default PF (18)
Beet, sugar, ensiled pulp	0.03	STMR[(b)] × default PF (3)	0.03	STMR[(b)] × default PF (3)
Beet, sugar, molasses	0.28	STMR[(b)] × default PF (28)	0.28	STMR[(b)] × default PF (28)
Barley, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Barley, silage	0.21	STMR[(b)] × default PF (1.3) × CF (1.5)	0.55	HR[(b)] × default PF (1.3) × CF (1.5)
Millet, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Corn, field, forage/ silage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Oat, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Oat, hay	0.50	STMR[(b)] × default PF (3) × CF (1.5)	1.26	HR[(b)] × default PF (3) × CF (1.5)
Rye, forage (greens)	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Sorghum, grain, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Sorghum, grain, silage	0.10	STMR[(b)] × default PF (0.6) × CF (1.5)	0.25	HR[(b)] × default PF (0.6) × CF (1.5)
Triticale, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)
Triticale, hay	0.48	STMR[(b)] × default PF (2.9) × CF (1.5)	1.22	HR[(b)] × default PF (2.9) × CF (1.5)
Wheat, forage	0.17	STMR[(b)] × CF (1.5)	0.42	HR[(b)] × CF (1.5)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, hay (fodder dry)	0.58	STMR[(b)] × default PF (3.5) × CF (1.5)	1.47	HR[(b)] × default PF (3.5) × CF (1.5)
Barley, straw	0.15	STMR[(b)] × CF (1.1)	1.21	HR[(b)] × CF (1.1)
Corn, field, stover (fodder)	0.42	STMR	1.70	HR
Corn, pop, stover	0.42	STMR	1.70	HR
Oat, straw	0.15	STMR[(b)] × CF (1.1)	1.21	HR[(b)] × CF (1.1)
Rye, straw	0.17	STMR[(b)] × CF (1.1)	1.21	HR[(b)] × CF (1.1)
Triticale, straw	0.17	STMR[(b)] × CF (1.1)	1.21	HR[(b)] × CF (1.1)
Wheat, straw	0.17	STMR[(b)] × CF (1.1)	1.21	HR[(b)] × CF (1.1)
Beet, mangel, roots	0.01	STMR[(b)]	0.01	HR[(b)]
Beet, mangel, tops	0.01	STMR[(b)]	0.01	HR[(b)]
Beet, sugar, tops	0.01	STMR[(b)]	0.01	HR[(b)]

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Tentative PF, based on only 1 value (EFSA, 2020).
(b): The STMR and HR values reflect the combined residues from both primary and rotational crops (sum of the HR/STMR values) (EFSA, 2020).
(c): For corn, field by-products no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected (EFSA, 2020).
(d): STMR values proposed based on the trials for apple and soyabeans assessed in the current application.

