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Review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA),

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fluopyram. To assess the occurrence of fluopyram residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible chronic risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Summary

Fluopyram was approved on 1 February 2014 by means of Commission Implementing Regulation (EU) No 802/2013 under Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 13 October 2017 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 November 2017 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) Germany to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 9 May 2018. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were provided by the RMS to EFSA on 27 September 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in July 2019 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 3 September 2019 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fluopyram in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the **plant residue definition for enforcement** can be proposed as **'fluopyram'** and for **risk assessment** as **'sum of fluopyram and fluopyram-benzamide** (M25), expressed as fluopyram'. These residue definitions are also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs, the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Fluopyram is a persistent substance which may accumulate in soil following multiannual uses. To account for the potential uptake of such residues accumulated in soil in rotational crops two options were considered. Both options assumed that **the most critical indoor GAP on tomatoes is restricted** to growing on artificial substrates or other means to prevent carry-over of residues from treated soil to succeeding crops. In addition to this restriction:

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. These measures included a plant-back interval (PBI) of 1 year for root and tuber vegetables, and leafy vegetables; and a PBI of 120 days for cereals.

Option 2: assumed that no risk mitigation is implemented other than the above restriction on the most critical indoor GAP on tomatoes.

For Option 1, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for lemons, mandarins, cherries, banana, spring onions, tomatoes, melons, watermelon, Chinese cabbage, escaroles, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes and leeks, where tentative MRLs are derived, and for lime, cherimoya and chicory roots where the available data were insufficient to derive tentative MRLs.

For Option 2, specific MRLs, considering that residues uptake in succeeding crops are not avoided, were also derived for cassava roots/manioc, sweet potatoes, yams, arrowroots, root vegetables, broccoli, cauliflower, Brussels sprouts, head cabbage, kales, kohlrabies, watercress, herbal infusions (roots), sugar beets, sweet corn, maize grain, buckwheat and millet grain, as well as tentative MRLs



for chicory roots. It is underlined that MRLs values derived from rotational crop field data are subject to a high degree of uncertainty.

Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

The effect of industrial processing and/or household preparation was assessed and robust processing factors could be derived for processed commodities from wine grapes, strawberries, tomatoes, melons, apples, bananas and rapeseeds. Tentative processing factors are also proposed for citrus, sugar beet, potato and peanuts.

Fluopyram is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Residues from primary uses without (Option 1) or with (Option 2) residues in rotational crops were considered. For both scenarios, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM) in both cases. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of fluopyram residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review. According to the results of these studies, the **residue definition for enforcement** in all **livestock commodities** was proposed as the '**sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram**' and for **risk assessment** as the '**sum of fluopyram, fluopyram-benzamide (M25), and fluopyram**-*E*/*Z*-**olefine (M02/M03), expressed as fluopyram**'. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in all matrices is available. According to the EURLs, a combined LOQ of 0.02 mg/kg is achievable for commodities of animal origin.

Livestock feeding studies on cows and laying hens were used to derive two sets of MRL and risk assessment values in milk, eggs, and tissues of ruminants and poultry in view of the two dietary burdens (with or without rotational crops), each set corresponding to one of the 2 options described above. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation.

In the light of the possible contribution of residues from rotational uses to consumer exposure pending the implementation of risk mitigation measures, the two options described above were considered.

The highest chronic exposure was calculated for the Dutch toddler, representing 86% (Option 1) and 100% (Option 2) of the acceptable daily intake (ADI). The highest acute exposure was calculated for lettuce, representing 76% of the acute reference dose (ARfD) for both options.

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for fluopyram. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out.

The highest chronic exposure was calculated for Dutch toddler, representing 110% (Option 1) and 128% (Option 2) of the ADI. The highest acute exposure was calculated for lettuce, accounting 76% of the ARfD for both options.

For Option 1, as a potential risk management option, the risk assessment was re-calculated by considering the European animal diet for cattle and swine and thus disregarding the CXLs for these animal commodities. According to this scenario, the chronic exposure represents 92% of the ADI. Nonetheless, it is highlighted that this scenario was only provided as a potential option for risk managers to consider and does not exclude or suggest alternative options may not be available for risk managers.

For Option 2, given that the chronic exposure based on the authorised EU uses, import tolerances and the uptake of fluopyram accumulated in soil following multiannual use already accounted for 100% of the ADI (NL toddlers), and as there may be several alternative options at the discretion of risk managers to exclude a potential chronic risk, the only safe scenario assessed was that disregarding from the calculation all CXLs higher than the derived EU MRL.

Altogether, the calculations indicate a potential chronic risk to consumers if all the existing CXLs are incorporated in the assessment. For Option 1, a safe scenario could be identified, excluding the CXLs for cattle and swine tissues from the calculation. For Option 2, a safe scenario could be identified disregarding from the calculation all CXLs higher than the derived EU MRL.



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Background

Regulation (EC) No $396/2005^1$ (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive $91/414/EEC^2$ a reasoned opinion on the review of the existing MRLs for that active substance.

As fluopyram was approved on 1 February 2014 by means of Commission Implementing Regulation (EU) No $802/2013^3$ in accordance with Regulation (EC) No $1107/2009^4$ as amended by Commission Implementing Regulations (EU) No $540/2011^5$ and $541/2011^6$, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011⁷ Fluopyram was evaluated by Germany, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific report (EFSA, 2013a).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 13 October 2017, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 November 2017 their Good Agricultural Practices (GAPs), in a standardised way, in the format of specific GAP forms. In the framework of this consultation 17 Member States provided feedback on their national authorisations of fluopyram. Based on the GAP data submitted, the designated RMS Germany was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 9 May 2018.

¹ Regulation (EC) No 396/2005 of the European 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.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

³ 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.

⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

⁷ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51–55.



On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked Germany to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 27 September 2018. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit (CXLs)), EFSA prepared in July 2019 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 3 September 2019 including additional GAPs submitted (Netherlands, 2019) were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Germany, 2018), taking into account also the information provided by Member States during the collection of data, the **EURL report on analytical methods** (EURL, 2018) and the evaluation reports received during the Member State consultation (Belgium, 2019; Netherlands, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the **completeness check report** (EFSA, 2019c) and the **Member States consultation report** (EFSA, 2019e). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (**PRIMo**) and the **PROFile** as well as the **GAP overview file** listing all authorised uses and import tolerances are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

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 structure of the active substance and its main metabolites are reported in Appendix F. The EU MRLs for fluopyram are established in Annex IIIA of Regulation (EC) No 396/2005. CXLs for fluopyram were also established by the CAC. An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).



Procedure	Legal implementation	Remarks
MRL application	Not yet implemented	Modification of the existing maximum residue level for fluopyram in herbal infusions from leaves, herbs and flowers (EFSA, 2019d)
MRL application	Commission Regulation (EU) 2019/1791 ^(a)	Modification of the existing maximum residue level for fluopyram in broccoli (EFSA, 2019a)
Implementation of CAC 2018	Commission Regulation (EU) 2019/552 ^(b)	On 6 July 2018, the Codex Alimentarius Commission (CAC) adopted Codex limits (CXLs) for fluopyram. These CXLs have been included in Regulation (EC) No 396/2005 as MRLs
MRL application	Commission Regulation (EU) 2018/685 ^(c)	Modification of the existing maximum residue level for fluopyram in purslanes (EFSA, 2017)
MRL application	Commission Regulation (EU) 2017/978 ^(d)	Modification of the existing maximum residue levels for fluopyram in solanacea, other fruiting vegetables, cardoons, celeries, Florence fennels, other stem vegetables, cotton seeds, other oilseeds, common millet/proso millet, other cereals, herbal infusions from any other parts of the plant, seed spices, carawayand other sugar plants (EFSA, 2016)
Implementation of CAC 2015	Commission Regulation (EU) 2017/626 ^(e)	On 11 July 2015, the Codex Alimentarius Commission (CAC) adopted Codex limits (CXLs) for fluopyram. These CXLs have been included in Regulation (EC) No 396/2005 as MRLs
MRL application	Commission Regulation (EU) 2017/171 ^(f)	Modification of the existing maximum residue levels for apricots, peppers, 'spinaches and similar leaves', witloof, 'herbs and edible flowers', peas (with pods), lentils, other legume vegetables of code 0260990, sesame seeds, sunflower seeds, pumpkin seeds, safflower seeds, borage seeds, hemp seeds, castor beans, barley, buckwheat, oats and sugar beet (EFSA, 2016)
Implementation of CAC 2014	Commission Regulation (EU) 2016/567 ^(g)	On 18 July 2014, Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for fluopyram. These CXLs have been included in Regulation (EC) No 396/2005 as MRLs
MRL application	Commission Regulation (EU) 2015/1101 ^(h)	Modification of the existing MRLs in various crops: apricots, peaches, plums, cane fruit, small fruits and berries, root and tuber vegetables, aubergines, escaroles, spinaches, witloof, beans (without pods), peas (with pods), linseed, poppy seed, mustard seed, gold of pleasure, herbal infusions (dried roots), hops, spices (roots or rhizome), chicory roots (EFSA, 2014)
Implementation of CAC 2013	Commission Regulation (EU) No 491/2014 ⁽ⁱ⁾	On 5 July 2013, Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for fluopyram. These CXLs have been included in Regulation (EC) No 396/2005 as MRLs
MRL application	Commission Regulation (EU) No 270/2012 ^(j)	Setting new MRLs and import tolerances in various commodities (EFSA, 2011)

Table 1:	Overview of the MRL	changes since the entry	y into force of Regulation	(EC) No 396/2005
		changes since are end	fine force of regulation	

MRL: maximum residue level.

(a): Commission Regulation (EU) 2019/1791 of 17 October 2019 amending Annexes II, III and IV to Regulation (EC) No 396/ 2005 of the European Parliament and of the Council as regards maximum residue levels for 1-decanol, 2,4-D, ABE-IT 56, cyprodinil, dimethenamid, fatty alcohols, florpyrauxifen-benzyl, fludioxonil, fluopyram, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben, S-abscisic acid and trifloxystrobin in or on certain products.OJ L 277, 29.10.2019, p. 1–65.

(b): Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6–49.

(c): Commission Regulation (EU) 2018/685 of 3 May 2018 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products. OJ L 121, 16.5.2018, p. 1–29.

(d): Commission Regulation (EU) 2017/978 of 9 June 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products. OJ L 151, 14.6.2017, p. 1–37.



- (e): Commission Regulation (EU) 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, flutriafol, fluxapyroxad, imazapic, imazapyr, lambdacyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L 96, 7.4.2017, p. 1–43.
- (f): Commission Regulation (EU) 2017/171 of 30 January 2017 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products. OJ L 30, 3.2.2017, p. 45–111.
- (g): Commission Regulation (EU) 2016/567 of 6 April 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products. OJ L 100, 15.4.2016, p. 1–60.
- (h): Commission Regulation (EU) 2015/1101 of 8 July 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin in or on certain products. OJ L 181, 9.7.2015, p. 27–53.
- (i): Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, azoxystrobin, cycloxydim, cyfluthrin, dinotefuran, fenbuconazole, fenvalerate, fluopyram, fluopyram, flutriafol, fluxapyroxad, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, spinetoram and trifloxystrobin in or on certain products. OJ L 146, 16.5.2014, p. 1–91.
- (j): Commission Regulation (EU) No 270/2012 of 26 March 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amidosulfuron, azoxystrobin, bentazone, bixafen, cyproconazole, fluopyram, imazapic, malathion, propiconazole and spinosad in or on certain products. OJ L 89, 27.3.2012, p. 5–63.

For the purpose of this MRL review, all the uses of fluopyram currently authorised within the EU and in third countries as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for fluopyram are given in Appendix A.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Germany, 2018);
- the draft assessment report (DAR) and its addenda prepared under in the framework of Commission Regulation (EU) No 188/2011 (Germany, 2011, 2012);
- the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram (EFSA, 2013a);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2010, 2012, 2014, 2015, 2017);
- the previous reasoned opinions on fluopyram (EFSA, 2011, 2014, 2016, 2017, 2019a,d).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011⁸ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013, 2018).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

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



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 peer review (Germany, 2011; EFSA, 2013a). Studies are available after foliar treatment in three crop groups: fruits and fruiting vegetables (grapes), root and tuber (potato) and pulses (beans) and following drip irrigation in fruiting vegetables (pepper). In addition, as supporting information to assist the identification of the metabolic pathway, a study using cell culture is also available.

In grapes, metabolism was limited after 100 g a.s./ha foliar spray application followed bsy 2 \times 200 g a.s./ha. Fluopyram represented over 95% of the total radioactive residues (TRR) 18 days after the last treatment.

Another study investigated metabolism following drip irrigation in mature pepper fruits 55–97 days following treatment. Plants treated with 5 mg [phenyl-UL-¹⁴C]fluopyram/plant, resulted in low TRR (0.038 mg eq/kg), with parent accounting for 49% of TRR and metabolite fluopyram-benzamide (M25) for 16% of TRR. When [pyridyl-2,6-¹⁴C]fluopyram was applied at a rate of 5 or 20 mg/plant, the TRR was 0.06 or 0.149 mg eq/kg, with fluopyram present at 16% or 33% TRR, and metabolites fluopyram-pyridyl-acetic-acid-glycoside (M42) accounting for 32% or 38%, while fluopyram-pyridyl-carboxylic acid (M43) for 20% or 44% of the TRR, respectively.

In potatoes, after three foliar applications of 167 g a.s./ha using two different radiolabels, the overall TRR was low (0.008 and 0.012 mg eq/kg in potato tubers). In the study using the phenyl label, fluopyram accounted for 69% and metabolite M25 for 7% of the TRR. In the case of the pyridyl-2,6 label, metabolite fluopyram-pyridyl-carboxylic acid (M43) was identified up to 50% of the TRR, whereas fluopyram was present at 23% of the TRR.

In beans, after two foliar applications of 250 g a.s./ha, while initially metabolism was not observed, later it became more extensive. In green beans, 4 days following treatment, fluopyram accounted for 94-99% of the TRR (1.3 and 3.9 mg e.g./kg). By 29 days after treatment, the overall TRR dropped substantially in succulent (0.07–0.17 mg eq/kg) and dry beans (0.12–0.31 mg eq/kg). While fluopyram represented only up to 13% of the TRR, metabolite M25 represented up to 64% of the TRR, whereas metabolites M43 and fluopyram-pyridyl-acetic acid (M40) contributed up to 30 and 32 of the TRR% in succulent and dry beans, respectively.

In all foliar applications (grapes, potato and bean), very limited metabolism was observed in the leaves/foliage with parent contributing in the range of 87–98% of the TRR. Even following drip irrigation parent remained above 70% of the TRR in the whole plant.

In addition, a cell suspension study derived from apples was submitted and was considered as supporting information to help identification of metabolites in plant and animal metabolism studies.

It can be concluded that the metabolic pathway of fluopyram was 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).

1.1.2. Nature of residues in rotational crops

Fluopyram is authorised on crops that may be grown in rotation. It is a highly persistent substance; the field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was above 1,000 days (EFSA, 2013a). 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 M25 and M43, with M43 further metabolised to methyl-sulfoxide (M45) (Germany, 2011). None of the soil metabolites were highlighted as persistent during the peer review (EFSA, 2013a).

Two confined rotational crop studies with fluopyram radiolabelled on either the phenyl or the pyridyl moiety were assessed during the peer review (Germany, 2011; EFSA, 2013a). Fluopyram was applied at a rate of 534 or 514 g a.s./ha onto bare soil, which covers the accumulated multiannual soil plateau concentration calculated for the second most critical GAPs (outdoor strawberry, 1.2N) but not that of



the indoor tomato GAP submitted during the Member State Consultation (0.12 N) (see Section 1.2.2). Crops were planted at nominal plant-back intervals (PBIs) of 30, 139 and 280 days after treatment (DAT). Crops planted at each interval consisted of leafy vegetables (Swiss chard), roots (turnips) and cereals (spring wheat).

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; up to 4.9 mg eq/kg in straw at 30 DAT) 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 at low levels. Similarly to 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. 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

Studies investigating the nature of residues in processed commodities were assessed (Germany, 2011; EFSA, 2013a). Studies were conducted with radiolabelled fluopyram and metabolites M08, M25, M40 and M43 on either their phenyl or their 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, 2013a) whereas M40 ([3-chloro-5-(trifluoromethyl)pyridin-2-yl]acetic acid) degraded to fluopyram-picoline (3-chloro-2-methyl-5-(trifluoromethyl)pyridine). Nonetheless, based on the peer review, M40 is not expected to be present in significant levels in raw agricultural commodities (EFSA, 2013a). 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. Methods of analysis in plants

During the peer review a hyphenated analytical method based on gas chromatography (GC) coupled to mass spectrometry (MS) detection was fully validated for the enforcement of fluopyram in high water content (lettuce), high oil content (oilseed rape), high acid content (orange) and dry matrices (wheat grain, peas seed), with a LOQ of 0.01 mg/kg. This primary method is supported by independent laboratory validation (ILV) (EFSA, 2013a). During the completeness check, the EURLs concluded that fluopyram can be monitored by using the QuEChERS method in high water content and high acid content commodities with a LOQ of 0.002 mg/kg and in high oil content and dry commodities with a LOQ of 0.01 mg/kg (EURL, 2018).

EFSA notes that specific analytical methods for dill seeds (seed spice) were not provided, whereas for hops, the ILV of the method is missing. Nonetheless, considering that for all four main groups fully validated analytical methods were provided with an LOQ of 0.01 mg/kg and the MRLs proposed based on CXLs for these commodities are high (\geq 60 mg/kg), this is considered a minor deficiency and therefore submission of the fully validated analytical methods specific for these matrices is only desirable.

1.1.5. Stability of residues in plants

The storage stability of parent and its metabolite M25 was investigated in the framework of the peer review (EFSA, 2013a) and in a subsequent reasoned opinion on fluopyram (EFSA, 2014). Storage stability for both fluopyram and its metabolite M25 was demonstrated 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 hops, seed spices and straw. However, as storage stability was investigated and demonstrated in the four main plant matrices for at least 36 months, and considering that samples from these crops were stored for a maximum of 18 months, a significant decline of residues in these samples is not excepted to have occurred. Therefore, no additional storage stability studies are required.

During the peer review, storage stability was proven for M40 and M43 for at least 2 years in water-, starch-, protein- and oil-containing matrices and at least 6 months in acidic matrices, and for M08 and M45 for at least 2 years in water and starch containing matrices when stored at or below -18° C (EFSA, 2013a).

1.1.6. Proposed residue definitions

A wide range of growing conditions and crop groups was investigated (spraying in fruits, pulses, and tuber crops; drip irrigation in fruits; as well as cereals, root crops and leafy crops grown in rotation). Fluopyram is also authorised as primary seed treatment on oil seeds and as a local treatment (pre-forcing) on chicory roots (witloofs). As the metabolite pattern is essentially the same in all crop categories even under different application systems, the above studies are considered to cover also the latter uses. Overall, the studies experimental designs were representative of the authorised uses and no further study is required.

As the parent compound was found to be a sufficient marker in all crops investigated, the residue definition for enforcement is proposed as **'fluopyram'** only.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices is available (EFSA, 2013a). According to the EURLs, the LOQ of 0.002 mg/kg in high water content and high acid content commodities and the LOQ of 0.01 mg/kg in high oil content and dry commodities is achievable by using the QuEChERS method in routine analyses (EURL, 2018).

The metabolic pathway of fluopyram in plants can be regarded as essentially the same in all crops investigated, with the parent compound being one of the major constituents of the residues. The metabolic pathway primarily consists of the hydroxylation of parent compound (M08), followed by cleavage of the hydroxylated parent compound leading to metabolite M25 (fluopyram-benzamide) from the phenyl moiety and metabolites M40 (primary crops only, including its hexose-conjugate M42), M45 (rotational crop only) and M43 from the pyridyl moiety of the active substance.

In the supervised field trials assessed in the current review M25 was detected only in a few commodities (up to a level of 0.16 mg/kg in rape seed) (see Section 1.2.1). In rotational crop field trials, solely M25 and M08 were found in significant amounts, and only in straw (see Section 1.2.2). However, as the relative contribution of M08 is little and would have very limited impact on the animal burden, if at all, its inclusion in the residue definition for risk assessment that would be specific to rotational cereals (straw) is not proposed. The peer review concluded that metabolite M40 does not need to be included in the residue definition as is of no toxicological concern at the levels detected in supervised field trials and it may be covered by the concurrently detected phenyl specific M25, included in the residue definition (Germany, 2011).

M08, M25, M40 and its conjugate M42 were considered covered by the toxicological profile of the parent compound (EFSA, 2013a). M43 and M45, are common metabolites with active substance fluopicolide. In the light of their levels in food and feed items, and the conclusion for fluopicolide, the peer review considered these metabolites as toxicologically not relevant (Germany, 2011).

Altogether, the residue definition for risk assessment is proposed to remain '**sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram**' as set by the peer review (EFSA, 2013a).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fluopyram residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Germany, 2018) and the evaluation reports received during the Member State Consultation (Belgium, 2019; Netherlands, 2019) as well as the residue trials evaluated in the framework of previous MRL applications (EFSA, 2011, 2014, 2016, 2017, 2019a,d). Based on the information received during the Member States Consultation, EFSA disregarded the uses initially mistakenly considered as existing uses (EFSA, 2019e). All residue trial



samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on lime, cherimoyas, and chicory roots. Therefore, MRL and risk assessment values could not be derived for these crops and the following data gaps were identified:

- Lime: Four trials compliant with the import tolerance GAP are required.
- Cherimoyas: Four trials compliant with the indoor GAP are required.
- Chicory roots: Four trials compliant with the northern outdoor GAP are required. The available trials are not GAP compliant, as they include an additional treatment of the roots by dipping and therefore cannot be used to support the outdoor use.