D.2. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Risk assessment residue definition: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram						
Grapefruits	0.5	Existing EU MRL, EFSA (2020)	0.12	STMR-RAC	0.32	HR-RAC
Oranges	0.5[(e)]	Existing EU MRL, EFSA (2020)	0.12	STMR-RAC	0.32	HR-RAC
Lemons	0.9[(c)]	Existing EU MRL, EFSA (2020)	0.23	STMR-RAC	0.32	HR-RAC
Mandarins	0.9[(d)]	Existing EU MRL, EFSA (2020)	0.23	STMR-RAC	0.32	HR-RAC
Almonds	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Brazil nuts	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Cashew nuts	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Chestnuts	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Coconuts	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.03	MRL	0.03	MRL
Hazelnuts/cobnuts	0.03[(e)]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Macadamia	0.03[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Pecans	0.03[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Pine nut kernels	0.03[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Pistachios	0.03[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Walnuts	0.03[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.02	HR-RAC
Apples	Scenario 1: 0.8[f]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.6	HR-RAC
	Scenario 2: 0.6[g]	MRL proposal	0.14	STMR-RAC	0.5	HR-RAC
Pears	Scenario 1: 0.8[f]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.6	HR-RAC
	Scenario 2: 0.6[g]	MRL proposal	0.14	STMR-RAC	0.5	HR-RAC
Quinces	Scenario 1: 0.8[f]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.6	HR-RAC
	Scenario 2: 0.6[g]	MRL proposal	0.14	STMR-RAC	0.5	HR-RAC
Medlar	Scenario 1: 0.8[f]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.6	HR-RAC
	Scenario 2: 0.6[g]	MRL proposal	0.14	STMR-RAC	0.5	HR-RAC
Loquats/Japanese medlars	Scenario 1: 0.8[f]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.6	HR-RAC
	Scenario 2: 0.6[g]	MRL proposal	0.14	STMR-RAC	0.5	HR-RAC
Apricots	1.5	Existing EU MRL, EFSA (2020)	0.33	STMR-RAC	0.95	HR-RAC
Cherries (sweet)	2	Existing EU MRL, EFSA (2020)	0.56	STMR-RAC	1.1	HR-RAC
Peaches	1.5	Existing EU MRL, EFSA (2020)	0.343	STMR-RAC	0.95	HR-RAC
Plums	0.6	Existing EU MRL, EFSA (2020)	0.19	STMR-RAC	0.27	HR-RAC
Table grapes	2	Existing EU MRL, EFSA (2020)	0.59	STMR-RAC	1	HR-RAC
Wine grapes	1.5[e]	Existing EU MRL, EFSA (2020)	0.46	STMR-RAC	0.95	HR-RAC
Strawberries	2	Existing EU MRL, EFSA (2020)	0.431	STMR-RAC	1.01	HR-RAC
Blackberries	5	Existing EU MRL, EFSA (2020)	1.12	STMR-RAC	2.39	HR-RAC
Dewberries	5	Existing EU MRL, EFSA (2020)	1.12	STMR-RAC	2.39	HR-RAC
Raspberries (red and yellow)	5	Existing EU MRL, EFSA (2020)	1.12	STMR-RAC	2.39	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Blueberries	7	Existing EU MRL, EFSA (2020)	1.14	STMR-RAC	4.33	HR-RAC
Cranberries	4	Existing EU MRL, EFSA (2020)	0.78	STMR-RAC	2.1	HR-RAC
Currants (red, black and white)	4[e]	Existing EU MRL, EFSA (2020)	0.78	STMR-RAC	2.1	HR-RAC
Gooseberries (green, red and yellow)	4[e]	Existing EU MRL, EFSA (2020)	0.78	STMR-RAC	2.1	HR-RAC
Rose hips	3[e]	Existing EU MRL, EFSA (2020)	0.69	STMR-RAC	1.58	HR-RAC