For all other crops, available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

- Lemons, mandarins: Although tentative MRL and risk assessment values can be derived from the import tolerance limited data set, two additional trials compliant with the import tolerance GAP are still required.
- Rose hips: Trials on currants were scaled to the northern outdoor GAP (scaling factor of 0.75). Further residue trials are not required.
- Banana: Although tentative MRL and risk assessment values can be derived from the southern outdoor data, four trials compliant with the southern outdoor GAP are required.
- Apricots: Although MRL and risk assessment values can be derived from the southern outdoor data, eight trials compliant with the import tolerance GAP are still required.
- Cherries: Although tentative MRL and risk assessment values can be derived from the northern limited data set, one additional trial compliant with the northern GAP and two additional trials compliant with the import tolerance are still required.
- Plums: Although MRL and risk assessment values can be derived from the northern data, two additional trials compliant with the import tolerance GAP are still required.
- Hazelnuts: MRL and risk assessment values can be derived from the import tolerance data. As the northern GAP is clearly less critical, further residue trials compliant with the northern outdoor GAP are not required.
- Carrots: Trials on carrots and radishes were combined in the import tolerance application, since residue levels in carrot and radish roots are expected to be comparable as the foliar application is done close to the harvest. Further residue trials are therefore not required.
- Radishes: Trials on carrots and radishes were combined in the import tolerance application, since residue levels in carrot and radish roots are expected to be comparable as the foliar application is done close to the harvest. Although MRL and risk assessment values can be derived from the import tolerance GAP, four trials compliant with the northern outdoor GAP are still required.
- Tomatoes: Although tentative MRL and risk assessment values can be derived from the indoor limited data set, one additional trial compliant with the indoor GAP is still required.
- Aubergines: Six trials were compliant with the indoor GAP and eight indoor residue trials were conducted with two applications instead of three. The trials on tomatoes performed with two instead of three applications were deemed acceptable since residues are in the same range or higher compared to residues of the GAP compliant trials. Further residue trials are therefore not required.
- Spring onions: Residue trials supporting the northern and the southern outdoor GAPs were conducted with two applications instead of one. Although tentative MRL and risk assessment values can be derived from the southern overdosed residue trials, four trials compliant with the southern GAP are still required. As the northern GAP is clearly less critical, further residue trials compliant with the northern outdoor GAP are not required.
- Sweet peppers: As MRL and risk assessment values can be derived from the import tolerance data and the reduced number of residue trials supporting the southern outdoor GAP confirms that this use is less critical, additional trials compliant with the southern outdoor GAP are not required.



- Cucumbers, courgettes: As MRL and risk assessment values can be derived from the indoor data and the reduced number of residue trials (at least 4) supporting the outdoor GAPs confirms that the outdoor uses are less critical, additional trials compliant with the outdoor GAPs are not required.
- Melons: Although tentative MRL and risk assessment values can be derived from the import tolerance limited data set, two additional trials compliant with the import tolerance GAP and four additional trials compliant with the indoor GAP are still required. EFSA highlights, in case the MRL is to be lowered in the future, risk managers should consider that another GAP leading to a lower MRL (0.3 mg/kg) fully supported by data is authorised in France.
- Watermelons: Although tentative MRL and risk assessment values can be derived from the indoor limited data set, four additional trials compliant with the indoor GAP are still required. EFSA highlights that in case the MRL is to be lowered in the future, risk managers should consider that another GAP leading to a lower MRL (0.3 mg/kg) fully supported by data is authorised in France.
- Sweet corn: The number of residue trials supporting the import tolerance GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials for this minor crop is considered acceptable in this case because all results were below the LOQ and no residue is expected. Further residue trials are therefore not required.
- Chinese cabbage: Residue trials were conducted with two applications instead of one. Although tentative MRL and risk assessment values can be derived from these northern overdosed trials, four trials compliant with the northern GAP are still required.
- Lettuces: The southern outdoor residue trials were conducted with two applications instead of one. Nevertheless, as the indoor GAP is clearly more critical, further residue trials compliant with the outdoor GAP are not required.
- Lamb's lettuces, cresses and other sprouts and shoots, Roman rocket, purslanes (sea lavender), baby leaf crops: Northern outdoor residue trials were conducted with two applications instead of one. Nevertheless, as the indoor GAP is clearly more critical, further residue trials compliant with the northern outdoor GAPs are not required.
- Escaroles, land cresses, red mustards, spinaches, chards/beet leaves: Residue trials were conducted with two applications instead of one. Although tentative MRL and risk assessment values can be derived from these northern overdosed residue trials, four trials compliant with the northern GAP are still required.
- Herbs and edible flowers: Residue trials were conducted in parsley, chervil, sage and savoury. As the highest residue was measured in savoury, all trials in fresh herbs were included in the MRL derivation for the whole group of fresh herbs. It is noted that according to the current EU guidance on extrapolation (European Commission, 2017), extrapolation from sage and savoury to the whole group is not supported, and if these trials are disregarded a lower MRL may be derived.
- Globe artichokes: Although tentative MRL and risk assessment values can be derived from the import tolerance limited data set, one additional trial compliant with the import tolerance GAP is still required.
- Leeks: Residue trials were conducted with two applications instead of one. Although tentative MRL and risk assessment values can be derived from these southern overdosed residue trials, four trials compliant with the southern GAP are still required.
- Beans, peas (dry): Although MRL and risk assessment values can be derived from the import tolerance data, eight additional trials compliant with the northern outdoor GAPs are still required.

The available residue trials also allow to derive conversion factors (CFs) from enforcement to risk assessment. In order to avoid excessive overestimation of the risk assessment the following considerations were applied when calculating the CFs. A CF of 1 was applied for all commodities where the metabolite M25 was found at or below the LOQ in all trials. The results from trials performed in different geographical zones were combined, if mode of application allowed. For the import tolerances (with the exception of cotton) the metabolite M25 was not measured. In these cases, and where applicable, the CFs for the same commodities or group of commodities were used. For all import tolerances on fruit crops, the CF of 1 as derived from the available trials on other fruits crops with foliar treatment was applied; for pulses, a CF of 1.3 based on beans/peas without pods; whereas for oilseeds the CF of 1.2 was based on rapeseed. An overview of the derived CFs is reported in



Appendix B.1.2.1. Considering the overall data available, although the metabolite was not always analysed, additional trials are not required to confirm the proposed conversion factors.

1.2.2. Magnitude of residues in rotational crops

The confined rotational crop studies suggest that residues of fluopyram cannot be excluded in rotational crops. Therefore, rotational field studies were required to assess potential residues uptake in rotational crops following multiannual use of fluopyram.

1.2.2.1. Plateau concentration in soil

As the DT₉₀ value exceeds one year, fluopyram is likely to accumulate in soils treated for several consecutive years. Therefore particular attention has to be paid to the plateau concentration expected in soil after several years of applications. The total soil concentration of fluopyram (PEC_{soil total}) resulting from the multiannual use of fluopyram at the critical GAP (plateau background 0.08 mg/kg soil at 20 cm depth) plus from the maximal seasonal application rate is calculated as 0.146 mg/kg after 10 years based on the most critical authorised use of strawberries (foliar, 2 × 250 g/ha). During the Member States consultation, data to support a recently authorised more critical GAP was submitted (Netherlands, 2019). Based on this indoor GAP on tomatoes (4 × 500 g/ha; soil drip application, preharvest interval (PHI) of 1 day), the calculated total plateau concentration over 20 cm is 1.42 mg/kg after 11 years.

Several rotational crop field trials conducted in Europe, the USA or Canada provided in the framework of the peer review (Germany, 2011; EFSA, 2013a) or submitted in the framework of an MRL application (EFSA, 2014) were considered in the present MRL review. In all these trials, fluopyram was applied on bare soil, or early post-emergence applications of a primary crop at the dose rate of 500 g a.s./ha equivalent to a PEC_{soil total} of 0.17 mg a.s./kg soil (20 cm soil of a density of 1.5 g/cm³; no plant-soil interception). Therefore, the dose rate of the rotational field studies represents roughly 1.2N and 0.12N compared to the PEC_{soil} estimated at 0.146 and 1.42 mg/kg for the northern European Union (NEU) GAP on strawberries and the indoor GAP on tomato, respectively.

Since the rotational crop field studies were underdosed compared to the plateau concentration for the indoor soil application on tomato, the possible occurrence of residues of fluopyram following multiannual applications according to this GAP could not be assessed for this use. Therefore, Member States granting an authorisation for this indoor tomato GAP should request additional rotational crop field studies conducted with application rates that cover the plateau background concentrations for this use. Pending the submission of these studies, Member States are recommended to implement mitigation measures (e.g. restriction on the use to growing substrate) in order to avoid uptake of residues from soil following the above use, not covered by the present assessment.

The current assessment covers residue uptake from previously treated soils following multiannual applications for all other authorised uses.

1.2.2.2. Rotational crop field trials: residues in succeeding crops

In the above rotational field trials, residues in succeeding crops with PBIs of around 30 days (28–49 days), 90–240 days or 286–320 days were evaluated (EFSA, 2013a). Samples from rotational crops (turnips/carrot, head lettuce and wheat) were taken 100–425 days following last treatment and residues were analysed for parent, and metabolites M08, M25, M43 and M45. Fluopyram was found at up to 0.05 and 0.03 mg/kg in carrots, 0.03 and 0.01 mg/kg in lettuce (PBI: 30–36 days and 90–240 days, respectively); and in one sample at 0.01 mg/kg (PBI 30 days) in wheat grains. At 286/320 PBIs, in the edible part of crops, residues of fluopyram and its metabolites were all below the LOQ of 0.01 mg/kg. With regard to feed items, in straw and green material (considered as surrogate for forage) fluopyram was detected at all PBIs, with highest residues observed at the PBI of \sim 30 days (up to 0.28 mg/kg and 0.12 mg/kg, respectively).

Regarding the metabolites, none were detected in lettuce or root crops at any of the PBIs. In straw, M08 was detected up to 0.11 mg/kg and M25 at up to 0.14 mg/kg at the PBI of \sim 30 days. M45 was also detected in all wheat parts, with highest residue detected at the PBI of 30 days.

In the rotational crop field trials submitted under a previous MRL application, residues at the PBI of 30 days were investigated in potato and spinach (EFSA, 2014). Fluopyram was detected between 0.02 to 0.09 mg/kg in spinach, whereas in potato tubers it was detected at 0.02 mg/kg. Compared to the previous trials on lettuce (EFSA, 2013a), residue data on spinach leaves show higher residues levels.

Additional field rotational crop trials (mustard green, alfalfa and cotton) conducted in the US and Canada using 2 applications of 250 g/ha fluopyram sprayed on bare soil or early post-emergence



applications (primary crops) with a target PBI of 14 days or 240 DAT, considered less representative than the European trials, completed the data set (Germany, 2011). These trials indicate that fluopyram is present in mustard green grown in rotation (up to 0.035 mg/kg at the PBI of 240 days), whereas in succeeding cotton its presence is unlikely. Cotton was grown following 14 days of bare soil treatment and fluopyram was not detected in cotton seeds, only in cotton gin by-products in 2 out of 11 trials (0.02 mg/kg) (Germany, 2011).

Results of the rotational field studies are reported in Appendix B.1.2.2(b).

There are no rotational field trials available on fruits and fruiting vegetables. Therefore, the available authorised soil treatment uses on tomatoes (excluding the new indoor use), sweet peppers and cucurbits (see Appendix B.1.2.1) were considered as surrogate for fruits and fruiting vegetables grown in rotation. These trials suggests that significant residue uptake from rotated uses might not be expected in this group of crops. As the application rate of the new indoor use on tomato is much higher compared to the plateau expected in soil (see above), this use was not considered.

Based on the available rotational crop trials, residues may only be expected to be below 0.01 mg/kg in the edible parts of succeeding crops if appropriate risk mitigation measures are implemented, such as limiting the use of the new indoor GAP on tomato to substrate growth, setting a PBI of 120 days for cereals, and a PBI of 1 year for root and tuber vegetables and leafy crops, and provided that fluopyram is applied in compliance with the GAPs reported in Appendix A. EFSA investigated two options to account for the possible carry-over of residues to crops grown in rotation following multiannual use. In both options, the most critical indoor GAP on tomatoes is considered to be restricted to substrate growth.

Option 1: assumed that adequate risk mitigation measures are in place to avoid residues above 0.01 mg/kg in the edible part of crops grown in rotation with crops treated with fluopyram. As described above, these measures included a PBI of 1 year for root and tuber vegetables, and leafy vegetables; and a PBI of 120 days for cereals. It is highlighted that at national level alternative risk mitigations measures may be also be available.

Option 2: assumed that no additional risk mitigation is implemented.

1.2.2.3. Calculation of MRLs in rotational crops (Option 2)

On the basis of the above reported studies the peer review proposed default MRLs of 0.1 mg/kg for root/tuber and leafy crops and of 0.01 mg/kg for cereals and oilseed (EFSA, 2013a), and EFSA recommended 0.2 mg/kg for spinaches and similar leaves, except purslanes and 0.05 mg/kg for potatoes (EFSA, 2014).

In the framework of this MRL review, EFSA further considered the available data to estimate the impact of residue uptake from soil following multiannual use on the MRLs and risk assessment values, in case appropriate risk mitigation measures are not in place to prevent carry-over (Option 2).

The MRL review should be performed according to the old data requirements applicable at the time of the peer review. Nevertheless, as the European Commission guidance document on rotational crops (European Commission, 1997c) provides only limited guidance on how to derive MRLs for rotational crops, EFSA considered the methodology described by the recent OECD guidance on rotational crops (OECD, 2018) which is in principle fully applicable only with the new data requirements.

For annual crops, EFSA performed a rough estimate whether or not uptake of fluopyram residues from the soil could contribute significantly to the overall fluopyram residue levels.

Based on the rotational field studies, considering the worst case scenario of crop failure (PBI of 30 days) highest fluopyram residues were 0.05, 0.09 and 0.28 mg/kg in root and tuber vegetables, leafy vegetables and straw, respectively. Residues were below the LOQ of 0.01 mg/kg in cotton seeds (pulses and oil seeds) (see Section 1.2.2.2 and Appendix B.1.2.2). Residues from soil uptake in succeeding crops were extrapolated from spinaches/lettuces to all leafy vegetables, brassicas; from potatoes to all tuber vegetables; from carrots/turnips to root; and from wheat to cereals. Residues resulting from the primary crop use were compared to the residue levels observed through soil uptake in the rotational field trials. If the additional contribution by rotational crop residues (highest residue (HR) values) is < 25% of the residues arising after primary treatment (HR values), the primary use was considered as representative of the residues from the combined sources.

For root and tuber vegetables, and brassica vegetables, the uptake of residues from rotational crops exceeded 25% of the residue from primary uses. Therefore, the HR and supervised trials median residue (STMR) values from the two uses were summed and the MRL was rounded up to account for the combined uses. It is noted, when residues from soil uptake were combined with does originating from the primary use, the existing GAPs from third countries (import tolerances) were disregarded. For



all crops that may be grown in rotation but for which no primary crop use is authorised, the STMR, HR and MRL values were derived from extrapolation from the relevant rotational crops data.

As in succeeding crops M25 was above the LOQ only in cereal green material and straw, for which residues following primary use were significantly higher, the CF from enforcement to risk assessment derived for primary crops are considered applicable for the combined uses.

In the absence of data on the primary crop use of chicory roots the MRL proposal and risk assessment values were also derived directly from the rotational field trials. It is stressed that setting MRLs for rotational crops based on the available limited data set is associated with large uncertainties.

An overview of the derived MRLs is reported Appendix B.1.2.2(c).

In fruit crops, the available data suggest that potential uptake in succeeding crops is likely covered by the MRLs derived from the authorised uses. The following data are therefore considered desirable but not essential:

• additional rotational field trials on fruits and fruiting vegetables.

Moreover, for bulb and stem vegetables specific data for rotational crops are not available, EFSA was not able to assess the potential uptake in succeeding crops. Although it is not expected to modify the outcome of the risk assessment, the following data should be generated if risk managers intend to set MRLs in these crops:

• four additional rotational field trials on bulb and stem vegetables.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on oranges, grapes, strawberries, tomato, melon, apple, banana, oilseed, potato, sugar beet, peanuts (EFSA, 2011; Germany, 2011). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for grapes (washed; juice, dry and wet pomace, must, wine, and dried raisins) strawberries (jam), tomatoes (peeled and canned; juice), melons (peeled), apples (washed; juice, dry and wet pomace, and sauce), bananas (peeled) and rapeseeds (crude oil, refined oil and meal/press cake). 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.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for lemons, mandarins, cherries, banana, spring onions, tomatoes, melons, watermelon, Chinese cabbage, escaroles, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes and leeks, where tentative MRLs are derived, and for lime, cherimoya, and chicory roots, where the available data were insufficient to derive tentative MRLs. As fluopyram is a very persistent substance, these MRL proposals assume that appropriate risk mitigation measure are implemented to avoid carry-over from treated soil (such as limiting the use of the new indoor GAP on tomato to substrate growth, setting a PBI of 120 days for cereals, and a PBI of one year for root and tuber vegetables and leafy crops; Option 1).

In addition, specific MRLs from rotational crops considering a worst case scenario (PBI of 30 days, no risk mitigation measure other than restricting the new tomato indoor use is in place; Option 2) were also derived for: cassava roots/manioc, sweet potatoes, yams, arrowroots, root vegetables, broccoli, cauliflower, Brussels sprouts, head cabbage, kales, kohlrabies, watercress, herbal infusions (roots), spice roots, sugar beets, chicory roots (tentative), sweet corn, maize, rice, buckwheat and millet grain.

It is noted that following multiannual applications according to the new indoor soil treatment use on tomato, if carry-over of treated soil is not mitigated, the possible occurrence of residues of fluopyram at levels higher than the derived MRL reported in this review cannot be excluded for this use.

Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

2. Residues in livestock

Fluopyram is authorised for use on several crops that might be fed to livestock, in addition residues in feed items from crops grown in rotation cannot be ruled out. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013).

In a first scenario only the residues from primary uses were considered. In order to cover the possible contribution from rotational crops, a second calculation was carried out considering the STMR and HR values as derived in Appendix B.1.2.2.(c) based on the combined residues from primary and rotational crops. The input values for all relevant commodities, corresponding to each option, have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Appendix D.

The calculated dietary burdens for all groups of livestock are summarised in Appendix B.2.(a) considering primary uses only (Option 1) and in Appendix B.2.(b) considering also residues from additional soil uptake (Option 2). The calculated dietary burden for ruminants nearly doubled in Option 2, driven by residues in processed potato waste, whereas it had only a minor impact the dietary burden for poultry (most critical commodity swede roots).

It is highlighted that for turnip tops, no residue data were available for primary crops. Nonetheless, residues extrapolated from rotated carrot leaves were considered in the second calculation. The animal intake of fluopyram residues via the primary use of turnip leaves has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the overwhelming contribution of other feed items (e.g. cereals and potato).

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of fluopyram residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review (Germany, 2011). These studies were assessed in the framework of the peer review (EFSA, 2013a).

In all studies fluopyram was radiolabelled in the phenyl or pyridyl ring of the molecule and administered at nominal rates of 2 mg/kg body weight (bw) per day to lactating goats or laying hens. The studies indicate a significant transfer of residues to all animal matrices. Substantial label dependent differences were observed in the uptake and distribution of radioactivity in both hens and goats. The rate of uptake of pyridyl labelled compounds was faster, in contrast, the accumulation of the phenyl labelled compounds in milk, eggs and tissues were several fold higher. In lactating goats, highest residue levels (phenyl label) were found in liver and kidney (8.7 and 2.3 mg eq/kg, respectively) whilst lower transfer is expected in milk (up to 0.3 mg eq/kg), muscle (0.7 mg eq/kg), and fat (0.4 mg eq/kg). In hens, the highest residue transfer was observed in liver (9.4 mg eq/kg), followed by eggs, muscle and fat (3.6, 3.3 and 1.6 mg eq/kg, respectively).

Fluopyram was extensively metabolised in all animals and was only detected at very low levels in poultry and goat matrices in the metabolism studies. Radioactive residues were composed of several metabolites. The phenyl specific metabolite fluopyram-benzamide (M25) was the most predominant compound in all matrices identified; in hen between 67% and 99% TRR and in goat in the range of 49% to 98% TRR. Other main metabolites were fluopyram-*E*/*Z*-olefine (M02, M03), observed at significant levels in fat of poultry (up to 0.425 mg/kg; 26% TRR) and ruminant (up to 0.125 mg/kg; 34% TRR). In addition, in goat other metabolites found above 10% TRR included fluopyram-7-hydroxy (M08), its conjugates. Their relative contribution to the consumer exposure compared to other metabolites is expected to be low. All other identified metabolites were present at lower levels (< 10% TRR).

As fluopyram and fluopyram-benzamide were found to be sufficient markers in all livestock commodities, the residue definition for enforcement is proposed as the **`sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram**'.

An analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) was fully validated for the determination of fluopyram and fluopyrambenzamide in all animal tissues, milk and eggs, with a combined LOQ of 0.02 mg/kg (EFSA, 2013a). According to the EURLs, a combined LOQ of 0.02 mg/kg is achievable for the proposed residue



definition for commodities of animal origin (sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram) (EFSA, 2019e).

Based on the metabolism and feeding studies fluopyram residues are not fat soluble, as preferential concentration in fat tissues and/or milk is not observed.

For risk assessment, fluopyram and fluopyram-benzamide (M25), fluopyram-*E*/*Z*-olefine (M02/M03) are considered toxicologically relevant. Fluopyram-benzamide (M25) and fluopyram-*E*/*Z*-olefine (M02/M03) are encountered in the rat metabolism (EFSA, 2013a). Therefore, the residue for risk assessment was defined as the **'sum of fluopyram, fluopyram-benzamide (M25), and fluopyram-***E***/***Z***-olefine (M02/M03), expressed as fluopyram'.**

It is noted that a study was provided on the metabolism of fish in the framework of the peer review (Germany, 2011). In case MRLs will need to be set for fish commodities in the future, this study could be considered.

2.2. Magnitude of residues in livestock

In the framework of the peer review, feeding studies were performed with dairy cows and laying hens (Germany, 2011). In the ruminant feeding study, fluopyram was administered using different dosing levels ranging from 0.04 to 4.05 mg/kg bw per day and. The study also included a separate group to investigate depuration of fluopyram residues, that was fed at a dose rate of 4.38 mg/kg bw per day during the feeding phase. In the poultry feeding study, fluopyram was administered at dosing levels ranging from 0.035 to 0.32 mg/kg bw per day.

The studies performed on cows and hens were used to derive MRL and risk assessment values in milk, eggs, and tissues of ruminants and poultry. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs. In these studies, samples of tissues, milk and eggs were analysed for fluopyram, and its metabolites fluopyram-benzamide (M25), fluopyram-*E*/*Z*-olefine (M02/M03), and are expressed as fluopyram. All tissue, milk and eggs samples were analysed within 30 days of collection and stored $\leq -18^{\circ}$ C thus decline of residues during storage of the trial samples is not expected.

Based on these studies, MRL and risk assessment values were derived for all commodities of ruminants, pigs and poultry in compliance with the latest recommendations on this matter considering the dietary burdens with or without risk mitigation measures preventing residue uptake from rotational uses (FAO, 2009).

Based on the livestock feeding studies and the calculated livestock dietary burden, EFSA also derived a conversion factor for risk assessment of 1.3 and 1.4 in fat for poultry and ruminants, respectively and a CF of 1 for all other tissues (see Appendix B.2.2).