Mulberries (black and white)	4	Existing EU MRL, EFSA (2020)	0.79	STMR-RAC	2.1	HR-RAC
Elderberries	4	Existing EU MRL, EFSA (2020)	0.78	STMR-RAC	2.1	HR-RAC
Kiwi fruits (green, red, yellow)	1.5	MRL proposal	0.02	STMR-RAC* PeF (0.07)	0.04	HR-RAC* PeF (0.07)
Bananas	0.8[d]	Existing EU MRL, EFSA (2020)	0.19	STMR-RAC* PeF (0.98)	0.52	HR-RAC* PeF (0.98)
Potatoes	0.08[e]	Existing EU MRL, EFSA (2020)	0.03	STMR-RAC	0.07	HR-RAC
Cassava roots/ manioc	0.06[h]	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC	0.02	HR-RAC
Sweet potatoes	0.15[h]	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC	0.052	HR-RAC
Yams	0.15[h]	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC	0.05	HR-RAC
Arrowroots	0.06[h]	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC	0.02	HR-RAC
Beetroots	0.2[h]	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC	0.1	HR-RAC
Carrots	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Celeriacs/turnip-rooted celeries	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Horseradishes	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Jerusalem artichokes	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Parsnips	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Parsley roots/ Hamburg roots parsley	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Radishes	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Salsifies	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Swedes/rutabagas	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Turnips	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.18	HR-RAC
Garlic	0.07	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.04	HR-RAC
Onions	0.07	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.04	HR-RAC
Shallots	0.07	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.04	HR-RAC
Spring onions/green onions and Welsh onions	3[c]	Existing EU MRL, EFSA (2020)	5.25	STMR-RAC	1.22	HR-RAC
Tomatoes	0.5[d]	Existing EU MRL, EFSA (2020)	0.15	STMR-RAC	0.24	HR-RAC
Sweet peppers/bell peppers	2[e]	Existing EU MRL, EFSA (2020)	0.29	STMR-RAC	1.23	HR-RAC
Aubergines/egg plants	0.4[e]	Existing EU MRL, EFSA (2020)	0.12	STMR-RAC	0.23	HR-RAC
Cucumbers	0.6	Existing EU MRL, EFSA (2020)	0.14	STMR-RAC	0.3	HR-RAC
Gherkins	0.6	Existing EU MRL, EFSA (2020	0.14	STMR-RAC	0.3	HR-RAC
Courgettes	0.6	Existing EU MRL, EFSA (2020)	0.14	STMR-RAC	0.3	HR-RAC
Melons	0.9[d]	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC* PeF (0.13)	0.06	HR-RAC* PeF (0.13)
Pumpkins	0.4	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC	0.12	HR-RAC
Watermelons	0.4[d]	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC	0.12	HR-RAC
Sweet corn	0.02[h]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	HR-RAC
Broccoli	0.5[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.23	HR-RAC
Cauliflowers	0.3[h]	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC	0.14	HR-RAC
Brussels sprouts	0.4[h]	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC	0.23	HR-RAC
Head cabbages	0.3[h]	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC	0.17	HR-RAC
Chinese cabbages/ pe-tsai	2[d]	Existing EU MRL, EFSA (2020)	0.36	STMR-RAC	0.84	HR-RAC
Kales	0.15[h]	Existing EU MRL, EFSA (2020)	0.03	STMR-RAC	0.09	HR-RAC