3. Consumer risk assessment

In the framework of this review, only the uses of fluopyram reported by the RMS in Appendix A were considered; however, the use of fluopyram was previously also assessed by the JMPR (FAO, 2010, 2012, 2014, 2015, 2017). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

In the light of the possible contribution of residues from rotational uses to consumer exposure pending the implementation of risk mitigation measures, two options were considered.

In both options, it is assumed that **the most critical indoor GAP on tomatoes is restricted** to growing on artificial substrates or other means to prevent carry-over of residues from treated soil to succeeding crops. In addition to this restriction:

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. These measures included a PBI of 1 year for root and tuber vegetables, and leafy vegetables; and a PBI of 120 days for cereals.

Option 2: assumed that no risk mitigation is implemented other than the restriction on the most critical indoor GAP on tomatoes.

Finally, it is highlighted that fluopyram-benzamide (M25) was recently identified to be a common metabolite with flutolanil in the on-going renewal of the latter (Netherlands, 2018). Although the MRL review for flutolanil did not assess the presence of M25 (EFSA, 2013b), as only a limited number of



GAPs are authorised with relatively low existing MRLs, it can be reasonably expected that exposure to M25 from the use of flutolanil is not significant compared to the uses on fluopyram and will not impact the risk assessment performed under the present MRL review.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed with revision 3.1 (EFSA, 2018, 2019b). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, risk assessment values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. Further to the crops reported in the framework of this review, these calculations also include the potential uptake of fluopyram residues in crops that may be grown in rotation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for fluopyram, derived by EFSA (2013a).

The highest chronic exposure was calculated for the Dutch toddler, representing 86% (Option 1) and 100% (Option 2) of the acceptable daily intake (ADI). The highest acute exposure was calculated for lettuce, representing 76% of the acute reference dose (ARfD) for both options. As the exposure calculated did not exceed the toxicological reference values, no further refinement of the risk assessment was performed but it is noted that for Option 2 the major contributors to the chronic exposure are milk (20%), apples (18%) and banana (9%).

Although uncertainties remain due to the data gaps identified in the previous sections, it is highlighted that chronic intake is 100% of the ADI if risk mitigation measures are not in place to avoid carry-over of residues from previously treated soils (Option 2).

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. It is highlighted that the existing EU MRL established by Reg. (EU) 2017/626 for milk of 0.6 mg/kg was based on a CXL adopted by CAC in 2016. However, in 2018, CAC adopted a higher CXL for milk and revoked the associated CXL. The increased CXL was not taken over in Reg. (EU) 2019/552 due to intake concerns. As the original CXL was revoked, there were no longer basis to consider the former CXL of 0.6 mg/kg for milk. An overview of the input values used for this exposure calculation is also provided in Appendix D.

It is noted that for plant commodities the residue definition established by the JMPR for both enforcement and risk assessment of the CXLs is 'fluopyram'. For risk assessment the definition proposed by EFSA is wider compared to the one for CXLs. Therefore, the relevant conversion factors derived in Sections 1.2 and 2.2 were applied for the same commodities or group of commodities.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for fluopyram.

The highest chronic exposure was calculated for Dutch toddler, representing 110% (Option 1) and 128% (Option 2) of the ADI. The highest acute exposure was calculated for lettuce, accounting for 76% of the ARfD for both options.

For Option 1, as a possible option for risk managers consideration, the risk assessment was recalculated by disregarding the CXLs for cattle and swine tissues and considering for these commodities the STMR values derived from the European animal diet. According to this calculation, the chronic exposure represents 92% of the ADI.

For Option 2, given that the chronic exposure considering the authorised EU uses and import tolerances and the uptake from rotational crops already accounted for 100% of the ADI (NL toddlers), and as there may be several alternative options to exclude a potential chronic risk, the only safe scenario assessed was disregarding from the calculation all CXLs higher than the derived EU MRL. Overall, for Option 1, a safe scenario could be identified, excluding the CXLs for cattle and swine



tissues from the calculation. For Option 2, a safe scenario could be identified disregarding from the calculation all CXLs higher than the derived EU MRL.

Conclusions

The metabolism of fluopyram in plant was investigated in primary and rotational crops. According to the results of the metabolism studies, the **plant residue definition for enforcement** can be proposed as **'fluopyram'** and for **risk assessment** as **'sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram**'. These residue definitions are also applicable to processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all major matrices at the LOQ of 0.01 mg/kg. According to the EURLs the LOQ of 0.01 mg/kg is achievable by using the QuEChERS method in routine analyses.

Fluopyram is a persistent substance which may accumulate in soil following multiannual uses. To account for the potential uptake of such residues accumulated in soil in rotational crops two options were considered. Both options assumed that **the most critical indoor GAP on tomatoes is restricted** to growing on artificial substrates or other means to prevent carry-over of residues from treated soil to succeeding crops. In addition to this restriction:

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. These measures included a plant back interval (PBI) of 1 year for root and tuber vegetables, and leafy vegetables; and a PBI of 120 days for cereals.

Option 2: assumed that no risk mitigation is implemented other than the above restriction on the most critical indoor GAP on tomatoes.

For Option 1, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for lemons, mandarins, cherries, banana, spring onions, tomatoes, melons, watermelon, Chinese cabbage, escaroles, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes and leeks, where tentative MRLs are derived, and for lime, cherimoya and chicory roots where the available data were insufficient to derive tentative MRLs.

For Option 2, specific MRLs, considering that residues uptake in succeeding crops are not avoided, were also derived for cassava roots/manioc, sweet potatoes, yams, arrowroots, root vegetables, broccoli, cauliflower, Brussels sprouts, head cabbage, kales, kohlrabies, watercress, herbal infusions (roots), sugar beets, sweet corn, maize grain, buckwheat and millet grain, as well as tentative MRLs for chicory roots. It is underlined that MRLs values derived from rotational crop field data are subject to a high degree of uncertainty.

Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

The effect of industrial processing and/or household preparation was assessed and robust processing factors could be derived for processed commodities from wine grapes, strawberries, tomatoes, melons, apples, bananas and rapeseeds. Tentative processing factors are also proposed for citrus, sugar beet, potato and peanuts.

Fluopyram is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Residues from primary uses without (Option 1) or with (Option 2) residues in rotational crops were considered. For both scenarios, the dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM in both cases. Behaviour of residues was therefore assessed in all commodities of animal origin.

The metabolism of fluopyram residues in livestock was investigated in lactating goats and laying hens at dose rates covering the maximum dietary burdens calculated in this review. According to the results of these studies, the **residue definition for enforcement** in all **livestock commodities** was proposed as the '**sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram**' and for **risk assessment** as the '**sum of fluopyram, fluopyram-benzamide (M25), and fluopyram**' and for **risk assessment** as the '**sum of fluopyram**'. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.02 mg/kg in all matrices is available. According to the EURLs a combined LOQ of 0.02 mg/kg is achievable for commodities of animal origin.

Livestock feeding studies on cows and laying hens were used to derive two sets of MRL and risk assessment values in milk, eggs, and tissues of ruminants and poultry in view of the two dietary



burdens (with or without rotational crops), each set corresponding to one of the 2 options described above. Since extrapolation from ruminants to pigs is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in pigs.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation.

In the light of the possible contribution of residues from rotational uses to consumer exposure pending the implementation of risk mitigation measures, the two options described above were considered.

The highest chronic exposure was calculated for the Dutch toddler, representing 86% (Option 1) and 100% (Option 2) of the ADI. The highest acute exposure was calculated for lettuce, representing 76% of the ARfD for both options.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for fluopyram. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out.

The highest chronic exposure was calculated for Dutch toddler, representing 110% (Option 1) and 128% (Option 2) of the ADI. The highest acute exposure was calculated for lettuce, accounting 76% of the ARfD for both options.

For Option 1, as a potential risk management option, the risk assessment was re-calculated by considering the European animal diet for cattle and swine and thus disregarding the CXLs for these animal commodities. According to this scenario, the chronic exposure represents 92% of the ADI. Nonetheless, it is highlighted that this scenario was only provided as a potential option for risk managers to consider and does not exclude or suggest alternative options may not be available for risk managers.

For Option 2, given that the chronic exposure based on the authorised EU uses, import tolerances and the uptake of fluopyram accumulated in soil following multiannual use already accounted for 100% of the ADI (NL toddlers), and as there may be several alternative options at the discretion of risk managers to exclude a potential chronic risk, the only safe scenario assessed was that disregarding from the calculation all CXLs higher than the derived EU MRL.

Altogether, the calculations indicate a potential chronic risk to consumers if all the existing CXLs are incorporated in the assessment. For Option 1, a safe scenario could be identified, excluding the CXLs for cattle and swine tissues from the calculation. For Option 2, a safe scenario could be identified disregarding from the calculation all CXLs higher than the derived EU MRL.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix ${\sf E}$ of the reasoned opinion.

Since fluopyram is highly persistent in the soil, for root, tuber and brassica vegetables as well as certain crops that may be grown in rotation but for which no primary crop use is authorised (kales, kohlrabies, watercresses, buckwheat and millet grain), it cannot be excluded that residues above the derived MRLs occur in succeeding crops, unless appropriate risk mitigation measures are in place.

Therefore, two different options were derived. In both options, it is assumed **that the most critical indoor GAP on tomatoes is restricted** to growing on artificial substrates or other means to prevent carry-over of residues from treated soil to succeeding crops. In addition to this restriction:

- **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. These measures included a PBI of 1 year for root and tuber vegetables, and leafy vegetables; and a PBI of 120 days for cereals.
- **Option 2:** assumed that no risk mitigation is implemented other than the restriction on the most critical indoor GAP on tomatoes.

For **Option 1**, all MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:



• additional residue trials on lime, mandarins, bananas, cherimoya, tomatoes, melons, watermelons, Chinese cabbage, escaroles, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes, leeks and chicory roots.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

• additional residue trials on lemons, cherries, apricots, plums, spring onions, radishes, dry beans and peas.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Option 2 is presented in order to facilitate decision by risk managers but, it is underlined that all MRLs values derived from rotational crop field data are subject to a higher degree of uncertainty. They are based on a limited data set, with conservative assumptions and a very high degree of uncertainty with regards to actual concentrations of fluopyram in soil, and is also pending on the actual use pattern of fluopyram. EFSA recommends that residues uptake in succeeding crops should be avoided as much as possible. Furthermore, given that the chronic exposure based on the European authorised uses, the import tolerances and the uptake from soil accounted already for 100% of the ADI (NL toddlers), according to this option, it was not possible to consider the current CXLs higher than the derived EU MRL. As there may be several alternative options, at the discretion of risk managers, to exclude the potential chronic risk, MRLs not covering the existing CXLs require further considerations by risk managers. In particular, a chronic risk was identified if also all CXLs are considered, but it does not mean that all CXLs contribute significantly to the chronic intake and would lead to a potential intake concern. For Option 2, all MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:

• additional residue trials on lime, lemons, mandarins, bananas, cherimoyas, spring onions, tomatoes, melons, watermelons, Chinese cabbage, escaroles, land cresses, red mustards, spinaches, chards/beet leaves, globe artichokes, leeks and chicory roots.

It is highlighted, however, that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional residue trials on cherries, apricots, plums, radishes, dry beans and peas.
- additional rotational field trials on fruit and fruiting vegetables.

Moreover, for bulb and stem vegetables specific data for rotational crops are not available, EFSA was not able to assess the potential uptake in succeeding crops. Although it is not expected to modify the outcome of the risk assessment, the following data should be generated if risk managers intend to set MRLs in these crops:

• 4 additional rotational field trials on bulb and stem vegetables.

Minor deficiencies were also identified in the assessment but they are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

• a fully validated analytical method for the determination of fluopyram in seed spices and an ILV of the method in hops.



Table 2:Summary table

					Out	come of the	e review
Code number	Commodity	Existing EU MRL	Existing CXL (mg/kg)	Option 1	(PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato use)
		(mg/kg)	(119/19)	MRL (mg/kg) Comment		MRL (mg/kg)	Comment
Enforcement r	esidue definitior	: Fluopyram					
110010	Grapefruit	0.4	0.4	0.5	Recommended ^(a)	0.5	Recommended ^(a)
110020	Oranges	0.6	0.6	0.6	Recommended ^(b)	0.5	Further consideration needed ^(c)
110030	Lemons	1	1	1	Recommended ^(d)	0.9	Further consideration needed ^(e)
110040	Limes	1	1	1	Further consideration needed ^(f)	1	Further consideration needed ^(f)
110050	Mandarins	0.6	0.6	0.9	Further consideration needed ^(g)	0.9	Further consideration needed ^(g)
120010	Almonds	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120020	Brazil nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120030	Cashew nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120040	Chestnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120050	Coconuts	0.04	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120060	Hazelnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120070	Macadamia	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120080	Pecans	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120090	Pine nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120100	Pistachios	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
120110	Walnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)
130010	Apples	0.6	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)
130020	Pears	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)
130030	Quinces	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)
130040	Medlar	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)
130050	Loquat	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)
140010	Apricots	1.5	1	1.5	Recommended ^(a)	1.5	Recommended ^(a)
140020	Cherries	2	2	2	Recommended ^(d)	2	Recommended ^(d)
140030	Peaches	1.5	1	1.5	Recommended ^(a)	1.5	Recommended ^(a)
140040	Plums	0.5	0.5	0.6	Recommended ^(a)	0.6	Recommended ^(a)
151010	Table grapes	1.5	2	2	Recommended ^(a)	2	Recommended ^(a)



					Out	come of the	e review	
Code number	Commodity	Existing EU MRL	Existing CXL	Option 1	(PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato use)		
		(mg/kg)	(mg/kg)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment	
151020	Wine grapes	1.5	2	2	Recommended ^(b)	1.5	Further consideration needed ^(c)	
152000	Strawberries	2	0.4	2	Recommended ^(a)	2	Recommended ^(a)	
153010	Blackberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)	
153020	Dewberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)	
153030	Raspberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)	
154010	Blueberries	7	7	7	Recommended ^(a)	7	Recommended ^(a)	
154020	Cranberries	3	_	4	Recommended ^(h)	4	Recommended ^(h)	
154030	Currants (red, black and white)	7	7	7	Recommended ^(b)	4	Further consideration needed ^(c)	
154040	Gooseberries	7	7	7	Recommended ^(b)	4	Further consideration needed ^(c)	
154050	Rose hips	7	7	7	Recommended ^(b)	3	Further consideration needed ^(c)	
154060	Mulberries	7	_	4	Recommended ^(h)	4	Recommended ^(h)	
154080	Elderberries	7	_	4	Recommended ^(h)	4	Recommended ^(h)	
163020	Bananas	0.8	0.8	0.8	Further consideration needed ^(g)	0.8	Further consideration needed ^(g)	
163030	Mangoes	1	1	1	Recommended ⁽ⁱ⁾	_	Further consideration needed ^(j)	
163060	Cherimoyas	0.01*	_	_	Further consideration needed ^(k)	_	Further consideration needed ^(k)	
211000	Potatoes	0.15	0.15	0.15	Recommended ^(b)	0.08	Further consideration needed ^(c)	
212010	Cassava	0.1	_	-	Further consideration needed ^(I)	0.06	Recommended ^(h)	
212020	Sweet potatoes	0.1	_	0.06	Recommended ^(h)	0.15	Recommended ^(h)	
212030	Yams	0.1	_	0.06	Recommended ^(h)	0.15	Recommended ^(h)	
212040	Arrowroot	0.1	_	-	Further consideration needed ^(I)	0.06	Recommended ^(h)	
213010	Beetroot	0.3	_	0.06	Recommended ^(h)	0.2	Recommended ^(h)	
213020	Carrots	0.4	0.4	0.4	Recommended ^(b)	0.4	Recommended ^(a)	
213030	Celeriac	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213040	Horseradish	0.3	-	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213050	Jerusalem artichokes	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213060	Parsnips	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	



					Out	MRL (mg/kg)Commentand0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(h)0.4Recommended(h)ended(a)0.07Recommended(a)ended(a)0.07Recommended(a)ended(h)0.07Recommended(h)ended(b)3Further consideration needed(e)ended(b)3Further consideration needed(c)ended(b)2Further consideration needed(c)ended(b)0.6Recommended(a)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)ended(h)0.6Recommended(h)		
Code number	Commodity	Existing EU MRL	Existing CXL (mg/kg)			Option 2 (Restriction on indoor tomato use		
		(mg/kg)	(1119/149)	MRL (mg/kg)	Comment		Comment	
213070	Parsley root	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213080	Radishes	0.3	_	0.3	Recommended ^(h)	0.4	Recommended ^(h)	
213090	Salsify	0.3	-	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213100	Swedes	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
213110	Turnips	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)	
220010	Garlic	0.1	0.07	0.07	Recommended ^(a)	0.07	Recommended ^(a)	
220020	Onions	0.1	0.07	0.07	Recommended ^(a)	0.07		
220030	Shallots	0.1	_	0.07	Recommended ^(h)	0.07	Recommended ^(h)	
220040	Spring onions	15	15	15	Recommended ^(b)	3	Further consideration needed ^(e)	
231010	Tomatoes	0.9	0.5	0.5	Further consideration needed ^(g)	0.5	Further consideration needed ^(g)	
231020	Peppers	3	3	3	Recommended ^(b)	2	Further consideration needed ^(c)	
231030	Aubergines (egg plants)	0.9	0.5	0.5	Recommended ^(b)	0.4	Further consideration needed ^(c)	
232010	Cucumbers	0.5	0.5	0.6	Recommended ^(a)	0.6	Recommended ^(a)	
232020	Gherkins	0.5	_	0.6	Recommended ^(h)	0.6	Recommended ^(h)	
232030	Courgettes	0.5	_	0.6	Recommended ^(h)	0.6	Recommended ^(h)	
233010	Melons	0.4	_	0.9	Further consideration needed ^(m)	0.9	Further consideration needed ^(m)	
233020	Pumpkins	0.4	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)	
233030	Watermelons	0.4	-	0.4	Further consideration needed ^(m)	0.4	Further consideration needed ^(m)	
234000	Sweet corn	0.01*	0.01*	0.01*	Recommended ^(a)	0.02	Recommended ^(a)	
241010	Broccoli	0.4	0.3	0.4	Recommended ^(a)	0.5	Recommended ^(a)	
241020	Cauliflower	0.2	0.09	0.1	Recommended ^(a)	0.3	Recommended ^(a)	
242010	Brussels sprouts	0.3	0.3	0.3	Recommended ^(a)	0.4	Recommended ^(a)	
242020	Head cabbage	0.3	0.15	0.15	Recommended ^(a)	0.3	Recommended ^(a)	
243010	Chinese cabbage	0.7	-	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)	



				Outcome of the review					
Code number	Commodity	Existing EU MRL	Existing CXL (mg/kg)	Option 1	(PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato use)		
		(mg/kg)	(119/19)	MRL (mg/kg) Comment		MRL (mg/kg)	Comment		
243020	Kale	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		
244000	Kohlrabi	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		
251010	Lamb's lettuce	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
251020	Lettuce	15	15	15	Recommended ^(a)	15	Recommended ^(a)		
251030	Escarole (broad-leaf endive)	1.5	-	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251040	Cress	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
251050	Land cress	15	-	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251060	Rocket, Rucola	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
251070	Red mustard	15	-	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251080	Baby leaf crops	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
252010	Spinach	0.2	-	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
252020	Purslane	20	_	20	Recommended ^(h)	20	Recommended ^(h)		
252030	Beet leaves (chard)	0.2	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
254000	Watercress	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		
255000	Witloof	0.3	0.15	0.3	Recommended ^(a)	0.3	Recommended ^(a)		
256010	Chervil	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256020	Chives	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256030	Celery leaves	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256040	Parsley	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256050	Sage	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256060	Rosemary	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256070	Thyme	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256080	Basil	70	70	70	Recommended ^(b)	60	Further consideration needed ^(c)		
256090	Bay leaves (laurel)	8	_	6	Recommended ^(h)	6	Recommended ^(h)		



			Existing CXL (mg/kg)	Outcome of the review					
Code number	Commodity	Existing EU MRL		Option 1	(PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato use)			
		(mg/kg)	(119/19)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
256100	Tarragon	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
260010	Beans (fresh, with pods)	1	1	3	Recommended ^(a)	3	Recommended ^(a)		
260020	Beans (fresh, without pods)	0.2	0.2	0.2	Recommended ^(b)	0.15	Further consideration needed ^(c)		
260030	Peas (fresh, with pods)	1.5	-	3	Recommended ^(h)	3	Recommended ^(h)		
260040	Peas (fresh, without pods)	0.2	0.2	0.2	Recommended ^(b)	0.15	Further consideration needed ^(c)		
260050	Lentils (fresh)	0.2	_	0.15	Recommended ^(h)	0.15	Recommended ^(h)		
270010	Asparagus	0.01*	0.01*	0.01*	Recommended ^(a)	0.01*	Recommended ^(a)		
270030	Celery	0.01*	_	20	Recommended ^(h)	20	Recommended ^(h)		
270050	Globe artichokes	0.5	0.4	4	Further consideration needed ^(g)	4	Further consideration needed ^(g)		
270060	Leek	0.7	0.15	0.8	Further consideration needed ^(g)	0.8	Further consideration needed ^(g)		
300010	Beans (dry)	0.4	0.15	0.5	Recommended ^(a)	0.5	Recommended ^(a)		
300020	Lentils (dry)	0.4	0.7	0.7	Recommended ^(b)	0.5	Further consideration needed ^(c)		
300030	Peas (dry)	0.4	0.7	0.7	Recommended ^(b)	0.5	Further consideration needed ^(c)		
300040	Lupins (dry)	0.4	0.15	0.5	Recommended ^(a)	0.5	Recommended ^(a)		
401020	Peanuts	0.2	0.2	0.2	Recommended ^(b)	0.02	Further consideration needed ^(c)		
401030	Poppy seed	0.3	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)		
401050	Sunflower seed	0.7	0.7	0.7	Recommended ^(a)	0.7	Recommended ^(a)		
401060	Rape seed	1	1	1	Recommended ^(a)	1	Recommendedded ^(a)		
401070	Soya bean	0.3	0.3	0.3	Recommended ^(b)	0.08	Further consideration needed ^(c)		
401080	Mustard seed	0.3	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)		
401090	Cotton seed	0.8	0.8	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
500010	Barley grain	0.2	0.2	0.2	Recommended ^(a)	0.2	Recommended ^(a)		
500020	Buckwheat grain	0.2	_	_	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500030	Maize grain	0.02	0.02	0.02	Recommended ^(b)	0.02	Recommended ^(a)		



				Outcome of the review					
Code number	Commodity	Existing EU MRL	Existing CXL (mg/kg)	Doption 1 (PBIs, restriction on indoor tomato use)		Option 2 (Restriction on indoor tomato use			
		(mg/kg)	(119/19)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
500040	Millet grain	0.01*	_	_	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500050	Oats grain	0.2	0.2	0.2	Recommended ^(a)	0.2	Recommended ^(a)		
500060	Rice	0.01*	1.5	_	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500070	Rye grain	0.9	0.9	0.9	Recommended ^(b)	0.07	Further consideration needed ^(c)		
500080	Sorghum grain	1.5	_	4	Recommended ^(h)	4	Recommended ^(h)		
500090	Wheat grain	0.9	0.9	0.9	Recommended ^(a)	0.9	Recommended ^(a)		
631000	Herbal infusions (dried, flowers)	0.1	-	40	Recommended ^(h)	40	Recommended ^(h)		
632000	Herbal infusions (dried, leaves)	0.1	-	40	Recommended ^(h)	40	Recommended ^(h)		
633000	Herbal infusions (dried, roots)	2.5	-	_	Further consideration needed ^(I)	1	Recommended ^(h)		
700000	Hops (dried)	50	50	60	Recommended ^(a)	60	Recommended ^(a)		
810060	Dill seeds	70	70	70	Recommended ^(a)	70	Recommended ^(a)		
840000	Spices (roots and rhizome)	_	-	_	Further consideration neededded ^(I)	1	Recommended ^(h)		
900010	Sugar beet (root)	0.1	0.04	0.04	Recommended ⁽ⁱ⁾	0.1	Further consideration needed ^(c)		
900030	Chicory roots	0.1	_	_	Further consideration needed ^(k)	0.1	Further consideration needed ^(k)		
Enforcement r	esidue definition 2	: Sum of fluopy	ram and fluop	yram-benza	amide (M25), expressed as fluopy	ram			
1011010	Swine muscle	0.8	1.5	0.09	Further consideration needed ^(c)	0.1	Further consideration needed ^(c)		
1011020	Swine fat tissue	0.5	1.5	0.08	Further consideration needed ^(c)	0.09	Further consideration needed ^(c)		
1011030	Swine liver	5	8	0.50	Further consideration needed ^(c)	0.5	Further consideration needed ^(c)		
1011040	Swine kidney	0.8	8	0.08	Further consideration needed ^(c)	0.08	Further consideration needed ^(c)		
1012010	Bovine muscle	0.8	1.5	0.10	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)		
1012020	Bovine fat tissue	0.5	1.5	0.09	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)		
1012030	Bovine liver	5	8	0.50	Further consideration needed ^(c)	0.8	Further consideration needed ^(c)		
1012040	Bovine kidney	0.8	8	0.08	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)		
1013010	Sheep muscle	0.8	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		



1013020 1013030 1013040 1014010 1014020 1014030 1014040 1015010 1015020 1015020 1015030 1015040 1016010		Existing EU MRL		Outcome of the review					
Code number	Commodity		Existing CXL (mg/kg)	Option 1 (PBIs, restriction on indoor tomato use)		Option 2 (Restriction on indoor tomato use)			
		(mg/kg)		MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
1013020	Sheep fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1013030	Sheep liver	5	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)		
1013040	Sheep kidney	0.8	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1014010	Goat muscle	0.8	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1014020	Goat fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1014030	Goat liver	5	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)		
1014040	Goat kidney	0.8	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1015010	Equine muscle	0.8	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1015020	Equine fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1015030	Equine liver	0.7	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)		
1015040	Equine kidney	0.7	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)		
1016010	Poultry muscle	0.5	1.5	1.5	Recommended ^(b)	0.07	Further consideration needed ^(c)		
1016020	Poultry fat tissue	0.2	1	1	Recommended ^(b)	0.07	Further consideration needed ^(c)		
1016030	Poultry liver	2	5	5	Recommended ^(b)	0.3	Further consideration needed ^(c)		
1020010	Cattle milk	0.6	0.8	0.05	Recommended ^(h)	0.07	Further consideration needed ^(h)		
1020020	Sheep milk	0.6	0.8	0.05	Recommended ^(h)	0.06	Further consideration needed ^(h)		
1020030	Goat milk	0.6	0.8	0.05	Recommended ^(h)	0.06	Further consideration needed ^(h)		
1020040	Horse milk	0.6	0.8	0.05	Recommended ^(h)	0.07	Further consideration needed ^(h)		
1030000	Birds eggs	1	2	2	Recommended ^(b)	0.15	Further consideration needed ^(c)		
_	Other commodities of plant and/or animal origin	See Reg. 2019/1791	_	_	Further consideration needed ⁽¹⁾		·		

MRL: maximum residue level; CXL: codex maximum residue limit; PBI: plant-back interval.

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).

- (c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a chronic risk to consumers cannot be excluded considering some (Option 1)/or all additional CXLs (Option 2) (combination H-VI/VII in Appendix E).
- (d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower or same tentative MRL (combination F-VII in Appendix E).
- (e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition; CXL is higher, supported by data but a chronic risk to consumers cannot be excluded considering some (Option 1)/or all additional CXLs (Option 2) (combination F-VI/VII in Appendix E).
- (f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).
- (g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
- (h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available or CXL was not considered further due to reservations raised by the EU delegation. (combination H-I in Appendix E).
- (i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).
- (j): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a chronic risk to consumers cannot be excluded considering all additional CXLs (Option 2). Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).
- (k): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
- (I): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available or CXL was not considered further due to reservations raised by the EU delegation. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
- (m): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).

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Abbreviations

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CAC Codex Alimentarius Commission
- CF conversion factor for enforcement residue definition to risk assessment residue definition



CXL DAR DAT DB DF DM DT ₉₀ EC eq EURLs	codex maximum residue limit draft assessment report days after treatment dietary burden default drying factor dry matter period required for 90% dissipation (define method of estimation) emulsifiable concentrate residue expressed as a.s. equivalent European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO GAP	Food and Agriculture Organization of the United Nations Good Agricultural Practice
GC-MS	gas chromatography with mass spectrometry
HPLC-MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR IEDI	highest residue international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardization
IUPAC JMPR	International Union of Pure and Applied Chemistry Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the
	Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting
	on Pesticide Residues)
LOQ	limit of quantification
Мо	monitoring
MRL	maximum residue level
MS	Member States
NEDI	national estimated daily intake
NESTI NEU	national estimated short-term intake northern European Union
NTMDI	national theoretical maximum daily intake
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PEC _{soil}	predicted environmental concentration in soil
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
ra Rac	risk assessment raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SE	suspoemulsion
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR WHO	total radioactive residue World Health Organization

Appendix A – Summary of critical authorised uses considered for the review of MRLs

A.1. Authorised outdoor uses in northern EU

		F	Prepa	ration	Ар	Application						
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Hazelnuts	PL	F	SC	250 g/L	Foliar treatment – spraying		1		-	_	120 g a.i./ha	21
Apples	HU	F	SC	200 g/L	Foliar treatment – spraying	57–84	3	7	_	_	150 g a.i./ha	14
Pears	NL	F	SC	200 g/L	Foliar treatment – spraying	72–87	3	21	-	-	150 g a.i./ha	14
Quinces	NL	F	SC	200 g/L	Foliar treatment – spraying	72–87	3	21	-	_	150 g a.i./ha	14
Medlars	NL	F	SC	200 g/L	Foliar treatment – spraying	72–87	3	21	-	_	150 g a.i./ha	14
Loquats	NL	F	SC	200 g/L	Foliar treatment – spraying	72–87	3	21	-	-	150 g a.i./ha	14
Apricots	CZ	F	SC	200 g/L	Foliar treatment – spraying	59–87	2	21	-	_	150 g a.i./ha	3
Cherries	HU	F	SC	500 g/L	Foliar treatment – spraying	61–85	2	7	-	_	250 g a.i./ha	7
Peaches	FR	F	SC	200 g/L	Foliar treatment – spraying	77–89	2		_	_	100 g a.i./ha	3
Plums	FR	F	SC	200 g/L	Foliar treatment – spraying	77–89	2	7	-	_	100 g a.i./ha	3
Table grapes	RO	F	SC	500 g/L	Foliar treatment – spraying	69–89	2	12	-	_	250 g a.i./ha	21
Wine grapes	RO	F	SC	500 g/L	Foliar treatment – broadcast spraying	69–89	2	12	-	-	250 g a.i./ha	21
Strawberries	CZ	F	SC	500 g/L	Foliar treatment – broadcast spraying	15–87	2	7	-	_	250 g a.i./ha	1
Blackberries	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	-	200 g a.i./ha	3
Dewberries	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	_	200 g a.i./ha	3
Raspberries	AT, DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2		-	_	200 g a.i./ha	3
Blueberries	AT, DE, PL	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	-	200 g a.i./ha	7
Cranberries	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	_	200 g a.i./ha	7
Currants	AT, DE	F	SC	250 g/L		15–89	2	7	_	_	200 g a.i./ha	7



Crop and/or situation	MS or country	F G or I ^(a)	Preparation		Application				Application rate per treatment			
			Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
					Foliar treatment – broadcast spraying							
Gooseberries	AT, DE	F	SC	250 g/L	Foliar treatment – general	15–89	2		_	_	200 g a.i./ha	7
Rose hips	NL	F	SC	250 g/L	Foliar treatment – broadcast spraying	_	2	14	_	_	150 g a.i./ha	7
Mulberries	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	_	_	200 g a.i./ha	3
Elderberries	AT, DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	_	200 g a.i./ha	7
Sweet potatoes	NL	F	SC	400 g/L	Soil treatment – spraying	BBCH 00	1	-	_	_	250 g a.i./ha	n.a.
Yams	NL	F	SC	400 g/L	Soil treatment – spraying	BBCH 00	1	-	-	_	250 g a.i./ha	n.a.
Carrots	SI	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	1–2	14	-	_	150 g a.i./ha	14
Beetroots	NL	F	SC	400 g/L	Soil treatment – spraying	BBCH 00	1	-	_	_	250 g a.i./ha	n.a.
Celeriacs	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	_	150 g a.i./ha	14
Horseradishes	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	_	_	150 g a.i./ha	14
Jerusalem artichokes	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	_	150 g a.i./ha	14
Parsnips	DE, PL	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	_	_	150 g a.i./ha	14
Parsley roots	DE, PL	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	_	150 g a.i./ha	14
Radishes	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	1		_	_	200 g a.i./ha	7
Salsifies	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	_	150 g a.i./ha	14
Swedes	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	2		-	-	150 g a.i./ha	14



		F	Prepa	ration	Ар	plication			Арр	olication treatn	rate per nent	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Turnips	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	2		-	-	150 g a.i./ha	14
Garlic	AT	F	SC	200 g/L	Foliar treatment – general	41–49	2		_	_	100 g a.i./ha	7
Onions	AT	F	SC	200 g/L	Foliar treatment – general	41–49	2		_	_	100 g a.i./ha	7
Shallots	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	_	100 g a.i./ha	7
Spring onions	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	1		-	-	200 g a.i./ha	21
Cucumbers	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	61–79	2	14	-	_	200 g a.i./ha	3
Gherkins	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	61–79	2	14	-	-	200 g a.i./ha	3
Sweet corn	HU	F	SE	125 g/L	Foliar treatment – broadcast spraying	30–69	2	14	-	_	125 g a.i./ha	14
Broccoli	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	2		-	-	180 g a.i./ha	14
Cauliflowers	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	2		-	_	180 g a.i./ha	14
Brussels sprouts	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	-	180 g a.i./ha	14
Head cabbages	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	2	14	-	-	180 g a.i./ha	14
Chinese cabbages	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	1		-	-	200 g a.i./ha	7
Lamb's lettuces	AT, DE	F	SC	250 g/L	Foliar treatment – general	13–49	1		_	_	200 g a.i./ha	7
Lettuces	PL	F	SC	250 g/L	Foliar treatment – broadcast spraying	41–49	1–2	7	-	-	200 g a.i./ha	7
Escaroles	AT, DE	F	SC	250 g/L	Foliar treatment – general	13–49	1		-	-	200 g a.i./ha	7
Cresses	AT	F	SC	250 g/L	Foliar treatment – general	13–49	1		_	_	200 g a.i./ha	7



		F	Prepa	ration	Ар	plication			Арі	olication treatn	rate per nent	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Land cresses	AT	F	SC	250 g/L	Foliar treatment – general	13–49	1		_	_	200 g a.i./ha	7
Roman rocket	AT, DE	F	SC	250 g/L	Foliar treatment – general	13–49	1		-	_	200 g a.i./ha	7
Red mustards	AT	F	SC	250 g/L	Foliar treatment – general	13–49	1		-	_	200 g a.i./ha	7
Baby leaf crops	AT, DE	F	SC	250 g/L	Foliar treatment – general	13–49	1		-	_	200 g a.i./ha	7
Spinaches	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	1		-	_	200 g a.i./ha	7
Purslanes	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	1		-	-	200 g a.i./ha	7
Chards	DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	13	1		-	_	200 g a.i./ha	7
Chervil	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Chives	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Celery leaves	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Parsley	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Sage	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Rosemary	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Thyme	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	_	200 g a.i./ha	14
Basil	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Laurel	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		_	_	200 g a.i./ha	14



		F	Prepa	ration	Ар	plication			Ар	olication treatn	ı rate per nent	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Tarragon	DE	F	SC	200 g/L	Foliar treatment – broadcast spraying	n.a.	1		-	-	200 g a.i./ha	14
Beans (with pods)	BE, CZ, NL	F	SC	500 g/L	Foliar treatment – broadcast spraying	51–79	2	7	-	_	250 g a.i./ha	7
Beans (without pods)	BE, CZ, NL	F	SC	500 g/L	Foliar treatment – broadcast spraying	60–79	2	7	-	_	250 g a.i./ha	7
Peas (with pods)	CZ	F	SC	502 g/L	Foliar treatment – general	60–79	1–2	7	_	_	250 g a.i./ha	7
Peas (without pods)	CZ, NL	F	SC	500 g/L	Foliar treatment – broadcast spraying	51–79	2	7	-	_	250 g a.i./ha	7
Asparagus	AT, DE	F	SC	250 g/L	Foliar treatment – broadcast spraying	49–95	1–2	10	-	_	200 g a.i./ha	> 200
Leeks	SI	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–49	1–2	14	-	_	200 g a.i./ha	21
Beans (dry)	BE, CZ	F	SC	501 g/L	Foliar treatment – general	60–79	1–2	7	-	_	250 g a.i./ha	7
Peas (dry)	CZ	F	SC	500 g/L	Foliar treatment – broadcast spraying	60–79	2	7	-	_	250 g a.i./ha	7
Poppy seeds	CZ, HU	F	SE	125 g/L	Foliar treatment – broadcast spraying	14–65	2	21	-	_	125 g a.i./ha	56
Sunflower seeds	CZ, HU	F	SE	125 g/L	Foliar treatment – broadcast spraying	16–69	2	14	-	_	125 g a.i./ha	28
Rapeseeds	HU	F	SE	125 g/L	Foliar treatment – broadcast spraying	14–73	2	14	-	_	125 g a.i./ha	28
Mustard seeds	CZ, HU	F	SE	125 g/L	Foliar treatment – broadcast spraying	57–69	2	14	-	_	125 g a.i./ha	56
Barley	DK	F	SE	125 g/L	Foliar treatment – broadcast spraying	30–61	1–2	14	-	_	125 g a.i./ha	35
Maize	CZ, DE, DK, EE, HU, LT	F	SE	125 g/L	Foliar treatment – broadcast spraying	30–69	2	14	-	_	125 g a.i./ha	n.a.

		F	Prepa	ration	Ар	plication			Арј	olication treatn	rate per ient	
Crop and/or situation	MS or country	G	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min_	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Oat	DK	F			Foliar treatment – broadcast spraying	30–61	1		-	_	125 g a.i./ha	n.a.
Rye	DK	F	SE	125 g/L	Foliar treatment – broadcast spraying	30–61	1–2	14	-	_	125 g a.i./ha	35
Wheat	DK	F	SE	125 g/L	Foliar treatment – broadcast spraying	30–61	1–2	14	-	_	125 g a.i./ha	35
Hops	PL	F	SC	250 g/L	Foliar treatment – broadcast spraying	37–79	1–2	14	-	_	150 g a.i./ha	21
Chicory roots	BE	F	SC	250 g/L	Foliar treatment – general	41–49	1	_	_	_	150 g a.i./ha	7

MS: Member State; a.s.: active substance; a.i.: active ingredient; n.a.: not applicable; SC: suspension concentrate; SE: suspoemulsion.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(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.

A.2. Authorised outdoor uses in southern EU

		_	Prepa	ration	Ар	plication			Applica	tion rate p	er treatment	
Crop and/or situation	MS or country	F G Or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min_	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Apples	EL	F	SC	200 g/L	Foliar treatment – spraying	57–87	2	7	-	-	150 g a.i./ha	14
Pears	EL, IT	F	SC	200 g/L	Foliar treatment – spraying	57–87	2	7	_	-	150 g a.i./ha	14
Quinces	FR	F	SC	200 g/L	Foliar treatment – spraying	57–89	1		_	-	150 g a.i./ha	14
Medlars	FR	F	SC	200 g/L	Foliar treatment – spraying	57–89	1		_	_	150 g a.i./ha	14
Loquats	FR	F	SC	200 g/L	Foliar treatment – spraying	57–89	1		_	-	150 g a.i./ha	14
Apricots	IT	F	SC	500 g/L	Foliar treatment – spraying	61–87	2		_	-	250 g a.i./ha	3



		_	Prepa	ration	Ар	olication			Applica	tion rate p	er treatment	
Crop and/or situation	MS or country	F G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Cherries	IT	F	SC	500 g/L	Foliar treatment – broadcast spraying	61–87	1–2	7	_	_	250 g a.i./ha	3
Peaches	IT	F	SC	500 g/L	Foliar treatment – spraying	61–87	2		_	_	250 g a.i./ha	3
Plums	IT	F	SC	500 g/L	Foliar treatment – spraying	61–87	2		_	_	250 g a.i./ha	3
Table grapes	HR	F	SC	500 g/L	Foliar treatment – spraying	71–83	2	12	_	_	250 g a.i./ha	3
Wine grapes	HR	F	SC	500 g/L	Foliar treatment – broadcast spraying	71–83	2	12	_	_	250 g a.i./ha	21
Strawberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	40–89	1		_	_	200 g a.i./ha	3
Blackberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	13–89	1		-	-	200 g a.i./ha	3
Dewberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	13–89	1		-	-	200 g a.i./ha	3
Raspberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	13–89	1		_	_	200 g a.i./ha	3
Blueberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	13–89	1		_	_	200 g a.i./ha	7
Gooseberries	FR	F	SC	250 g/L	Foliar treatment – broadcast spraying	13–89	1		_	_	200 g a.i./ha	7
Bananas	FR	F	SC	500 g/L	Foliar treatment – broadcast spraying	13–81	1–3	7	_	_	300 g a.i./ha	1
Potatoes	IT	F	SC	400 g/L	Soil treatment – general	BBCH 00	1–1		_	_	250 g a.i./ha	n.a.
Carrots	IT	F	SC	400 g/L	Soil treatment – general	BBCH 00	1–1		_	_	250 g a.i./ha	n.a.
Garlic	EL; ES, PT	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–91	1–1		_	_	200 g a.i./ha	7
Onions	EL; ES, PT	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–91	1–1		_	_	200 g a.i./ha	7
Shallots	EL	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–91	1–1		_	_	0.2 kg a.i./ha	7



		-	Prepa	ration	Арр	olication			Applica	tion rate p	er treatment	
Crop and/or situation	MS or country	F G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Spring onions	EL	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–91	1–1		_	_	200 g a.i./ha	7
Tomatoes	IT	F	SC	400 g/L	Soil treatment – general	0–9	1–1		_	_	250 g a.i./ha	n.a.
Sweet peppers	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Aubergines	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Cucumbers	IT	F	SC	400 g/l	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Gherkins	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Courgettes	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Melons	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Pumpkins	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Watermelons	IT	F	SC	400 g/L	Soil treatment – general	n.a. to 9	1–1		_	_	250 g a.i./ha	n.a.
Lettuces	ES, IT	F	SC	250 g/L	Foliar treatment – broadcast spraying	41–49	1–1		_	_	200 g a.i./ha	7
Beans (with pods)	IT	F	SC	250 g/L	Foliar treatment – broadcast spraying	59–75	1–2	14	_	_	200 g a.i./ha	14
Asparagus	IT	F	SC	200 g/L	Foliar treatment – broadcast spraying	43–91	1–2	10	-	-	150 g a.i./ha	> 200
Globe artichokes	EL, IT	F	SC	250 g/L	Foliar treatment – broadcast spraying	14–87	1–3	7	_	_	75 g a.i./ha	7
Leeks	EL	F	SC	200 g/L	Foliar treatment – broadcast spraying	41–91	1–1		-	-	200 g a.i./ha	14
Rapeseeds	FR, HR, IT, PT	F	SE	125 g/L	Foliar treatment – broadcast spraying	14–73	1		-	_	125 g a.i./ha	56
Barley	FR	F	EC	65 g/L	Foliar treatment – broadcast spraying	30–61	1		-	_	78 g a.i./ha	n.a.
Oat	FR	F	EC	65 g/L	Foliar treatment – broadcast spraying	30–61	1		_	_	78 g a.i./ha	n.a.

		_	Prepa	ration	Арг	olication			Applica	tion rate p	er treatment	
Crop and/or situation	MS or country	F G Or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Rye	FR	F	EC	65 g/L	Foliar treatment – broadcast spraying	30–61	1		_	_	97.5 g a.i./ha	n.a.
Wheat	FR	F	EC	65 g/L	Foliar treatment – broadcast spraying	30–61	1		-	-	97.5 g a.i./ha	n.a.

MS: Member State; a.s.: active substance; a.i.: active ingredient; n.a.: not applicable; SC: suspension concentrate; SE: suspoemulsion; EC: emulsifiable concentrate.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(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.