Kohlrabies	0.15[h]	Existing EU MRL, EFSA (2020)	0.03	STMR-RAC	0.09	HR-RAC
Lamb's lettuce/corn salads	20	Existing EU MRL, EFSA (2020)	1.6	STMR-RAC	10	HR-RAC
Lettuces	15	Existing EU MRL, EFSA (2020)	1.5	STMR-RAC	10	HR-RAC
Escaroles/broad-leaved endives	2[d]	Existing EU MRL, EFSA (2020)	0.37	STMR-RAC	0.98	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Cress and other sprouts and shoots	20	Existing EU MRL, EFSA (2020)	1.6	STMR-RAC	10	HR-RAC
Land cress	2[d]	Existing EU MRL, EFSA (2020)	0.37	STMR-RAC	0.98	HR-RAC
Roman rocket/ rucola	20	Existing EU MRL, EFSA (2020)	1.6	STMR-RAC	10	HR-RAC
Red mustards	2[d]	Existing EU MRL, EFSA (2020)	0.37	STMR-RAC	0.98	HR-RAC
Baby leaf crops (including brassica species)	20	Existing EU MRL, EFSA (2020)	1.6	STMR-RAC	10	HR-RAC
Spinaches	2[d]	Existing EU MRL, EFSA (2020)	0.37	STMR-RAC	0.98	HR-RAC
Purslanes	20	Existing EU MRL, EFSA (2020)	1.6	STMR-RAC	10	HR-RAC
Chards/beet leaves	2[d]	Existing EU MRL, EFSA (2020)	0.37	STMR-RAC	0.98	HR-RAC
Watercress	0.15[h]	Existing EU MRL, EFSA (2020)	0.03	STMR-RAC	0.09	HR-RAC
Witloofs/Belgian endives	0.3	Existing EU MRL, EFSA (2020)	0.11	STMR-RAC	0.14	HR-RAC
Chervil	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Chives	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Celery leaves	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Parsley	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Sage	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Rosemary	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Thyme	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Basil and edible flowers	60[e]	Existing EU MRL, EFSA (2020)	19.07	STMR-RAC	30	HR-RAC
Laurel/bay leaves	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Tarragon	6	Existing EU MRL, EFSA (2020)	0.38	STMR-RAC	3.64	HR-RAC
Beans (with pods)	3	Existing EU MRL, EFSA (2020)	0.45	STMR-RAC* CF (1.1)	1.65	HR-RAC* CF (1.1)
Beans (without pods)	0.15[e]	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC* CF (1.3)	0.1	HR-RAC* CF (1.3)
Peas (with pods)	3	Existing EU MRL, EFSA (2020)	0.45	STMR-RAC* CF (1.1)	1.65	HR-RAC* CF (1.1)
Peas (without pods)	0.15	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC* CF (1.3)	0.1	HR-RAC* CF (1.3)
Lentils (fresh)	0.15	Existing EU MRL, EFSA (2020)	0.05	STMR-RAC* CF (1.3)	0.1	HR-RAC* CF (1.3)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Asparagus	0.01	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	HR-RAC
Cardoons	15	MRL proposal	0.36	STMR-RAC	5.6	HR-RAC
Celeries	20	Existing EU MRL, EFSA (2020)	3.03	STMR-RAC	9.74	HR-RAC
Florence fennels	15	MRL proposal	0.36	STMR-RAC	5.6	HR-RAC
Globe artichokes	4[d]	Existing EU MRL, EFSA (2020)	1.27	STMR-RAC	1.37	HR-RAC
Leeks	0.8[d]	Existing EU MRL, EFSA (2020)	0.22	STMR-RAC	0.32	HR-RAC
Rhubarbs	15	MRL proposal	0.36	STMR-RAC	5.6	HR-RAC
Beans	0.5	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC* CF (1.3)	0.04	STMR-RAC* CF (1.3)
Lentils	0.5[e]	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC* CF (1.3)	0.04	STMR-RAC* CF (1.3)
Peas	0.5[e]	Existing EU MRL, EFSA (2020)	0.0442	STMR-RAC* CF (1.3)	0.04	STMR-RAC* CF (1.3)
Lupins/lupini beans	0.5	Existing EU MRL, EFSA (2020)	0.04	STMR-RAC* CF (1.3)	0.04	STMR-RAC* CF (1.3)
Peanuts/groundnuts	0.2	MRL proposal	0.04	STMR-RAC	0.043	STMR-RAC
Poppy seeds	0.4	Existing EU MRL, EFSA (2020)	0.13	STMR-RAC	0.13	STMR-RAC
Sunflower seeds	0.7	Existing EU MRL, EFSA (2020)	0.08	STMR-RAC	0.08	STMR-RAC
Rapeseeds/canola seeds	1	Existing EU MRL, EFSA (2020)	0.4	STMR-RAC	0.4	STMR-RAC
Soyabeans	0.3	MRL proposal	0.06	STMR-RAC	0.06	STMR-RAC
Mustard seeds	0.4	Existing EU MRL, EFSA (2020)	0.13	STMR-RAC	0.13	STMR-RAC
Cotton seeds	0.8	Existing EU MRL, EFSA (2020)	0.07	STMR-RAC* CF (1.2)	0.07	STMR-RAC* CF (1.2)
Barley	0.2	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC	0.02	STMR-RAC
Buckwheat and other pseudo-cereals	0.02[h]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	STMR-RAC
Maize/corn	0.02[h]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	STMR-RAC
Common millet/ proso millet	0.02[h]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	STMR-RAC
Oat	0.2	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC	0.02	STMR-RAC
Rice	0.02	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	STMR-RAC
Rye	0.07[e]	Existing EU MRL, EFSA (2020)	0.01	STMR-RAC	0.01	STMR-RAC
Sorghum	4	Existing EU MRL, EFSA (2020)	0.36	STMR-RAC	0.36	STMR-RAC
Wheat	0.9	Existing EU MRL, EFSA (2020)	0.19	STMR-RAC	0.19	STMR-RAC

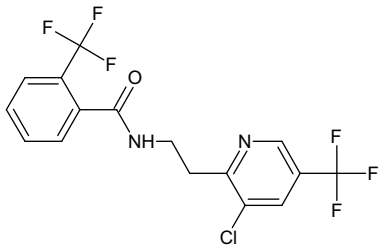
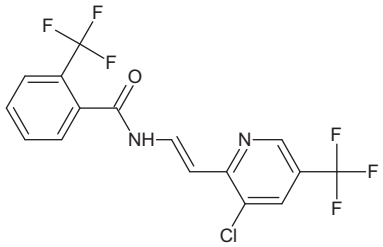
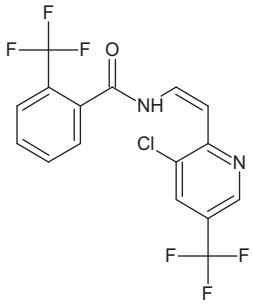
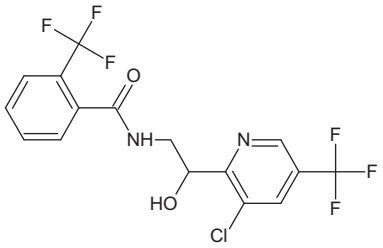
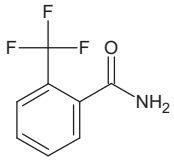
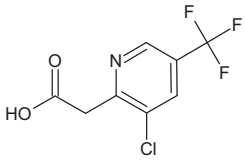
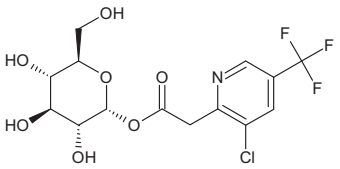
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Herbal infusions (dried flowers)	40	Existing EU MRL, EFSA (2019c)				
Chamomile	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Hibiscus/roselle	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Rose	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Jasmine	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Lime/linden	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Other herbal infusions (dried flowers)	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC		
Strawberry leaves	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Rooibos	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Mate/maté	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC	25.2	HR-RAC
Other herbal infusions (dried leaves)	40	Existing EU MRL, EFSA (2019c)	2.24	STMR-RAC		
Valerian root	1[(h)]	Existing EU MRL, EFSA (2019c)	0.2	STMR-RAC	0.5	HR-RAC
Ginseng root	1[(h)]	Existing EU MRL, EFSA (2019c)	0.2	STMR-RAC	0.5	HR-RAC
Other herbal infusions (dried roots)	1	Existing EU MRL, EFSA (2019c)	0.2	STMR-RAC		
HOPS (dried)	60	Existing EU MRL, EFSA (2020)	12.13	STMR-RAC	30.48	HR-RAC
Anise/aniseed	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Black caraway/black cumin	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Celery seed	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Coriander seed	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Cumin seed	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Dill seed	70	Existing EU MRL, EFSA (2020)	22.5	STMR-RAC	29.6	HR-RAC