A.3. Authorised indoor uses in EU

		_	Prepa	ration	Арр	lication			Applic	ation rate	per treatment	
Crop and/or situation	MS or country	F G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min–	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Strawberries	NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	_	-	250 g a.i./ha	1
Blackberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	51–89	2	7	_	_	200 g a.i./ha	3
Dewberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	51–89	2	7	_	-	200 g a.i./ha	3
Raspberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	51–89	2	7	_	_	200 g a.i./ha	3
Blueberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	_	_	200 g a.i./ha	7
Cranberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	-	_	200 g a.i./ha	7



		_	Prepa	ration	Appl	ication			Applic	ation rate	per treatment	
Crop and/or situation	MS or country	F G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Currants	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	_	-	200 g a.i./ha	7
Gooseberries	DE	I	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	_	_	200 g a.i./ha	7
Rose hips	NL	G/I	SC	250 g/L	Foliar treatment – broadcast spraying	-	2	7	-	-	200 g a.i./ha	7
Mulberries	DE	Ι	SC	250 g/L	Foliar treatment – broadcast spraying	51–89	2	7	_	_	200 g a.i./ha	3
Elderberries	DE	I	SC	250 g/L	Foliar treatment – broadcast spraying	15–89	2	7	_	_	200 g a.i./ha	7
Cherimoyas	PT	Ι	SC	150 g/L	Foliar treatment – general	15–89	2	7	-	_	120 g a.i./ha	3
Tomatoes	NL	G/I	SC	500 g/L	Soil treatment – drip irrigation	_	4	7	_	_	500 g a.i./ha	1
Sweet peppers	CZ	I	SC	500 g/L	Foliar treatment – broadcast spraying	61–83	2	7	_	-	300 g a.i./ha	3
Aubergines	EL	I	SC	250 g/L	Foliar treatment – broadcast spraying	14–89	1–3	14	_	_	150 g a.i./ha	3
Cucumbers	NL	I	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	_	-	300 g a.i./ha	1
Gherkins	NL	I	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	-	_	300 g a.i./ha	1
Courgettes	NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	_	_	300 g a.i./ha	1
Melons	ES	Ι	SC	250 g/L	Foliar treatment – general		3	14	_	_	100 g a.i./ha	3
Pumpkins	ES	Ι	SC	250 g/L	Foliar treatment – general		3	14	_	_	100 g a.i./ha	3
Watermelons	ES	Ι	SC	250 g/L	Foliar treatment – general		3	14	_	_	100 g a.i./ha	3
Lamb's lettuces	BE, NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	-	_	250 g a.i./ha	7
Lettuces	BE, CZ, NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	_	_	250 g a.i./ha	7

			Prepa	ration	Арр	lication			Applic	ation rate	per treatment	
Crop and/or situation	MS or country	F G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min–	Interval between application (min)	a.s./hL min– max	Water L/ha min–max	Rate and unit	PHI (days) ^(d)
Cresses	BE, NL	I	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	-	-	250 g a.i./ha	7
Roman rocket	BE, NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	-	-	250 g a.i./ha	7
Baby leaf crops	BE, NL	Ι	SC	500 g/L	Foliar treatment – broadcast spraying		2	7	_	_	250 g a.i./ha	7
Purslanes (sea lavender)	NL	G	SC	250 g/L	Foliar spraying	12–49	2	7	_	200–1,000	200 g a.i./ha	7
Witloofs	BE	Ι	SC	500 g/L	Local treatment – general		1		_	_	0.05 kg a.i./ton	21
Beans (with pods)	BE, NL	Ι	SC	501 g/L	Foliar treatment – general	60–79	2	7	_	_	250 g a.i./ha	7

MS: Member State; a.s.: active substance; a.i.: active ingredient; n.a.: not applicable; SC: suspension concentrate.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(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.

A.4. Import tolerance

		F	Prep	aration	A	oplication			Арр	lication treatm	rate per nent	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min_	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Grapefruits	US	F	SC	500 g/L	Foliar treatment – general	81–89	2	5	-	_	250 g a.i./ha	7
Oranges	US	F	SC	500 g/L	Foliar treatment – general	81–89	2	5	_	_	250 g a.i./ha	7
Lemons	US	F	SC	500 g/L	Foliar treatment – general	81–89	2	5	_	_	250 g a.i./ha	7
Limes	US	F	SC	500 g/L	Soil treatment – general	81–89	2	2	_	_	250 g a.i./ha	7
Mandarins	US	F	SC	500 g/L	Foliar treatment – general	81–89	2	5	-	_	250 g a.i./ha	7

		F	Prepa	aration	Ap	plication			Арр	olication treatm	rate per ient	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Almonds	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Brazil nuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	-	_	250 g a.i./ha	14
Cashew nuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	-	_	250 g a.i./ha	14
Chestnuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Coconuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	-	_	250 g a.i./ha	14
Hazelnuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Macadamias	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Pecans	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	-	_	250 g a.i./ha	14
Pine nut kernels	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Pistachios	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Walnuts	US	F	SC	500 g/L	Foliar treatment – general	79–89	2	6	_	_	250 g a.i./ha	14
Apples	US/CAN	F	SC	500 g/L	Foliar treatment – spraying	81–87	2	5	-	_	250 g a.i./ha	0
Pears	US/CAN	F	SC	500 g/L	Foliar treatment – spraying	81–87	2	5	_	_	250 g a.i./ha	0
Quinces	US/CAN	F	SC	500 g/L	Foliar treatment – spraying	81–87	2	5	_	_	250 g a.i./ha	0
Medlars	US/CAN	F	SC	500 g/L	Foliar treatment – spraying	81–87	2	5	_	_	250 g a.i./ha	0
Loquats	US/CAN	F	SC	500 g/L	Foliar treatment – spraying	81–87	2	5	-	_	250 g a.i./ha	0
Apricots	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	30	_	_	250 g a.i./ha	0
Cherries	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	30	_	_	250 g a.i./ha	0
Peaches	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	30	_	_	250 g a.i./ha	0
Plums	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	30	-	_	250 g a.i./ha	0
Table grapes	US	F	SC	500 g/L	Foliar treatment – spraying	85–89	2	12	_	_	250 g a.i./ha	7
Wine grapes	US	F	SC	500 g/L	Foliar treatment – spraying	85–89	2	12	-	_	250 g a.i./ha	7
Strawberries	US	F	SC	500 g/L	Foliar treatment – spraying	85–89	2	5	-	_	250 g a.i./ha	0
Blackberries	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	7	_	_	250 g a.i./ha	0
Dewberries	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	7	_	_	250 g a.i./ha	0
Raspberries	US	F	SC	500 g/L	Foliar treatment – spraying	87–89	2	7	_	_	250 g a.i./ha	0
Blueberries	US	F	SC	500 g/L	Foliar treatment – spraying	85–89	2	7	_	_	250 g a.i./ha	0

		F	Prepa	aration	Ap	plication			Арр	olication treatm	rate per ient	
Crop and/or situation	MS or country	G or I ^(a)	Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min– max	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Potatoes	US	F	SC	500 g/L	Foliar treatment – general	250	2	3	-	_	250 g a.i./ha	7
Carrots	US	F	SC	500 g/L	Foliar treatment – general	250	2	7	-	_	250 g a.i./ha	0
Radishes	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)	250	2	7	-	_	250 g a.i./ha	0
Tomatoes	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)	250	2	6	-	-	250 g a.i./ha	0
Sweet peppers	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)	250	2	7	-	_	250 g a.i./ha	0
Melons	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)	250	2	5	-	-	250 g a.i./ha	0
Basil	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)		2	7	-	-	250 g a.i./ha	0
Beans (with pods)	US	F	SC	500 g/L	Foliar treatment – general (see also comment field)	250	2	5	-	-	250 g a.i./ha	0
Beans (without pods)	US	F	SC	500 g/L	Foliar treatment – general	250	2	5	-	_	250 g a.i./ha	0
Peas (with pods)	US	F	SC	500 g/L	Foliar treatment – general	250	2	5	_	_	250 g a.i./ha	0
Peas (without pods)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	-	_	250 g a.i./ha	0
Lentils (fresh)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	_	_	250 g a.i./ha	0
Celeries	US	F			Foliar treatment – general	250	2		-	_	250 g a.i./ha	0
Globe artichokes	US	F			Foliar treatment – general	250	2		_	_	250 g a.i./ha	0
Beans (dry)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	-	_	250 g a.i./ha	14
Lentils (dry)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	_	_	250 g a.i./ha	14
Peas (dry)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	-	_	250 g a.i./ha	14
Lupins (dry)	US	F	SC	500 g/L	Foliar treatment – general	250	2–2	5	-	_	250 g a.i./ha	14
Peanuts	US	F	SC	500 g/L	Foliar treatment – general		2	12	-	_	250 g a.i./ha	7
Sunflower seeds	US	F	SC	500 g/L	Foliar treatment – general		2–2	12	-	_	250 g a.i./ha	14
Soya beans	US	F	SC	500 g/L	Seed treatment – general		1–2	7	_	_	250 g a.i./ha	14

Crop and/or situation	MS or country		Preparation		Application				Арр			
			Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	min-	Interval between application (min)	a.s./hL min– max	Water L/ha min– max	Rate and unit	PHI (days) ^(d)
Cotton seeds	US	F	SC	500 g/L	Foliar treatment – general		1–2		_	_	250 g a.i./ha	30
Maize	US	F	SC	500 g/L	Foliar treatment – general	85–89	2–2	5	_	_	250 g a.i./ha	14
Sorghum	US	F	SC	500 g/L	Foliar treatment – general	83–89	2–2	12	_	_	250 g a.i./ha	14
Wheat	US	F	SC	500 g/L	Foliar treatment – general	75–87	2–2	12	-	_	250 g a.i./ha	14
Hops	US	F	SC	500 g/L	Foliar treatment – general	88	2		_	_	250 g a.i./ha	7
Seed spices (Dill)	US	F	SC	500 g/L	Foliar treatment – general	85	2	7	_	_	250 g a.i./ha	14

MS: Member State; a.s.: active substance; n.a.: not applicable; SC: suspension concentrate.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide. (c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.



Appendix B – List of end points

B.1. Residues in plants

- **B.1.1.** Nature of residues and methods of analysis in plants
- **B.1.1.1.** Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Appli	cation(s)		Sampling (DAT)	Comment/Source	
	Fruit crops	Grape		1 imes100 + 00 g a.s./ha		18–19	Radiolabelled active substance: phenyl-UL- ¹⁴ C	
		Pepper	mg/plant		55–97	and Pyridyl-2,6- ¹⁴ C (Germany, 2011; EFSA,		
	Root/tuber crops	Potato	Foliar,	3 imes 167 g a	.s./ha	51	2013a)	
	Pulses/oilseeds	Bean	Foliar,	$2 \times 250 \text{ g a}$	a.s./ha	4–29		
	Cell culture	n.a.	n.a.			n.a.	Supplemental information (Germany, 2011)	
Rotational crops (available studies)	Crop groups	Crop(s)	Appli	cation(s)		PBI (DAT)	Comment/Source	
	Root/tuber crops	Turnips	Bare s a.s./h	soil, 534 or 514 g na		30, 139, 280	Phenyl-UL- ¹⁴ C and Pyridyl-2,6- ¹⁴ C (Germany,	
	Leafy crops	Swiss chard	Bare s a.s./h	soil, 534 or 5 a	14 g	30, 139, 280	2011; EFSA, 2013a) Rotational crop study on	
	Cereal (small grain)	Spring wheat	Bare s a.s./h	soil, 534 or 5 a	14 g	30, 139, 280	cereals surrogate for primary seed treatment	
Processed commodities (hydrolysis study)	Conditions			Stable?	ce			
	Pasteurisation (20	min, 90°C, p	H 4)	Yes	Fluop	yram, M08, I	M25 and M43 are stable.	
	Baking, brewing an (60 min, 100°C, pl	-	-	Yes	M40 is not stable, but not expected RAC in significant levels (Germany,			
	Sterilisation (20 m	in, 120°C, p⊦	16)	Yes	EFSA	, 2013a)		



Can a general residue definition be proposed for primary crops?	Yes	Covering also the authorised seed treatment and local treatment (pre-forcing for witloof) GAP
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)
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	fluopyram-benzamide (M25), expressed as
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	rape), high acid conter seed):	er content (lettuce), high oil content (oilseed ht (orange) and dry matrices (wheat grain, peas 12393) method, GC–MS, LOQ 0.01 mg/kg
		method and ILV available (EFSA, 2013a)
	QuEChERS m commodities	ethod in high water and high acid content with a LOQ of 0.002 mg/kg and in high oil Iry commodities with a LOQ of 0.01 mg/kg
		hods for dill seeds (seed spice) were not hops, the ILV of the method is missing eficiency)
a.s.: active substance; DAT: days after treatme	ent: n.a.: not applicable: P	BI: plant-back interval: RAC: raw agricultural

a.s.: active substance; DAT: days after treatment; n.a.: not applicable; PBI: plant-back interval; RAC: raw agricultural commodity; GC–MS: gas chromatography with mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification; ILV: independent laboratory validation.

Plant				Stabili	ty period		
products (available studies)	Category	Commodity	T (°C)	Value	Unit	Compounds covered	Comment/Source
	High water content	Lettuce, cabbage	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
		Lettuce	-18°C	24	Months	M40, M43, M08, M45	EFSA (2013a)
	High oil	Rapeseed	$-18^{\circ}C$	36	Months	Fluopyram, M25	EFSA (2014)
	content	Rapeseed	$-18^{\circ}C$	24	Months	M40, M43	EFSA (2013a)
	High protein/ starch 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 (2013a)
	High acid	Orange	-18°C	36	Months	Fluopyram, M25	EFSA (2014)
	content	Orange, grapes	−18°C	6	Months	M40, 43	EFSA (2013a)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Grapefruits, oranges	Import (US)	Mo: Oranges: 0.04; 0.06; 0.11; 0.12; 0.12; 0.12; 0.13; 0.14; 0.15; 0.25; 0.32; 0.25 Grapefruits: 0.06; 0.08; 0.14; 0.04; 0.11; 0.12 RA: –	Trials on oranges and grapefruits compliant with GAP (Germany, 2018). Extrapolation to oranges and grapefruits is possible MRL _{OECD} = 0.44	0.5	0.32	0.12	1.00 ^(e)
Lemons, mandarins	Import (US)	Mo: Lemons: 0.3; 0.29; 0.3; 0.32; 0.27 Mandarins: 0.2 RA: –	Trials on lemons and mandarins compliant with GAP. Extrapolation to lemons and mandarins is possible (Germany, 2018) MRL _{OECD} = 0.84	0.9 (tentative) ^(f)	0.32	0.29	1.00 ^(e)
Limes	Import (US)	-	No trials available for soil treatment	-	-	-	-
Hazelnuts	NEU	-	No trials available. However, the import tolerance GAP is clearly more critical (both application rate and PHI), therefore no further trials are required	_	_	_	_
Tree nuts	Import (US)	Mo: Almonds: $6 \times < 0.01$; 0.01; 0.017 Pecans: $4 \times < 0.01$; 0.024 RA: –	Trials on almonds and pecans compliant with GAP (Germany, 2018). Extrapolation to tree nuts is possible MRL _{OECD} = 0.03	0.03	0.02	0.01	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Pome fruits	NEU	 Mo: Apples: 0.08; 0.09; 0.10; 0.11; 2× 0.12; 0.13; 0.18; 0.21 Pears: 0.10; 0.11; 0.12; 0.13; 0.19; 0.26 RA: Apples: 0.09; 0.10; 0.11; 0.12; 2× 0.13; 0.14; 0.19; 0.22 Pears: 0.11; 0.12; 0.13; 0.14; 0.20; 0.27 	Combined data set on apples and pears compliant with GAP (Germany, 2018). Extrapolation to pome fruits is possible $MRL_{OECD} = 0.41$	0.5	0.26	0.12	1.00
	SEU	Mo: Apples: 0.03; 0.04; 0.06; 2× 0.08; 0.15 Pears: 0.20; 0.27 RA: Apples: 0.04; 0.05; 0.07; 2× 0.09; 0.16 Pears: 0.21; 0.28	Trials on apples and pears with application rate within 25% deviation. Extrapolation to pome fruits is proposed $MRL_{OECD} = 0.45$	0.5	0.27	0.08	1.00
	Import (US/CAN)	Mo: Apples: 0.08; 0.11; 0.11; 2× 0.15; 0.16; 0.17; 0.18; 0.19; 2× 0.21; 0.22; 0.23; 0.24; 0.24; 0.39; 0.6 Pears: 0.18; 2× 0.2; 0.29; 0.41; 0.51 RA: –	Combined data set on apples and pears compliant with GAP (Germany, 2018). Extrapolation to pome fruits is possible MRL _{OECD} = 0.75	0.8	0.60	0.20	1.00 ^(e)
Apricots	NEU	Mo: 0.12; 0.20; 0.30; 0.45 RA: 0.13; 0.21; 0.31; 0.46	Trials on apricots compliant with GAP (Germany, 2018) $MRL_{OECD} = 0.84$	1	0.45	0.25	1.00
	SEU	 Mo: Apricots 0.27; 0.28; 0.33; 0.37; 0.43; 0.55; 0.58; 0.95 Peaches: 0.20; 0.26; 2× 0.28; 0.31; 0.36; 0.63; 0.73 RA: 0.28; 0.29; 0.34; 0.38; 0.44; 0.56; 0.59; 0.96; 0.21; 0.27; 0.29; 0.29; 0.32; 0.37; 0.64; 0.74 	Combined data set on apricots and peaches compliant with GAP (Germany, 2018) Extrapolation to apricots and peaches is possible MRL _{OECD} = 1.28	1.5	0.95	0.33	1.00
	Import (US)	-	No data available	_	_	_	_
Cherries (sweet)	NEU	Mo: 0.20; 0.26; 0.27; 0.56; 0.56; 0.59; 1.1 RA: 0.21; 0.27; 0.28; 0.57; 0.57; 0.60; 1.11	Trials on cherries compliant with GAP (Germany, 2018) $MRL_{OECD} = 1.74$	2 (tentative) ^(f)	1.10	0.56	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	Mo: 0.12; 0.41; 0.47; 0.49 RA: 0.13; 0.42; 0.48; 0.50	Trials on cherries compliant with GAP (Germany, 2018) $MRL_{OECD} = 1.12$	1.5	0.49	0.44	1.00
	Import (US)	Mo: 0.11; 0.25; 0.41; 0.58; 0.6; 0.89 RA: –	Trials on cherries compliant with GAP (Germany, 2018) $MRL_{OECD} = 1.58$	2 (tentative) ^(f)	0.89	0.49	1.00 ^(e)
Peaches	NEU	Mo: 0.05; 0.16; 0.17; 0.47 RA: 0.06; 0.18; 0.20; 0.48	Overdosed trials on peaches performed with 3×125 g/ha, PHI 3 days (Germany, 2018). As the SEU GAP is clearly more critical no additional trials are required MRL _{OECD} = 0.93		0.47	0.16	1.00
	SEU	 Mo: Apricots 0.27; 0.28; 0.33; 0.37; 0.43; 0.55; 0.58; 0.95 Peaches: 0.20; 0.26; 2× 0.28; 0.31; 0.36; 0.63; 0.73 RA: Apricots 0.28; 0.29; 0.34; 0.38; 0.44; 0.56; 0.59; 0.96 Peaches: 0.21; 0.27; 0.29; 0.29; 0.32; 0.37; 0.64; 0.74 	Combined data set on apricots and peaches compliant with GAP (Germany, 2018). Extrapolation to apricots and peaches is possible MRL _{OECD} =1.28	1.5	0.95	0.33	1.00
	Import (US)	Mo: 0.17; 0.20; 0.22; 0.31; 0.34; 0.37; 0.4; 2× 0.42 RA: –	Trials on peaches compliant with GAP (Germany, 2018) MRL _{OECD} = 0.95	1	0.42	0.34	1.00 ^(e)
Plums	NEU	Mo: 0.10; 0.13; 0.14; 0.18; 0.19; 0.20; 0.22; 0.24; 0.27 RA: 0.11; 0.14; 0.15; 0.19; 0.20; 0.21; 0.23; 0.25; 0.28	Trials on plums performed with application rate within 25% deviation (Germany, 2018) MRL _{OECD} = 0.56	0.6	0.27	0.19	1.00
	SEU	Mo: 0.08; 0.09; 0.12; 0.15; 0.19; 0.05; 0.07; 0.09 RA: 0.09; 0.10; 0.13; 0.16; 0.20; 0.06; 0.08; 0.10	Trials on plums compliant with GAP (Germany, 2018) $MRL_{OECD} = 0.32$	0.4	0.19	0.09	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	Import (US)	Mo: 0.02; 0.04; 0.05; 0.06; 0.06; 0.27 RA: –	Trials on plums compliant with GAP (Germany, 2018) MRL _{OECD} = 0.46	0.5 (tentative) ^(f)	0.27	0.05	1.00 ^(e)
Table grapes	NEU	 Mo: 0.18; 0.29; 0.36; 0.44; 0.46; 0.56; 0.63; 0.65; 0.66 RA: 0.19; 0.30; 0.37; 0.45; 0.47; 0.57; 0.64; 0.66; 0.67 	Trials on grapes compliant with GAP (Germany, 2018). Extrapolation to table grapes is applicable $MRL_{OECD} = 1.41$	1.5	0.66	0.46	1.00
	SEU	 Mo: 0.30; 0.34; 0.36; 0.55; 0.58; 0.60; 0.63; 0.66; 0.96; 1.0 RA: 0.31; 0.35; 0.37; 0.58; 0.60; 0.61; 0.64; 0.68; 0.97; 1.02 	Trials on grapes compliant with GAP for table grapes (Germany, 2018) MRL _{OECD} = 1.79	2	1.00	0.59	1.00
	Import (US)	Mo: 0.1; 2× 0.15; 0.19; 0.21; 0.27; 0.32; 0.37; 0.43; 0.47; 0.49; 0.52; 0.58; 0.62; 0.63; 0.95 RA: -	Trials on table grapes compliant with GAP (Germany, 2018) MRL _{OECD} = 1.32	1.5	0.95	0.40	1.00 ^(e)
Wine grapes	NEU	Mo: 0.18; 0.29; 0.36; 0.44; 0.46; 0.56; 0.63; 0.65; 0.66 RA: 0.19; 0.30; 0.37; 0.45; 0.47; 0.57; 0.64; 0.66; 0.67	Trials on grapes compliant with GAP (Germany, 2018). Extrapolation to table grapes and wine grapes is applicable MRL _{OECD} = 1.41	1.5	0.66	0.46	1.00
	SEU	 Mo: 0.13; 0.22; 0.26; 0.28; 0.34; 0.35; 0.41; 0.44; 0.61; 0.63 RA: 0.15; 0.23; 0.28; 0.29; 0.36; 0.36; 0.43; 0.45; 0.65; 0.65 	Trials on wine grapes compliant with GAP (Germany, 2018) MRL _{OECD} = 1.1	1.5	0.63	0.35	1.00
	Import (US)	Mo: 0.1; 2× 0.15; 0.19; 0.21; 0.27; 0.32; 0.37; 0.43; 0.47; 0.49; 0.52; 0.58; 0.62; 0.63; 0.95 RA: -	Trials on table grapes compliant with GAP (Germany, 2018). Extrapolation to wine grapes is applicable MRL _{OECD} = 1.32	1.5	0.95	0.40	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Strawberries	NEU	 Mo: 0.15; 2× 0.17; 0.19; 0.24; 0.35; 0.36; 0.43; 0.69 RA: 0.16; 2× 0.18; 0.20; 0.25; 0.36; 0.37; 0.44; 0.70 	Trials on strawberries compliant with GAP (Germany, 2018) MRL _{OECD} = 1.01	1	0.69	0.24	1.00
	SEU	Mo: 0.07; 0.14; 0.18; 0.23; 0.28; 0.33; 0.50; 0.56 RA: 0.08; 0.15; 0.19; 0.24; 0.29; 0.34; 0.51; 0.57	Trials on strawberries performed with 2 applications instead 1 application (Germany, 2018). As the NEU GAP is clearly more critical no additional trials are required $MRL_{OECD} = 0.97$	1	0.56	0.26	1.00
	EU	Mo: 0.12; 0.13; 0.20; 0.25; 0.28; 0.33; 0.71; 0.79 RA: 0.13; 0.24; 0.21; 0.26; 0.29; 0.34; 0.72; 0.8	Trials on strawberries compliant with GAP (Germany, 2018) MRL _{OECD} = 1.38	1.5	0.79	0.27	1.00
	Import (US)	Mo: 0.20; 0.24; 0.29; 0.3; 0.36; 0.5; 0.68; 0.7; 0.83; 1.01 RA: -	Trials on strawberries compliant with GAP (Germany, 2018) MRL _{OECD} = 1.63	2	1.01	0.43	1.00 ^(e)
Cane fruits	NEU	Mo: 0.51; 0.70; 0.88; 1.2 RA: 0.52; 0.71; -; -	Trials on raspberries compliant with GAP (Germany, 2018). Extrapolation to cane fruits is applicable. Only 2 samples were analysed for fluopyram benzamide (M25) MRL _{OECD} = 2.47	3	1.20	0.79	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	Mo: 0.69; 0.87; 0.99; 0.84; 0.29; 0.42 RA: -; -; 1.0; 0.85; 0.30; 0.43	Trials on raspberries performed with 2 instead 1 application (Germany, 2018). As the NEU GAP is clearly more critical no additional trials are required. Extrapolation to blackberries and dewberries is applicable MRL _{OECD} = 2.05	2	0.99	0.77	1.00
	EU	Mo: 0.19; 0.35; 0.42; 0.98 RA: 0.20; 0.36; 0.43; 0.99	Trials on raspberries compliant with GAP (Germany, 2018). Extrapolation cane fruits is applicable MRL _{OECD} = 1.86	3	0.98	0.39	1.00
	Import (US)	Mo: Raspberries 0.43; 0.71; 1.12 Blackberries 1.53; 2.39 RA: –	Combined data set on raspberries and blackberries compliant with GAP (Germany, 2018). Extrapolation to cane fruits is applicable MRL _{OECD} = 4.31	5	2.39	1.12	1.00 ^(e)
Blueberries	Import (US)	Mo: 0.51; 0.58; 0.88; 1.14; 1.14; 1.32; 1.49; 4.33 RA: –	Trails on blueberries compliant with GAP (Germany, 2018) MRL _{OECD} = 6.32	7	4.33	1.14	1.00 ^(e)
Blueberries, cranberries, currants, gooseberries and elderberries	NEU	 Mo: 0.24; 0.26; 0.35; 0.40; 0.44; 0.64; 0.92; 0.96; 1.01; 1.63; 1.69; 2.1 RA: 0.25; 0.27; 0.36; 0.41; 0.45; 0.65; 0.93; 0.97; 1.02; 1.64; 1.70; 2.11 	Trials on currants compliant with GAP (Germany, 2018). Extrapolation to blueberries, cranberries, gooseberries and elderberries is applicable $MRL_{OECD} = 3.38$	4	2.10	0.78	1.00

Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	Mo: 0.12; 0.40; 0.47; 1.20 RA: 0.13; 0.41; 0.48; 1.21	Trials on currants performed with 2 instead 1 application (Germany, 2018). As the NEU GAP is clearly more critical no additional trials are required. Extrapolation to blueberries and gooseberries is applicable. No GAP is authorised for currants, cranberries, or elderberries MRL _{OECD} = 2.39	3	1.20	0.44	1.00
	EU	Mo: 0.15; 0.25; 0.36; 0.38; 0.42; 0.42 RA: 0.16; 0.26; 0.37; 0.39; 0.43; 0.43	Trials on currants compliant with GAP (Germany, 2018). Extrapolation to other small fruits and berries is applicable $MRL_{OECD} = 1.15$	1.5	0.42	0.37	1.00
Rose hips	NEU	 Unscaled: Mo: 0.24; 0.26; 0.35; 0.40; 0.44; 0.64; 0.92; 0.96; 1.01; 1.63; 1.69; 2.1 RA: 0.25; 0.27; 0.36; 0.41; 0.45; 0.65; 0.93; 0.97; 1.02; 1.64; 1.70; 2.11 Scaled: Mo: 0.18; 0.2; 0.26; 0.3; 0.33; 0.48; 0.69; 0.72; 0.76; 1.22; 1.22; 1.27; 1.58 RA: 0.19; 0.2, 0.27; 0.31; 0.34; 0.49; 0.7; 0.73; 0.77; 1.23; 1.28; 1.58 	Trials on currants scaled to GAP (scaling factor 0.75) (Netherlands, 2019). Extrapolation to rose hips is applicable MRL _{OECD} = 2.61	3	1.58	0.69	1.00
	EU	Mo: 0.15; 0.25; 0.36; 0.38; 0.42; 0.42 RA: 0.16; 0.26; 0.37; 0.39; 0.43; 0.43	Trials on currants compliant with GAP (Germany, 2018). Extrapolation to rose hips is applicable $MRL_{OECD} = 1.15$	1.5	0.42	0.37	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Mulberries (black and white)	NEU	Mo: 0.41; 0.44; 0.57; 1.0; 1.4; 2.1 RA: 0.42; 0.45; 0.58; 1.01; 1.41; 2.11	Trials on currents compliant with GAP (Germany, 2018). Extrapolation to mulberries is applicable $MRL_{OECD} = 3.65$	4	2.10	0.79	1.00
	EU	Mo: 0.15; 0.36; 0.37; 0.42; 0.42; 0.47 RA: 0.16; 0.37; 0.38; 0.43; 0.43; 0.48	Trials on currants compliant with GAP (Germany, 2018). Extrapolation to mulberries is applicable $MRL_{OECD} = 1.1$	1.5	0.47	0.40	1.00
Bananas	SEU	Mo: 0.02; 2× 0.04; 0.05; 0.06; 0.07; 0.19; 0.20; 0.25; 2× 0.26; 0.28; 0.37; 0.53 RA: 0.03; 2× 0.05; 0.06; 0.07; 0.08; 0.20; 0.21; 0.26; 2× 0.27; 0.29; 0.38; 0.54	Trials on banana performed with 6 instead of 3 applications with a PHI of 0 day used on a tentative basis (EFSA, 2011) $MRL_{OECD} = 0.79$	0.8 (tentative) ^(g)	0.53	0.2	1.00
Cherimoyas	EU	Mo/RA: –	No trials available. Applicant not aware of such use (EFSA, 2019e)	_	_	-	_
Potatoes	SEU	Mo: $7 \times < 0.01$; 0.02 RA: $7 \times < 0.02$; 0.03	Trails on potatoes compliant with GAP (Germany, 2018) $MRL_{OECD} = 0.02$	0.02	0.02	0.01	1.00
	Import (US)	Mo: 21× < 0.01; 6× 0.01; 5x 0.02; 2× 0.03; 0.04; 0.05; 0.06; 0.07 RA: -	Trials on potatoes compliant with GAP (Germany, 2018) $MRL_{OECD} = 0.07$	0.08	0.07	0.01	1.00 ^(e)
Sweet potatoes and yams	NEU	Mo: < 0.01; 5× 0.02; 2× 0.03 RA: < 0.02; 5× 0.03; 2× 0.04	Trials on potatoes compliant with GAP (Netherlands, 2018) $MRL_{OECD} = 0.06$	0.06	0.03	0.02	1.00
Other root and tuber vegetables except beetroots, carrots, radishes and sugar beets	NEU	Mo: 0.02; 0.03; 2× 0.04; 3× 0.05; 0.08; 0.13 RA: 0.03; 0.04; 2× 0.05; 3× 0.06; 0.09; 0.14	with CAD (Cormony 2019)	0.2	0.13	0.05	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Carrots	NEU	Mo: 0.02; 0.03; 2× 0.04; 3× 0.05; 0.08; 0.13		0.2	0.13	0.05	1.00
		RA: 0.03; 0.04; 2× 0.05; 3× 0.06; 0.09; 0.14	with GAP (Germany, 2018) $MRL_{OECD} = 0.18$				
	SEU	Mo: < 0.01; 2× 0.01; 3× 0.02; 0.03; 0.06	Trials on carrots compliant	0.09	0.06	0.02	1.00
		RA: < 0.02; 2× 0.03; 3× 0.03; 0.04; 0.07	with GAP (Germany, 2018) MRL _{OECD} = 0.09				
	Import (US)	Carrots:	Trials on carrots and	0.3	0.13	0.06	1.00 ^(e)
		Mo: 0.02; 2× 0.04; 2× 0.06; 0.09	radishes compliant with GAP (Germany, 2018).				
		Radishes: 0.05; 0.07; 0.1; 0.12; 0.13	Extrapolation to carrots				
		RA: –	accepted $MRL_{OECD} = 0.21$				
Radishes	NEU	Mo: -	No trials compliant with the	_	_	_	_
		RA: -	GAP is available				
	Import (US)	Carrots:	Trials on carrots and radishes compliant with GAP	0.3	0.13	0.06	1.00 ^(e)
		Mo: 0.02; 2× 0.04; 2× 0.06; 0.09	(Germany, 2018).				
		Radishes: Mo: 0.05; 0.07; 0.1; 0.12; 0.13	Extrapolation to radishes				
		RA: –	accepted $MRL_{OECD} = 0.21$				
Beetroots	NEU	Mo: 2× < 0.01; 0.01; 3× 0.02; 0.03; 0.04	Trials on carrots compliant	0.06	0.04	0.02	1.00
		RA: 2× < 0.02; 0.02; 3× 0.03; 0.04; 0.05	with the GAP (Netherlands, 2019). Extrapolation to beetroots possible				
Onions, garlic, shallots	NEU	Mo: 5× < 0.01; 0.02; 0.03; 0.04	MRL _{OECD} = 0.06 Trials on onions compliant	0.07	0.04	0.01	1.00
, galle, ellanoto		RA: 5× < 0.02; 0.03; 0.04; 0.05	with GAP (Germany, 2018). Extrapolation to shallots and garlic is applicable $MRL_{OECD} = 0.06$				
	SEU	Mo: 6× < 0.01; 0.03; 0.04	Trials on onions compliant	0.07	0.04	0.01	1.00
		RA: 6× < 0.02; 0.04; 0.05	with GAP (Germany, 2018). Extrapolation to shallots and garlic is applicable MRL _{OECD} = 0.06				



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Spring onions/green onions and Welsh onions	NEU	Mo: 0.07; 0.11; 0.12; 0.29 RA: 0.16; 0.18; 0.13; 0.30	Overdosed trials on spring onions performed with 2 instead 1 application (Germany, 2018). As the SEU GAP is clearly more critical no additional trials are required MRL _{OECD} = 0.54	0.7	0.29	0.12	1.10
	SEU	Mo: 0.27; 0.41; 0.61; 1.2 RA: 0.32; 0.42; 0.63; 1.22	1; 0.61; 1.2Overdosed trials on spring onions performed with 2 instead 1 application (Germany, 2018) used on tentative basis MRL_OECD = 2.2631.200.51	1.10			
Tomatoes	SEU	Mo: $4 \times < 0.01$ RA: $4 \times < 0.02$	Trials on tomato compliant with soil application GAP (Germany, 2018) MRL _{OECD} = 0.01	0.01*	0.01	0.01	1.00
	EU	Mo: 0.01; 0.04; 0.08; 0.11; 0.14; 0.18; 0.23 RA: 0.03; 0.05; 0.1; 0.15; 0.5; 0.23; 0.24	Trials compliant with the GAP using drip irrigation submitted during Member States Consultation (Netherlands, 2019) MRL _{OECD} = 0.42	0.5 (tentative) ^(f)	0.23	0.11	1.3
	Import (US)	Mo: 0.02; 0.06; 0.07; 2× 0.08; 0.09; 0.10; 0.11; 0.16; 0.17; 0.18; 2× 0.19; RA: -	Trials on tomatoes compliant with GAP (Germany, 2018) MRL _{OECD} = 0.35	0.4	0.19	0.11	1.00 ^(e)
Aubergines	SEU	Mo: $4 \times < 0.01$ RA: $4 \times < 0.02$	Trials on tomato compliant with soil application GAP (Germany, 2018). Extrapolation to aubergines is possible $MRL_{OECD} = 0.01$	0.01*	0.01	0.01	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	EU	$ \begin{array}{c} \textbf{Mo:} 0.04; \ 0.04^{(h)}; \ 0.05^{(h)}; \ 0.07; \ 2\times \ 0.08; \\ 0.11^{(h)}; \ 0.12^{(h)}; \ 0.12; \ 0.13^{(h)}; \ 0.13; \ 0.15^{(h)}; \\ 0.21^{(h)}; \ 0.23^{(h)}; \\ \textbf{RA:} \ 0.05; \ 0.05^{(h)}; \ 0.06^{(h)}; \ 0.08; \ 2\times \ 0.09; \\ 0.12^{(h)}; \ 0.13^{(h)}; \ 0.13; \ 0.14^{(h)}; \ 0.14; \ 0.16^{(h)}; \\ 0.22^{(h)}; \ 0.24^{(h)} \end{array} $	Trials on tomatoes GAP compliant, or performed with 2 instead of 3 foliar applications deemed acceptable, since residues are in the same range or higher compared to residues of the GAP compliant trials (Germany, 2018). Extrapolation to aubergines is possible MRL _{OECD} = 0.34		0.23	0.12	1.00
Sweet peppers/bell peppers	SEU	Mo: < 0.01; 0.01; 2× 0.02 RA: < 0.02; 0.02; 2× 0.03	Four trials compliant with soil application GAP (Germany, 2018). As the indoor GAP is clearly more critical no additional trials are required $MRL_{OECD} = 0.03$	0.04	0.02	0.01	1.00
	EU	Mo: 0.16; 2× 0.25; 2× 0.29; 2× 0.31; 0.42; 0.58 RA: 0.17; 0.26; 0.26; 0.30; 0.30; 0.32; 0.32; 0.43; 0.59	Trials on peppers compliant with GAP (Germany, 2018) $MRL_{OECD} = 0.95$	1	0.58	0.29	1.00
	Import (US)	Mo: sweet peppers: 0.04; 0.09; 0.13; 0.14; 0.17; 0.36; Chilli peppers: 0.12; 1.23	Trials on peppers and chilli peppers compliant with GAP (Germany, 2018) MRL _{OECD} = 1.86	2	1.23	0.14	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
courgettes	NEU	Mo: 0.02; 0.03; 0.04; 0.05; 0.06 RA: 0.03; 0.04; 0.05; 0.06; 0.07	Trials on cucumbers compliant with the GAP. (Germany, 2018) Extrapolation to gherkins is applicable. No authorised NEU GAP for courgettes reported. As the indoor GAP is clearly more critical no additional trials are required MRL _{OECD} = 0.12	0.15	0.06	0.04	1.00
	SEU	Mo: 2× < 0.01; 0.01; 0.02 RA: 2× < 0.02; 0.02; 0.03	Trials on cucumbers compliant with the soil application GAP (Germany, 2018). Extrapolation to courgettes and gherkins is applicable. As the indoor GAP is clearly more critical no additional trials are required MRL _{OECD} = 0.02	0.03	0.02	0.01	1.00
	EU	Mo: 0.08; 0.10; 2× 0.13; 0.14; 0.22; 0.26; 0.30 RA: 0.09; 0.11; 0.14; 0.14; 0.15; 0.23; 0.27; 0.31	Trails on cucumbers compliant with GAP (Germany, 2018). Extrapolation to courgettes and gherkins is applicable MRL _{OECD} = 0.51	0.6	0.30	0.14	1.00
	SEU	Mo: 6× < 0.01; 0.02; 0.04; 2× 0.06 RA: 6× < 0.02; 0.04; 0.06; 2× 0.07	Trials on melons compliant with soil application GAP (Germany, 2018). Extrapolation to pumpkins and watermelons is applicable $MRL_{OECD} = 0.11$	0.15	0.06	0.01	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	EU	Mo: < 0.01; 0.02; 0.07; 0.12 RA: < 0.02; 0.03; 0.08; 0.13	Trials on melons compliant with GAP used (Germany, 2018). Extrapolation to pumpkins and watermelons is applicable MRL _{OECD} = 0.26	0.4 (tentative for watermelons and melons) ^(f)	0.12	0.05	1.00
	Import (US)	Mo: 0.07; 0.08; 0.14; 0.23; 0.38; 0.44 RA: –	Trials on melons compliant with GAP (Germany, 2018). Authorised GAP only for melons MRL _{OECD} = 0.85	0.9 (tentative) ^(f)	0.44	0.19	1.00 ^(e)
Sweet corn	NEU	Mo: 3× < 0.01 RA: 3× < 0.02	Trials on sweet corn compliant with the GAP (Germany, 2018). The reduced number of residue trials is considered acceptable as all results were below the LOQ and no residue is expected MRL _{OECD} = 0.01	0.01*	0.01	0.01	1.00
Broccoli	NEU	Mo: < 0.01; 0.02; 0.05; 0.14 RA: < 0.02; 0.03; 0.06; 0.15	Trials on broccoli compliant with the GAP (Germany, 2018) MRL _{OECD} = 0.29	0.4	0.14	0.04	1.00
Cauliflowers	NEU	Mo: 2× < 0.01; 3× 0.01; 0.02; 2× 0.05 RA: 2× < 0.02; 3× 0.02; 0.03; 2× 0.06	Trials on cauliflower with 25% deviation in application rate (Germany, 2018) MRL _{OECD} = 0.18	0.1	0.05	0.01	1.00
Brussels sprouts	NEU	Mo: 0.01; 4× 0.04; 2× 0.07; 0.14 RA: 0.02; 4× 0.05; 2× 0.08; 0.15	Trials on brussels sprouts with dose rates within 25% deviation (Germany, 2018) MRL _{OECD} = 0.21	0.3	0.14	0.04	1.00
Head cabbages	NEU	Mo: 3× < 0.01; 3× 0.01; 0.02; 0.04; 0.08 RA: 3× < 0.02; 3× 0.02; 0.03; 0.05; 0.09	Trials on head cabbage with dose rates within 25% deviation (Germany, 2018) MRL _{OECD} = 0.12	0.15	0.08	0.01	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Chinese cabbages/pe- tsai	NEU	Mo: 0.22; 0.29; 0.42; 0.84 RA: 0.23; 0.3; 0.43; 0.85	Trials with 2 applications instead of one on Chinese cabbage used on a tentative basis (Germany, 2018) MRL _{OECD} = 1.55	2 (tentative) ^(g)	0.84	0.36	1.00
Escaroles, land cresses, red mustards	NEU	 Mo: 0.05; 0.11; 0.21; 0.26; 0.37; 0.58; 0.62; 0.84; 0.98 RA: 0.06; 0.12; 0.22; 0.27; 0.38; 0.59; 0.63; 0.85; 0.99 	Trials on open leaf lettuce with 2 application instead of 1 (Germany, 2018). Extrapolation to escaroles, land cresses, and red mustards is possible MRL _{OECD} = 1.75	2 (tentative) ^(g)	0.98	0.37	1.00
Lamb's lettuces, cresses and other sprouts shoots, Roman rocket and purslanes (sea lavender) and baby leaf crops		 Mo: 0.05; 0.11; 0.21; 0.26; 0.37; 0.58; 0.62; 0.84; 0.98 RA: 0.06; 0.12; 0.22; 0.27; 0.38; 0.59; 0.63; 0.85; 0.99 	Trials on open leaf lettuce with 2 application instead of 1 (Germany, 2018). As the indoor GAP is clearly more critical no additional trials are required for. Extrapolation to subgroup of lettuces and salad plants is possible MRL _{OECD} = 1.75	2	0.98	0.37	1.00
	EU	Mo: 0.83; 0.92; 0.94; 1.6; 3.6; 3.9; 10 RA: 0.84; 0.94; 0.95; 1.61; 3.63; 3.91; 10.01	Trials on open leaf variety lettuce with dose rates within 25% deviation (Germany, 2018). Extrapolation to subgroup of lettuces and salad plants is possible MRL _{OECD} = 16.31	20	10.00	1.60	1.00
Lettuces	NEU	 Mo: 0.12; 0.13; 2× 0.18; 0.26; 0.53; 0.57; 0.61; 0.62; 0.63; 0.93; 0.05; 0.11; 0.21; 0.26; 0.37; 0.58; 0.62; 0.84; 0.98 RA: 0.13; 0.14; 0.19; 0.19; 0.27; 0.55; 0.59; 0.62; 0.64; 0.65; 0.96; 0.06; 0.12; 0.22; 0.27; 0.38; 0.59; 0.63; 0.85; 0.99 	Trials on open and closed variety lettuces within 25% application rate (Germany, 2018). As the indoor GAP is clearly more critical no additional trials are required $MRL_{OECD} = 1.59$	2	0.98	0.45	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	Mo: 0.74; 1.5; 0.6; 0.55; 0.71; 0.14; 1.2; 2.2; 0.57 RA: 0.75; 1.52; 0.62; 0.56; 0.72; 0.15; 1.21; 2.21; 0.58	Trials on open leaf lettuce varieties with 2 applications instead of 1 (Germany, 2018). As the indoor GAP is clearly more critical no additional trials are required MRL _{OECD} = 3.4	4	2.20	0.71	1.00
	EU	Mo: 0.23; 0.83; 0.92; 0.94; 1.4; 1.6; 2.1; 3.6; 3.9; 10 RA: 0.24; 0.84; 0.94; 0.95; 1.42; 1.61; 2.11; 3.63; 3.91; 10.01	Trials on open and closed leaf variety lettuce within 25% deviation of application rate (Germany, 2018) MRL _{OECD} = 14.06	15	10.00	1.50	1.00
Spinaches, chards/beet leaves	NEU	Mo: 0.05; 0.11; 0.21; 0.26; 0.37; 0.58; 0.62; 0.84; 0.98 RA: 0.06; 0.12; 0.22; 0.27; 0.38; 0.59; 0.63; 0.85; 0.99	Trials on open leaf lettuce with 2 application instead of 1 used on a tentative basis (Germany, 2018). Extrapolation to spinaches and similar leaves possible MRL _{OECD} = 1.75	2 (tentative) ^(g)	0.98	0.37	1.00
Witloofs/Belgian endives	EU	Mo: 0.04; 0.07; 2× 0.12 RA: 0.06; 0.08; 0.13; 0.14	Trials on witloof compliant with GAP (EFSA, 2016) $MRL_{OECD} = 0.26$	0.3	0.12	0.10	1.20
Herbs, and edible flowers	NEU	Mo: Parsley: 0.31; 0.39; 0.54; 0.64; Chervil: 0.08; 0.38 Sage: 0.31 Savoury: 0.11; 3.64 RA: Parsley: 0.32; 0.4; 0.55; 0.65; Chervil: 0.09; 0.39 Sage: 0.32 Savoury: 0.12; 3.65	Combined data set of residue trials on parsley, chervil, sage and savoury (Germany, 2018). Extrapolation to fresh herbs possible $MRL_{OECD} = 5.16$ (1.16) (without savoury)	6 (1.5) ⁽ⁱ⁾	3.64 (0.67) ⁽ⁱ⁾	0.38 (0.38) ⁽ⁱ⁾	1.00
Basil	Import (US)	Mo: Chives: 6.05; 7.83; 19.8; Basil 18.78; 19.36; 30.0 RA: –	Combined data set on chives and basil compliant with the GAP. Only parent analysed (Germany, 2018) MRL _{OECD} = 52.28	60	30.00	19.07	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Beans, peas (with pods) Beans, peas (without pods), lentils (fresh)	NEU	 Mo: Beans: 0.05; 0.06; 0.10; 0.18 Peas: 0.03; 0.04; 0.05; 0.06; 0.13; 0.14; 0.19; 0.53 RA: Beans: 0.08; 0.10; 0.11; 0.19; Peas: 0.04; 0.05; 0.06; 0.08; 0.14; 0.15; 0.20; 0.54 	Trials in pea/bean (200 g/ha) scaled to the nominal rate of 250 g/ha (EFSA, 2016). Extrapolation to beans and peas with pods possible $MRL_{OECD} = 1.13$	0.7	0.53	0.08	1.10
	SEU		Trials on beans with pods, application rate within 25% deviation (Germany, 2018). No authorised use for peas (with pods) $MRL_{OECD} = 0.86$	0.9	0.82	0.05	1.10
	EU	 Mo: 0.07; 0.12; 2× 0.16; 0.20; 2× 0.22; 0.23; 0.26; 2× 0.40; 0.43; 0.69; 0.78; 0.95; 1.5; RA: 0.08; 0.13; 2× 0.17; 0.21; 2× 0.23; 0.24; 0.28; 0.41; 0.69; 0.44; 0.70; 0.8; 1.05; 1.51; 	Trials on beans with pods with application rate within 25% deviation (Germany, 2018). No authorised use for peas (with pods) MRL _{OECD} = 1.95	2	1.50	0.23	1.10
	Import (US)	Mo: 0.13; 0.15; 0.17; 0.25; 0.41; 0.7; 0.78; 1.14; 1.24 RA: –	Combined data set on beans and peas with pods (Germany, 2018). Extrapolation to beans and peas with pods is possible MRL _{OECD} = 2.28	3	1.24	0.41	1.10 ^(e)
	NEU	Mo: $3 \times < 0.01$; 2×0.01 ; 4×0.02 ; 3×0.03 ; 2×0.05 RA: $3 \times < 0.02$; 2×0.02 ; 4×0.03 ; 3×0.04 ; 2×0.06	Trials on peas without pods (Germany, 2018). Extrapolation to beans without pods possible. No authorised use for lentils in NEU $MRL_{OECD} = 0.08$	0.08	0.05	0.02	1.30



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	Import (US)	Mo: < 0.01; 2× 0.01; 0.02; 0.03; 0.04; 0.05; 2× 0.06; 2× 0.07 RA: -	Combined data sets from beans w/o pods and peas w/ o pods compliant with GAP (Germany, 2018). Extrapolation to legume vegetables possible MRL _{OECD} = 0.14	0.15	0.07	0.04	1.30 ^(e)
Asparagus	NEU	Mo: $4 \times < 0.01$ RA: $4 \times < 0.02$	Trials on asparagus compliant with the GAP (Germany, 2018) MRL _{OECD} = 0.01	0.01	0.01	0.01	1.00
	SEU	Mo: 4× < 0.01 RA: 4× < 0.02	Trials on asparagus with three applications instead of two (Germany, 2018). No further data needed as even overdosed trials are below the LOQ $MRL_{OECD} = 0.01$	0.01	0.01	0.01	1.00
Celeries	Import (US)	Mo: 0.20; 1.58; 2.24; 3.82; 5.44; 9.74 RA: –	Trials on celery compliant with the GAP. M-25 not analysed (Germany, 2018) MRL _{OECD} = 17.49	20	9.74	3.03	1.00
Globe artichokes	SEU	Mo: 0.05; 0.09; 0.1; 0.14; 0.16; 0.18; 0.21; 0.29 RA: 0.11; 0.15; 0.06; 0.1; 0.17; 0.19; 0.22; 0.30	Trials on globe artichokes with some applications slightly overdosed, outside the 25% range (3×100 g/ ha instead of 3×75 g/ha) (Germany, 2018) MRL _{OECD} = 0.46	0.5	0.29	0.15	1.00
	Import (US)	Mo: 1.02; 1.27; 1.37 RA: –	Trials on artichoke compliant with the GAP (Germany, 2018). Only parent analysed $MRL_{OECD} = 3.66$	4 (tentative) ^(f)	1.37	1.27	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Leeks	NEU	Mo: 0.01; 2× 0.02; 0.03; 0.07; 0.11; 0.17; 0.32 RA: 0.02; 0.03; 0.03; 0.04; 0.08; 0.12; 0.18; 0.33;	Trials on leek compliant with the GAP (Germany, 2018) MRL _{OECD} = 0.52	0.6	0.32	0.05	1.10
	SEU	Mo: 0.07; 0.16; 0.28; 0.31 RA: 0.08; 0.18; 0.3; 0.32	Overdosed trials on leek with two applications instead of one (Germany, 2018) $MRL_{OECD} = 0.65$	0.8 (tentative) ^(g)	0.31	0.22	1.10
Beans, Peas, Lentils, Lupins/lupini beans (dry)	NEU	Mo: RA:	No GAP compliant trials available. Only authorised use reported for beans and peas (dry)	_	_	_	_
	Import (US)	Mo: Beans 3× < 0.01; 0.01; 0.02; 0.03; 0.05; 0.07; Peas: 0.03; 0.04; 0.06; 0.16; 0.35 RA: -	Combined data set on dry beans and peas compliant with GAP (Germany, 2018). Extrapolation to pulses is possible. Only parent analysed MRL _{OECD} = 0.44	0.5	0.35	0.03	1.30 ^(e)
Peanuts/groundnuts	Import (US)	Mo: 10× < 0.01; 0.01; 0.0175 RA: -	Trials on peanuts compliant with the GAP. Only parent analysed (Germany, 2018) $MRL_{OECD} = 0.02$	0.02	0.02	0.01	1.20
Poppy seeds, mustard seeds	NEU	Mo: 0.02; 0.04; 0.08; 0.09; 0.1; 2× 0.11; 0.19; 0.26 RA: 0.03; 0.05; 0.09; 0.12; 0.13; 0.14; 0.13; 0.22; 0.30	Trials on rapeseed compliant with NEU GAP (Germany, 2018). Extrapolation to minor oilseeds possible MRL _{OECD} = 0.41	0.4	0.26	0.10	1.20
Sunflower seeds	NEU	Mo: 5× < 0.01; 0.01; 0.02; 0.17 RA: 5×3 < 0.02; 0.02; 0.03; 0.18	Trials on sunflower seeds compliant with the GAP (EFSA, 2016) MRL _{OECD} = 0.26	0.3	0.17	0.01	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	Import (US)	Mo: 0.02; 0.05; 0.06; 2× 0.08; 0.22; 0.25; 0.38 RA: –	Trials on sunflower seed compliant with the GAP (Germany, 2018) MRL _{OECD} = 0.65	0.7	0.38	0.08	1.00 ^(e)
Rapeseeds/canola seeds	NEU, SEU	NEU: Mo: 0.10; 0.26; 0.27; 0.29; 0.34; 0.35; 0.47; 0.61; RA: 0.13; 0.3; 0.34; 0.33; 0.42; 0.38; 0.51; 0.65 SEU: Mo: 0.14; 0.25; 0.27; 0.33; 2×0.38 ; 2×0.46 RA: 0.19; 0.27; 0.32; 0.42; 0.44; 0.51; 0.54; 0.62	Combined data set on rapeseed compliant with NEU and SEU GAP (EFSA, 2016) MRL _{OECD} = 1.01	1	0.61	0.34	1.20
Soya beans	Import (US)	Mo: 12× < 0.01; 3× 0.01; 2× 0.02; 2× 0.04; 0.06 RA: -	Trials on soya beans compliant with GAP. Only parent analysed (Germany, 2018) MRL _{OECD} = 0.07	0.08	0.06	0.01	1.20
Cotton seeds	Import (US)	Mo: 2× < 0.01; 2× 0.02; 0.04; 0.08; 0.14; 0.16; 0.29; 0.47 RA: -	Trials on cotton seeds not fully GAP compliant: seed treatment $+ 2 \times$ foliar altogether 500 g a.s./ha. Only parent analysed (Germany, 2018) MRL _{OECD} = 0.72	0.8	0.47	0.06	1.20
Barley grains, oat grains	NEU	Mo: 0.01; 3× 0.02; 4x 0.03; RA: 0.02; 3× 0.03; 3× 0.04; 0.05;	Trials on barley compliant with the GAP (Germany, 2018). Extrapolation to oat possible $MRL_{OECD} = 0.19$	0.07	0.03	0.02	1.00



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	$\label{eq:mo:2x} \begin{array}{l} \mbox{Mo: } 2\times < 0.01; \ 0.01; \ 0.02; \ 2\times \ 0.03; \ 0.08; \\ 0.11 \\ \mbox{RA: } 2\times < 0.02; \ 0.02; \ 0.03; \ 2\times \ 0.04; \ 0.09; \\ 0.12 \end{array}$	Trials on barley compliant with the GAP (Germany, 2018). Extrapolation to oat possible MRL _{OECD} = 0.19	0.2	0.11	0.02	1.00
Maize/corn grains	NEU	Mo: $8 \times < 0.01$ RA: $8 \times < 0.02$	Trials on maize compliant with the GAP (Germany, 2018) MRL _{OECD} = 0.01	0.01*	0.01	0.01	1.00
	Import (US)	Mo: 15× < 0.01 RA: -	Trials on maize (ear without husk) compliant with the GAP. Only parent analysed (Germany, 2018) MRL _{OECD} = 0.01	0.01*	0.01	0.01	1.00 ^(e)
Sorghum grains	Import (US)	Mo: 0.23; 0.24; 2× 0.25; 2× 0.26; 0.45; 0.50; 0.64; 0.69; 0.71; 3.03 RA: –	Trials on sorghum compliant with the GAP. Only parent analysed (Germany, 2018) MRL _{OECD} = 3.75	4	3.03	0.36	1.00
Wheat, rye grains	NEU	Mo: 4× < 0.01; 4× 0.01; 0.02 RA: 4× < 0.02; 4× 0.02; 0.03	Trials on wheat with application rate within 25% deviation (Germany, 2018). Extrapolation to rye possible MRL _{OECD} = 0.03	0.03	0.02	0.01	1.00
	SEU	Mo: 5× < 0.01; 0.01; 0.02; 0.05 RA: 5× < 0.02; 0.02; 0.03; 0.06	Trials on wheat compliant with the GAP (Germany, 2018). Extrapolation to rye possible MRL _{OECD} = 0.07	0.07	0.05	0.01	1.00
	Import (US)	Mo: 0.04; 2× 0.13; 0.15; 0.16; 0.17; 2× 0.19; 0.2; 0.21; 2× 0.23; 0.25; 0.30; 0.72 RA: -	Trials on wheat compliant with the GAP (Germany, 2018). Only parent analysed. No GAP on rye grain authorised MRL _{OECD} = 0.82	0.9	0.72	0.19	1.00 ^(e)



Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Hops	NEU	 Mo: 0.27; 0.40; 0.45; 0.92; 0.93; 1.1; 1.3; 1.0; 0.93 RA: 0.29; 0.45; 0.57; 0.96; 1.27; 1.46; 1.55; 1.05; 1.08 	Trials in hops compliant with the GAP (Germany, 2018) MRL _{OECD} = 2.43	3	1.30	0.93	1.20
	Import (US)	Mo: 5.80; 6.71; 13.5; 25.4 RA: -; -; 13.77; -	Trials on hops compliant with the GAP (Germany, 2018) $MRL_{OECD} = 49.02$	60	25.40	10.11	1.20 ^(e)
Dill (Seed spices)	Import (US)	Mo: 9.16; 25.9; 29.6; 19.1 RA: -; -; -; 19.17	Trials on dill seeds compliant with the GAP. M25 analysed in 1 trial only (Germany, 2018) MRL _{OECD} = 62.82	70	29.60	22.50	1.00
Chicory roots	NEU	Mo: – RA: –	No trials compliant with the GAP available	_	-	-	_
Barley, oat straw	NEU	Mo: 0.03; 0.06; 0.07; 0.08; 0.11; 0.13; 2× 0.14 RA: 0.04; 0.07; 0.08; 0.09; 0.14; 0.17; 0.15; 0.16;	Trials on barley compliant with the GAP (Germany, 2018). Extrapolation to oat possible MRL _{OECD} = 0.19	0.3 (tentative) ^(j)	0.14	0.10	1.10
	SEU	Mo: 0.03; 0.08; 2× 0.1; 0.18; 0.4; 0.77; 1.1 RA: 0.04; 0.12; 2× 0.12; 0.2; 0.42; 0.8; 1.16	Trials on barley compliant with GAP (Germany, 2018). Extrapolation to oat possible $MRL_{OECD} = 1.91$	2 (tentative) ^(j)	1.10	0.14	1.10
Maize/corn stover	NEU	 Mo: 0.13; 0.34; 0.37; 0.38; 0.46; 0.8; 0.99; 1.7 RA: 0.14; 0.35; 0.38; 0.39; 0.47; 0.81; 1; 1.75 	Trials on maize compliant with the GAP (Germany, 2018) MRL _{OECD} = 2.67	3 (tentative) ^(j)	1.70	0.42	1.00
Wheat, rye straw	NEU	Mo: 0.06; 0.09; 3× 0.11; 0.13; 0.16; 0.20; 0.21; 0.26; 0.28; 0.35 RA: 0.07; 0.12; 0.13; 2× 0.15; 0.16; 0.17; 2× 0.26; 0.29; 0.35; 0.38	Trials on wheat with application rate within 25% deviation (Germany, 2018). Extrapolation to rye possible $MRL_{OECD} = 0.53$	0.6 (tentative) ^(j)	0.35	0.15	1.10

Commodity	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
	SEU	Mo: 0.11; 2× 0.13; 0.17; 0.63; 0.09; 0.67; 1.1 RA: 0.12; 0.14; 0.15; 0.19; 0.67; 0.28; 0.71; 1.13	Trials on wheat compliant with the GAP (Germany, 2018). Extrapolation to rye possible MRL _{OECD} = 1.88	2 (tentative) ^(j)	1.10	0.15	1.10
Turnip tops	NEU	Mo: – RA: –	No GAP compliant trials available	-	_	-	-

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; PHI: preharvest interval.

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

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) 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): In the absence of residue data for metabolite M25 included in the RD-RA, the CF was derived from the same commodities or group of commodities. For pulses, a CF of 1.3 was based on beans/peas without pods, whereas for peanuts and soya beans the CF of 1.2 was based on rapeseed.

(f): MRL proposal is tentative because additional trials are required.

(g): MRL proposal is tentative as supporting trials were overdosed.

(h): Value from trials performed with 2 applications instead 3.

(i): Based on trials on parsley and chervil only. Trials on sage and savoury disregarded.

(j): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.



B.1.2.2. Residues in rotational crops

(a) Overall summary

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 \sim 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 \times 250 g/ha)
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 (e.g. including restriction on the indoor GAP on tomatoes with drip irrigation, and PBI of 120 days for cereals, and 320 days PBI for root and tuber vegetables and for leafy crops), 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)

DAT: days after treatment; a.s.: active substance; PEC_{soil}: predicted environmental concentration in soil; NEU: northern European Union; GAP: Good Agricultural Practice; PBI: plant-back interval.

(b) Summary of residues data from the rotational crops residue trials

Commodity (Relevant crop group/extrapolation)	Region/ Indoor ^(a)	PBI (days) ^(b)	Residue levels observed in the supervised residue trials	Comments/Source	Calculated MRL ^(c) (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)	CF ^(f)
Carrot and turnip root (root and tuber)	NEU	30	Mo: < 0.01; 0.01 RA: < 0.02; 0.02	Rotational crops field trials conducted at a dose rate	0.1	0.05	0.02	1
	SEU	30	Mo: 0.02; 0.05 RA: 0.03; 0.06	of application covering the max PEC _{soil} for parent				
	NEU	90/216	Mo: < 0.01; 0.02 RA: < 0.02; 0.03	(~ 1.2N) (Germany, 2011)	-	0.01	0.01	
	SEU	120	Mo: 0.03 RA: 0.04					
	NEU	320	Mo: < 0.01 RA: < 0.02		0.01*	0.01	0.01	
	SEU	365	Mo: < 0.01 RA: < 0.02					



Commodity (Relevant crop group/extrapolation)	Region/ Indoor ^(a)	PBI (days) ^(b)	Residue levels observed in the supervised residue trials	Comments/Source	Calculated MRL ^(c) (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)	CF ^(f)
	USA	228–245	Mo: $3 \times < 0.01$ RA: $3 \times < 0.02$					
Carrot and turnip top (leaves and tops)	NEU	30	Mo: 0.02; 0.04 RA: 0.03; 0.05		0.09	0.04	0.03	1
	SEU	30	Mo: 0.04; 0.01 RA: 0.05; 0.02					
	NEU	90/216	Mo: < 0.01; 0.04 RA: < 0.02; 0.05		0.04	0.02	0.01	
	SEU	154/240	Mo: 0.02; 0.01 RA: 0.03; 0.02					
Potato (tuber vegetables)	NEU	30	Mo: 2× 0.02 RA: 2× 0.03	Rotational crops field trials conducted at a dose rate	0.06	0.02	0.02	1
	SEU	30	Mo: 2× 0.02 RA: 2× 0.03	of application covering the max PEC_{soil} for parent (~ 1.2N) (EFSA, 2014)				
Spinach and lettuce (leafy vegetables)	NEU	30	Mo: 0.01; 0.02; 2×0.03 RA: 0.02; 0.03; 2×0.04	Rotational crops field trials conducted at a dose rate	0.15	0.09	0.03	1
	SEU	30	Mo: < 0.01; 0.02; 0.03; 0.09 RA: < 0.02; 0.03; 0.04; 0.1	of application covering the max PEC_{soil} for parent				
	NEU	90/230	Mo: 2×0.01 RA: 2×0.02	(Germany, 2011; EFSA, 2014)	0.02	0.01	0.01	
	SEU	155/240/ 320	Mo: $3 \times < 0.01$ RA: $3 \times < 0.02$					
Mustard green (Brassica vegetables)	USA	228–245	Mo: < 0.01; 0.01; 0.035 RA: -	Indicative rotational crop field studies performed at	_	0.035	0.01	-
Cotton seeds (Oil seeds)	USA/CAN	12–14	Mo: $11 \times < 0.01$ RA:-	1.2N PEC _{soil} , but considered less	0.01*	0.01	0.01	-
Cotton gin by-product (feed by-product)	USA/CAN	12–14	Mo: $9 \times < 0.01$; 2×0.02 RA:-	representative of European uses (Germany, 2011)	0.03	0.02	0.01	-
Wheat grain (cereals)	NEU	28–30	Mo: $2 \times < 0.01$ RA: $2 \times < 0.02$	Rotational crop field studies performed at \sim 1.2N PEC_{soil}	0.02	0.01	0.01	1
	SEU	30	Mo: < 0.01; 0.01 RA: < 0.02; 0.02	(Germany, 2011)				



Commodity (Relevant crop group/extrapolation)	Region/ Indoor ^(a)	PBI (days) ^(b)	Residue levels observed in the supervised residue trials	Comments/Source	Calculated MRL ^(c) (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)	CF ^(f)
	NEU	100–286	Mo: $3 \times < 0.01$ RA: $3 \times < 0.02$		0.01*	0.01	0.01	
	SEU	120–154	Mo: $2 \times < 0.01$ RA: $2 \times < 0.02$					
Wheat green material (forage)	NEU	28–30	Mo: 0.07; 0.12 RA: 0.08; 0.13		0.3	0.12	0.11	1
	SEU	30–49	Mo: 2× 0.11 RA: 2× 0.12					
	NEU	100–146	Mo: 0.08; 0.05 RA: 0.09; 0.06		0.15	0.05	0.04	
	SEU	120–154	Mo: 0.07; 0.05 RA: 0.08; 0.06					
	NEU	286	Mo: 0.1 RA: 0.11					
Wheat straw (straw and fodder)	NEU	28–30	Mo: 0.07; 0.28 RA: 0.12; 0.33		0.7	0.28	0.11	1.5
	SEU	30–49	Mo: 0.15; 0.05 RA: 0.2; 0.19					
	NEU	100–146	Mo: 0.09; 0.17 RA: 0.14; 0.22		0.4	0.19	0.09	1.5
	SEU	120–154	Mo: < 0.05; 0.19 RA: < 0.1; 0.24					
	NEU	286	Mo: 0.06 RA: 0.11					

PBI: plant-back interval; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; PEC_{soil}: predicted environmental concentration in soil.

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

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Country code: if non-EU trials.

(b): Plant-back interval (PBI): The interval (days, months, years) between the final application of a pesticide product to a primary crop and the planting of a rotational crop.

(c): Based on the shortest nominal PBI of 30 days representing crop failure.

(d): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(e): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(f): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment. When M25 was below the LOQ in all of the samples, a CF of 1 was derived.