Fennel seed	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Fenugreek	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Nutmeg	40	MRL proposal	6.8	STMR-RAC	13.2	HR-RAC
Other spices (seeds)	40	MRL proposal	6.8			
Liquorice	1[(h)]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC	0.5	HR-RAC
Turmeric/curcuma	1[(h)]	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC*CF	0.5	HR-RAC
Other spices (roots)	1	Existing EU MRL, EFSA (2020)	0.2	STMR-RAC*CF		HR-RAC

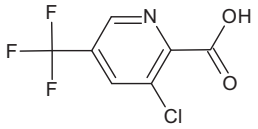
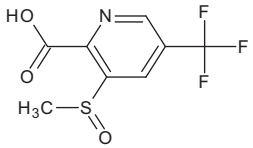
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Sugar beet roots	0.1[e]	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC*CF	0.05	HR-RAC
Chicory roots	0.1	Existing EU MRL, EFSA (2020)	0.02	STMR-RAC*CF	0.05	HR-RAC
Risk assessment residue definition: sum of fluopyram, fluopyram-benzamide (M25), and fluopyram-E/Z-olefine (M02/M03), expressed as fluopyram						
Swine: Muscle/meat	0.1[e]	Existing EU MRL	0.02	STMR-RAC	0.092	HR-RAC
Swine: Fat tissue	0.09[e]	Existing EU MRL	0.03	STMR-RAC*CF (1.4)	0.12	HR-RAC* CF (1.4)
Swine: Liver	0.5[e]	Existing EU MRL	0.32	STMR-RAC	0.49	HR-RAC
Swine: Kidney	0.08[e]	Existing EU MRL	0.03	STMR-RAC	0.08	HR-RAC
Bovine: Muscle/ meat	0.15[e]	Existing EU MRL	0.07	STMR-RAC	0.13	HR-RAC
Bovine: Fat tissue	0.15[e]	Existing EU MRL	0.07	STMR-RAC*CF (1.4)	0.16	HR-RAC* CF (1.4)
Bovine: Liver	0.8[e]	Existing EU MRL	0.51	STMR-RAC	0.71	HR-RAC
Bovine: Kidney	0.15[e]	Existing EU MRL	0.06	STMR-RAC	0.11	HR-RAC
Sheep: Muscle/meat	0.15[e]	Existing EU MRL	0.074	STMR-RAC	0.13	HR-RAC
Sheep: Fat tissue	0.15[e]	Existing EU MRL	0.073	STMR-RAC*CF (1.4)	0.15	HR-RAC* CF (1.4)
Sheep: Liver	0.8[e]	Existing EU MRL	0.53	STMR-RAC	0.70	HR-RAC
Sheep: Kidney	0.15[e]	Existing EU MRL	0.063	STMR-RAC	0.11	HR-RAC
Goat: Muscle/meat	0.15[e]	Existing EU MRL	0.074	STMR-RAC	0.13	HR-RAC
Goat: Fat tissue	0.15[e]	Existing EU MRL	0.073	STMR-RAC*CF (1.4)	0.15	HR-RAC* CF (1.4)
Goat: Liver	0.8[e]	Existing EU MRL	0.53	STMR-RAC	0.70	HR-RAC
Goat: Kidney	0.15[e]	Existing EU MRL	0.06	STMR-RAC	0.11	HR-RAC
Equine: Muscle/ meat	0.15[e]	Existing EU MRL	0.07	STMR-RAC	0.13	HR-RAC
Equine: Fat tissue	0.15[e]	Existing EU MRL	0.07	STMR-RAC* CF (1.4)	0.16	HR-RAC* CF (1.4)
Equine: Liver	0.8[e]	Existing EU MRL	0.51	STMR-RAC	0.71	HR-RAC
Equine: Kidney	0.15[e]	Existing EU MRL	0.06	STMR-RAC	0.11	HR-RAC
Poultry: Muscle/ meat	0.07[e]	Existing EU MRL	0.05	STMR-RAC	0.06	HR-RAC
Poultry: Fat tissue	0.07[e]	Existing EU MRL	0.07	STMR-RAC*CF (1.25)	0.08	HR-RAC* CF (1.25)
Poultry: Liver	0.3[e]	Existing EU MRL	0.21	STMR-RAC	0.26	HR-RAC
Milk: Cattle	0.07	Existing EU MRL	0.04	STMR-RAC	0.04	STMR-RAC
Milk: Sheep	0.06	Existing EU MRL	0.05	STMR-RAC	0.05	STMR-RAC
Milk: Goat	0.06	Existing EU MRL	0.05	STMR-RAC	0.05	STMR-RAC
Milk: Horse	0.07	Existing EU MRL	0.04	STMR-RAC	0.04	STMR-RAC
Eggs: Chicken	0.15[e]	Existing EU MRL	0.1	STMR-RAC	0.134	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Risk assessment residue definition for honey: sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram						
Honey and other apiculture products	0.01*	MRL proposal	0.02	STMR-RAC	0.02	HR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.
*: Indicates that the value is proposed at the limit of quantification.
(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.
(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
(c): Tentative MRL derived from a GAP evaluated at EU level in the MRL review, which is not fully supported by data. The existing CXL is higher (EFSA, 2020).
(d): Tentative MRL derived from a GAP evaluated at EU level in the MRL review, which is not fully supported by data (EFSA, 2020).
(e): MRL is derived from a GAP evaluated at EU level in the MRL review, which is supported by data (EFSA, 2020). The existing CXL is higher.
(f): MRL derived in the MRL review (EFSA, 2020) based on a US GAP in pome fruits (2 × 250 g a.s./ha, PHI = 0 days). The applicant claims that the GAP is no longer in used.
(g): MRL proposed for pome fruits based on a less critical import tolerance GAP (2 × 250 g a.s./ha, PHI = 0 days) than the one evaluated in the MRL review (Germany, 2023).
(h): MRL derived from rotational crops in the MRL review (EFSA, 2020).

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
fluopyram	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl] ethyl}-α,α,α-trifluoro-*o*-toluamide FC(F)(F)c1ccccc1C(=O)NCCc2ncc(cc2Cl)C(F)(F)F KVDJTXBXMWJJEF-UHFFFAOYSA-N	
M02 fluopyram-E-olefine	*N*-{(*E*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(=O)N\C=C\c2ncc(cc2Cl)C(F)(F)F ZBXOWVYWCBPUPM-AATRIKPKSA-N	
M03 fluopyram-Z-olefine	*N*-{(*Z*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F ZBXOWVYWCBPUPM-WAYWQWQTSA-N	
M08 fluopyram-7-hydroxy	*N*-{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]-2-hydroxyethyl}-2-(trifluoromethyl)benzamide Clc1cc(cnc1C(O)CNC(=O)c1ccccc1C(F)(F)F)C(F)(F)F LZWQFTDQXOXRHG-UHFFFAOYSA-N	
M25 fluopyram-benzamide	2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(N)=O QBAYIBZITZBSFO-UHFFFAOYSA-N	
M40 fluopyram-pyridyl-acetic acid fluopyram-PAA	[3-chloro-5-(trifluoromethyl)pyridin2-yl]acetic acid OC(=O)Cc1ncc(cc1Cl)C(F)(F)F ZCMWOZJSLGQSQV-UHFFFAOYSA-N	
M42 fluopyram pyridyl-acetic-acid-glycoside	1-*O*-{[3-chloro-5-(trifluoromethyl)pyridin-2-yl] acetyl}-α-D-glucopyranose O=C(O[C@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)Cc1ncc(cc1Cl)C(F)(F)F WLNHNRBMWFDQSH-KABOQKQYSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
M43 fluopyram pyridylcarboxylic acid fluopyram-PCA (AE C657188)	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid Clc1cc(cnc1C(O)=O)C(F)(F)F HXRMCZBDTDCCOP-UHFFFAOYSA-N	
M45 methyl-sulfoxide	3-(methylsulfinyl)-5-(trifluoromethyl)-2-pyridinecarboxylic acid OC(=O)c1ncc(cc1S(C)=O)C(F)(F)F RQFCURAIFZONFT-UHFFFAOYSA-N	

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