(c) Summary of residues data from the combined primary and rotational crops uses

	derive l		GAP used to ding import () uses)		Rotational crop	05	HR _{rotation} > 25%	Combine Europea	CF ^(a)		
Commodity	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Relevant crop group	Median residue (mg/kg)	Highest residue (mg/kg)	HR _{primary} (Y/N)	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF ^(a)
Potatoes	0.01	0.07	0.08	Tuber	0.02	0.02	Y	0.03 ^(b)	0.04 ^(b)	0.06 ^(b)	1
Sweet potatoes, yams	0.02	0.03	0.06	Tuber	0.02	0.02	Y	0.04	0.05	0.15	1
Arrowroot, Cassava	n.r.	n.r.	n.r.	Tuber	0.02	0.02	n.r.	0.02	0.02	0.06	1
Beetroot	0.03	0.05	0.06	Root	0.02	0.05	Y	0.05	0.1	0.2	1
Carrots, radishes	0.06	0.13	0.3	Root	0.02	0.05	Y	0.07 ^(b)	0.18	0.4	1
Celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, salsify, swedes, turnips		0.13	0.2	Root	0.02	0.05	Y	0.07	0.18	0.4	1
Broccoli	0.04	0.14	0.4	Leafy and brassicas	0.03	0.09	Y	0.07	0.23	0.5	1
Cauliflowers	0.01	0.05	0.1	Leafy and brassicas	0.03	0.09	Y	0.04	0.14	0.3	1
Brussels sprouts	0.04	0.14	0.3	Leafy and brassicas	0.03	0.09	Y	0.07	0.23	0.4	1
Head cabbages	0.01	0.08	0.15	Leafy and brassicas	0.03	0.09	Y	0.04	0.17	0.3	1
Chinese cabbages/ pe-tsai	0.36	0.84	2 (tentative) ^(c)	Leafy and brassicas	0.03	0.09	N	0.36	0.84	2 (tentative) ^(c)	1
Kales, kohlrabies, watercresses	n.r.	n.r.	n.r.	Leafy and brassicas	0.03	0.09	n.r.	0.03	0.09	0.15	1
Lamb's lettuces, cresses and other sprouts and shoots, Roman rocket and purslanes (sea lavender), baby leaf crops	1.60	10.00	20	Leafy and brassicas	0.03	0.09	Ν	1.60	10.00	20	1



	derive l		AP used to ding import) uses)		Rotational crop	DS	HR _{rotation} > 25%		ent, based on xcluding IT)	CF ^(a)	
Commodity	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Relevant crop group	Median residue (mg/kg)	Highest residue (mg/kg)	HR _{primary} (Y/N)	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	
Lettuces	1.50	10.00	15	Leafy and brassicas	0.03	0.09	N	1.50	10.00	15	1
Escaroles, land cresses, red mustards, spinaches, chards/beet leaves	0.37	0.98	2 (tentative) ^(c)	Leafy and brassicas	0.03	0.09	N	0.37	0.98	2 (tentative) ^(c)	1
Herbs, and edible flowers	0.38	3.64	6	Leafy and brassicas	0.03	0.09	Ν	0.38	3.64	6	1
Basil and edible flowers	19.07	30.00	60	Leafy and brassicas	0.03	0.09	N	19.07	30.00	60	1
Barley, oat (grain)	0.02	0.11	0.2	Cereals	< 0.01	0.01	N	0.02	0.11	0.2	1
Buckwheat, millet, rice (grain)	n.r.	n.r.	n.r.	Cereals	< 0.01	0.01	n.r.	< 0.01	0.01	0.02	1
Maize (grain), sweet corn	0.01*	0.01*	0.01*	Cereals	0.01*	0.01	Y	0.01*	0.01	0.02 ^(d)	1
Rye, wheat (grain)	0.72	0.19	0.9	Cereals	0.02	0.02	Ν	0.72	0.19	0.9	1
Sorghum (grain)	3.03	0.36	4	Cereals	0.02	0.02	N	3.03	0.36	4	1
Herbal infusions from flowers, leaves and herbs	2.24 ^(e)	25.2 ^(e)	40 ^(e)	Leafy and Brassicas	0.03 × 10 (DF)	0.09 × 10 (DF)	N	0.3	0.9	40	1
Herbal infusions (dried, roots)	n.r.	n.r.	n.r.	Root	0.02 × 10 (DF)	0.05 × 10 (DF)	n.r.	0.2	0.5	1	1
Spices (other than roots)	22.50	29.60	70	Leafy and Brassicas	0.02	0.05	N	22.50	29.60	70	1
Spices, roots	n.r.	n.r.	n.r.	Root	0.02 × 10 (DF)	0.05 × 10 (DF)	n.r.	0.2	0.5	1	1
Sugar beet (roots)	n.r.	n.r.	n.r.	Root	0.02	0.05	n.r.	0.02	0.05	0.1	1
Chicory roots	n.c.	n.c.	n.c.	Root	0.02	0.05	n.c.	0.02	0.05	0.1 tentative ^(c)	1



	derive l	MRL, inclu	/ crops (GAP used to IRL, including import erance (IT) uses)		Rotational crops			Combine Europea	CF ^(a)		
Commodity	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Relevant crop group	Median residue (mg/kg)	Highest residue (mg/kg)	HR _{primary} (Y/N)	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	
Barley, oat straw	0.14	1.1	2 (tentative) ^(f)	Cereal (straw)	0.11	0.28	N	0.14	1.1	2 (tentative) ^(f)	1.1
Maize/corn stover	0.42	1.70	3 (tentative) ^(f)	Cereal (straw)	0.06	0.14	N	0.42	1.70	3 (tentative) ^(f)	1
Wheat, rye straw	0.15	1.1	2 (tentative) ^(f)	Cereal (straw)	0.11	0.28	Ν	0.15	1.1	2 (tentative) ^(f)	1.1
Buckwheat, millet, rice (straw)	n.r.	n.r.	n.r.	Cereal (straw)	0.06	0.14	n.r.	0.11	0.28	(tentative) ^(f)	1.1
Turnip (top)	n.c.	n.c.	n.c.	Root (top)	0.03	0.04	n.c.	0.03	0.04	0.09 (tentative) ^(c,f)	1
Barley, common millet, grass, maize, oat, rye, wheat (forage)	n.r.	n.r.	n.r.	Cereal (forage)	0.22	0.24	n.r.	0.22	0.24	0.3 (tentative) ^(f)	1.1
Fodder beet (root)	n.r.	n.r.	n.r.	Root	0.02	0.05	n.c.	0.04	0.1	0.15 (tentative) ^(f)	1
Fodder beet (top)	n.r.	n.r.	n.r.	Root (top)	0.03	0.04	n.c.	0.06	0.06	0.09 (tentative) ^(f)	1

GAP: Good Agricultural Practice; MRL: maximum residue level; HR: highest residue; n.c.: not conclusive as residues trials on primary crops are not available; n.r.: not registered for use on primary crops; DF: default drying factor.

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

(a): Conversion factor to recalculate residues according to the residue definition for monitoring and to the residue definition for risk assessment. As in succeeding crops M25 was above the LOQ only in cereal green material and straw, for which commodities residues following primary use were significantly higher, the CF was derived for primary crops are considered applicable for the combined uses.

(b): Although residues derived from the import tolerance are higher compared to other European uses, for combining residues from rotation use with primary uses the most critical European use (NEU/SEU/EU) is considered.

(c): MRL proposal is tentative, as additional trials are required to support the primary crop use.

(d): Based on the rotational use, as a no residues are expected from primary use.

(e): Based on recently adopted opinion on modification of MRL (EFSA, 2019d).

(f): Tentative MRLs are derived for feed commodities in view of the future need to set MRLs in these commodities.



B.1.2.3. Processing factors

	Number of	Processing Facto	r (PF)			
Processed commodity	valid studies ^(a)	Individual values	Median PF	CF _P ^(b)	Comment/Source	
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	0.10; 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; 2× 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	2.00; 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)	
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	$\begin{array}{c} 0.03; \ 0.05; \ 2\times \ 0.06; \\ 0.08, \ 0.09; \ 2\times \ 0.11; \\ 4\times \ 0.13; \ 0.17; \ 0.20; \\ 2\times \ 0.25; \ 0.50 \end{array}$	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; 2× 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; 2× 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)	



Durand	Number of	Processing Facto	or (PF)				
Processed commodity	valid studies ^(a)	Individual values	Median PF	CF _P ^(b)	Comment/Source		
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)		

PF: Processing factor (= Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).

CF_p: 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

(a) Dietary Burden based on residues from primary uses (Option 1)

Relevant	Diet	ary burder	expres	sed in	Most			Trigger
groups	ps mg/kg bw per day mg/kg DM Cri		critical subgroup	Most critica	l commodity ^(b)	exceeded		
(subgroups)	Median	Maximum	Median	Maximum				(Y/N)
Cattle (all diets)	0.032	0.050	0.97	1.63	Dairy cattle	Corn, field	Stover	Yes
Cattle (dairy only)	0.032	0.050	0.83	1.29	Dairy cattle	Corn, field	Stover	Yes
Sheep (all diets)	0.042	0.061	0.99	1.48	Lamb	Wheat	Milled by-pdts	Yes
Sheep (ewe only)	0.031	0.049	0.94	1.48	Ram/Ewe	Potato	Process waste	Yes
Swine (all diets)	0.030	0.040	1.01	1.56	Swine (finishing)	Wheat	Milled by-pdts	Yes
Poultry (all diets)	0.045	0.056	0.64	0.82	Poultry layer	Wheat	Milled by-pdts	Yes
Poultry (layer only)	0.044	0.056	0.64	0.82	Poultry layer	Wheat	Milled by-pdts	Yes

bw: body weight; DM: dry matter.

(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet 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 'g/kg bw per day'.



Relevant	Die	tary burde	n expres	sed in	Most			Trigger	
groups	mg/kg l	ow per day	mg/kg DM			Most cri		exceeded	
(subgroups)	Median	Maximum	Median	Maximum	subgroup ^(a)	commot	commodity ^(b)		
Cattle (all diets)	0.074	0.092	2.48	3.13	Dairy cattle	Potato	Process waste	Yes	
Cattle (dairy only)	0.074	0.092	1.93	2.39	Dairy cattle	Potato	Process waste	Yes	
Sheep (all diets)	0.083	0.101	2.50	3.04	Ram/Ewe	Potato	Process waste	Yes	
Sheep (ewe only)	0.083	0.101	2.50	3.04	Ram/Ewe	Potato	Process waste	Yes	
Swine (all diets)	0.037	0.051	1.61	2.21	Swine (breeding)	Potato	Process waste	Yes	
Poultry (all diets)	0.049	0.061	0.72	0.90	Poultry layer	Swede	Roots	Yes	
Poultry (layer only)	0.049	0.061	0.72	0.90	Poultry layer	Swede	Roots	Yes	

(b) Dietary Burden based on residues from combined primary and rotational uses (Option 2)

bw: body weight; DM: dry matter.

(a): When several diets are relevant (e.g. cattle, sheep and poultry 'all diets'), the most critical diet is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

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

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

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

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment/Source
	Laying hens	2.03 or 2.02	14	Radiolabelled active substance: phenyl-UL- ¹⁴ C and Pyridyl- 2,6- ¹⁴ C (Germany, 2011)
	Lactating ruminants	1.91	5	Goat, radiolabelled active substance: phenyl-UL- ¹⁴ C and Pyridyl-2,6- ¹⁴ C (Germany, 2011)
	Fish	60 μg as/L water	7 or 14	Radiolabelled active substance: Pyridyl-2,6- ¹⁴ C (Germany, 2011)

bw: body weight.



Time needed to reach a plateau concentration in milk and eggs (days)	Milk:	8		
	Eggs:	21 days based on the feeding study		
Metabolism in rat and ruminant similar	Yes	-		
Can a general residue definition be proposed for animals?	Yes	EFSA (2013a)		
Animal residue definition for monitoring (RD-Mo)	Sum of fluopyram and f as fluopyram	luopyram-benzamide (M25), expressed		
Animal residue definition for risk assessment (RD-RA)	Sum of fluopyram, fluopyram-benzamide (M25), and fluopyram- <i>E/Z</i> -olefine (M02/M03), expressed as fluopyram			
Fat soluble residues	No	Based on the feeding studies, fluopyram does not indicate a preferential distribution to high fat content matrices		
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Milk, egg, muscle, fat, liver and kidney: HPLC–MS/MS, combined LOQ is 0.02 mg/kg. Confirmation by second MS/MS transition; ILV available (EFSA, 2013a) Muscle, meat, liver and kidney: QuEChERS, HPLC–MS/MS, LOQ of 0.01 mg/kg each, and a combined LOQ of 0.02 mg/kg (EURLs comment: EFSA, 2019e)			

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.2.1.2. Stability of residues in livestock

Storage stability studies are not available. As all samples of the feeding studies were stored $\leq -18^{\circ}$ C and analysed within 30 days of collection further storage stability studies are not required (Germany, 2011).

B.2.2. Magnitude of residues in livestock

(a) Summary of t	he residue data	I from livestock	feeding studies	based on	residues from
primary uses (Opti	on 1)				

Animal commodity	closest fe	es at the eding level g/kg)	Estimated va	alue at 1N	MRL proposal	CF ^(c)				
	Mean	Highest	STMR _{Mo} ^(a) HR _{Mo} ^(b) (mg/kg) (mg/kg)		(mg/kg)					
Cattle (all) – Closest feeding level (0.04 mg/kg bw; 0.8 N rate) ^(d)										
Muscle	0.02	0.02	0.02	0.09	0.1	1.0				
Fat	0.02	0.02	0.02	0.08	0.09	1.4				
Liver	0.34	0.36	0.27	0.49	0.5	1.0				
Kidney	0.03	0.03	0.02	0.08	0.08	1.0				
Cattle (dairy only) - Cl	osest feedir	ıg level (0.04 ı	mg/kg bw; 0.8 N	rate) ^(d)						
Milk ^(e)	0.03	0.04	0.02	0.05	0.05	1.0				
Sheep (all) – Closest fee										
Muscle	0.02	0.02	0.05	0.10	0.1	1.0				
Fat	0.02	0.02	0.04	0.09	0.09	1.4				



Animal commodity	Residues at the closest feeding level (mg/kg)		Estimated v	alue at 1N	MRL proposal	CF ^(c)
	Mean	Highest	STMR _{Mo} ^(a) (mg/kg)	HR _{Mo} ^(b) (mg/kg)	(mg/kg)	
Liver	0.34	0.36	0.37	0.53	0.6	1.0
Kidney	0.03	0.03	0.04	0.09	0.09	1.0
Sheep (ewe only) - Cl	osest feedin	g level (0.04 n	ng/kg bw; 0.8 N	rate) ^(d)		
Milk ^(e)	0.03	0.04	0.02	0.05	0.05	1.0
Swine (all) – Closest fe	eding level (0.04 mg/kg bv	w; 1.0 N rate) ^(d)			
Muscle	0.02	0.02	0.02	0.09	0.09	1.0
Fat	0.02	0.02	0.02	0.08	0.08	1.4
Liver	0.34	0.36	0.26	0.44	0.5	1.0
Kidney	0.03	0.03	0.02	0.07	0.08	1.0
Poultry (all) – Closest f	eeding level	(0.035 mg/kg	bw; 0.6 N rate)	d)		
Muscle	0.04	0.04	0.04	0.06	0.06	1.0
Fat	0.04	0.04	0.05	0.06	0.06	1.3
Liver	0.16	0.16	0.20	0.24	0.3	1.0
Poultry (layer only) –	Closest feed	ing level (0.03	5 mg/kg bw; 0.6	N rate) ^(d)		
Eggs ^(f)	0.08	0.09	0.1	0.13	0.15	1.0

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

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

(e): Highest residue level from day 21 to day 29 (daily mean of 3 cows).

(f): Highest residue level from day 21 to day 28 (daily mean of 3 laying hens).

(b) Summary of the residue data from livestock feeding studies based on residues from combined primary and rotational uses (Option 2)

Residues at the closest feeding level (mg/kg)		Estimated va	alue at 1N	MRL proposal	CF ^(c)
Mean	Highest	STMR _{Mo} ^(a) HR _{Mo} ^(b) (mg/kg) (mg/kg)		(mg/kg)	
ding level (0.04 mg/kg bv	w; 0.4 N rate) ^(d)			
0.02	0.02	0.07	0.13	0.15	1.0
0.02	0.02	0.05	0.11	0.15	1.4
0.34	0.36	0.51	0.71	0.8	1.0
0.03	0.03	0.06	0.11	0.15	1.0
osest feedin	g level (0.04 ı	mg/kg bw; 0.4 N	rate) ^(d)		
0.02	0.02	0.04	0.06	0.07	1.0
ding level (0.04 mg/kg bv	w; 0.4 N rate) ^(d)			
0.02	0.02	0.07	0.13	0.15	1.0
0.02	0.02	0.05	0.11	0.15	1.4
0.34	0.36	0.53	0.70	0.8	1.0
0.03	0.03	0.06	0.11	0.15	1.0
sest feeding	g level (0.04 m	ng/kg bw; 0.4 N i	rate) ^(d)		
0.02	0.02	0.05	0.06	0.06	1.0
	Closest fe (mg Mean ding level ((0.02 0.02 0.34 0.03 osest feedin 0.02 ding level (0.02 0.02 0.02 0.02 0.34 0.03 sest feeding	Closest feeding level (mg/kg) Mean Highest ding level (0.04 mg/kg by 0.02 0.02 0.02 0.02 0.02 0.02 0.34 0.36 0.03 0.03 best feeding level (0.04 mg/kg by 0.02 0.02 ding level (0.04 mg/kg by 0.02 0.02 0.02 0.02 0.03 0.03 sest feeding level (0.04 mg/kg by 0.02 0.02 0.02 0.02 0.03 0.03 sest feeding level (0.04 mg/kg by 0.02 0.02	closest feeding level (mg/kg) Estimated value Mean Highest STMR _{Mo} ^(a) (mg/kg) ding level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.02 0.07 0.02 0.02 0.07 0.02 0.02 0.05 0.34 0.36 0.51 0.03 0.03 0.06 Desest feeding level (0.04 mg/kg bw; 0.4 N 0.02 0.02 0.02 0.04 0.02 0.02 0.04 0.02 0.02 0.04 0.02 0.02 0.04 0.02 0.02 0.07 0.02 0.02 0.04 0.03 0.02 0.07 0.02 0.02 0.07 0.03 0.02 0.07 0.03 0.02 0.05 0.34 0.36 0.53 0.03 0.03 0.06 sest feeding level (0.04 mg/kg bw; 0.4 N	closest feeding level (mg/kg) Estimated value at 1N Mean Highest STMR _{Mo} ^(a) (mg/kg) HR _{Mo} ^(b) (mg/kg) ding level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.02 0.07 0.13 0.02 0.02 0.07 0.13 0.02 0.02 0.05 0.11 0.34 0.36 0.51 0.71 0.03 0.03 0.06 0.11 0sest feedim level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.06 0.01 0.02 0.02 0.04 0.06 oling level (0.04 mg/kg bm; 0.4 N rate) ^(d) 0.02 0.01 0.06 oling level (0.04 mg/kg bm; 0.4 N rate) ^(d) 0.01 0.01 0.01 0.02 0.02 0.07 0.13 0.01 0.02 0.02 0.07 0.13 0.01 0.02 0.02 0.05 0.11 0.34 0.36 0.53 0.70 0.03 0.03 0.06 0.11 0.13 0.11 0.11	closest feeding level (mg/kg) Estimated value at 1N MRL proposal (mg/kg) Mean Highest STMR _{Mo} ^(a) (mg/kg) HR _{Mo} ^(b) (mg/kg) MRL proposal (mg/kg) ding level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.13 0.15 0.02 0.02 0.07 0.13 0.15 0.02 0.02 0.05 0.11 0.15 0.34 0.36 0.51 0.71 0.8 0.03 0.03 0.06 0.11 0.15 osest feedim level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.07 0.13 0.15 0.02 0.02 0.04 0.06 0.07 osest feedim level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.15 0.07 0.13 0.02 0.02 0.04 0.06 0.07 oling level (0.04 mg/kg bw; 0.4 N rate) ^(d) 0.15 0.15 0.11 0.02 0.02 0.05 0.11 0.15 0.03 0.03 0.06 0.11 0.15 0.34 0.36 0.53 0.70 0



Animal commodity	closest fe	es at the eding level g/kg)	Estimated va	alue at 1N	MRL proposal (mg/kg)	CF ^(c)
,	Mean	Highest	STMR _{Mo} ^(a) (mg/kg)			
Swine (all) – Closest fee	eding level (0.04 mg/kg bv	w; 0.8 N rate) ^(d)			
Muscle	0.02	0.02	0.02	0.09	0.1	1.0
Fat	0.02	0.02	0.02	0.08	0.09	1.4
Liver	0.34	0.36	0.32	0.49	0.5	1.0
Kidney	0.03	0.03	0.03	0.08	0.08	1.0
Poultry (all) – Closest fe	eding level	(0.035 mg/kg	bw; 0.6 N rate)(d)		
Muscle	0.04	0.04	0.05	0.06	0.07	1.0
Fat	0.04	0.04	0.05	0.07	0.07	1.3
Liver	0.16	0.16	0.21	0.26	0.3	1.0
Poultry (layer only) –	Closest feed	ing level (0.03	5 mg/kg bw; 0.6	N rate) ^(d)		
Eggs ^(f)	0.07	0.08	0.10	0.13	0.15	1.0

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

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

(e): Highest residue level from day 21 to day 29 (daily mean of 3 cows).

(f): Highest residue level from day 21 to day 28 (daily mean of 3 laying hens).



B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

ARfD

Highest IESTI, according to EFSA PRIMo (rev.3.1)

NESTI (% ARfD)

Assumptions made for the calculations

0.5 mg/kg bw (EFSA, 2013a)

EU (Option 1): Lettuces: 76% of ARfD EU (Option 2): Lettuces: 76% of ARfD

Not assessed in this review

EU (Option 1):

The calculation is based on the highest residue levels expected in raw agricultural commodities, except for limes and chicory roots for which the EU MRL was used, and bulk commodities for which the median residue levels were used, **considering the exposure from primary uses** only, assuming that the following **risk mitigations** are in place:

- indoor tomato GAP restricted to substrate,
- PBI of 120 days for cereals,
- PBI of 1 year for leafy crops and root/tuber vegetables

The following CF for risk assessment were also applied:

- 1.1 for spring onions, leeks, beans with pods, cereal straw;
- 1.2 for witloof, rapeseed, cotton seed, hops peanuts and soya beans;
- 1.3 tomatoes, beans/peas without pods, fresh lentils, pulses.

EU (Option 2): indoor tomato GAP restricted The calculation is based on the highest residue levels expected in raw agricultural commodities considering the **combined exposure from primary and rotational crops,** assuming that the following **risk mitigation** is in place:

• indoor tomato GAP restricted to substrate,

The HR values were derived as the sum of the HR in the respective rotated crop and the HR of the primary crop. The same CF for risk assessment were as detailed above.

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; MRL: maximum residue level; GAP: Good Agricultural Practice; PBI: plant-back interval; HR: highest residue; CF: conversion factor for enforcement residue definition to risk assessment residue definition.



ADI

TMDI according to EFSA PRIMo NTMDI, according to (to be specified) Highest IEDI, according to EFSA PRIMo (rev.3.1)

NEDI (% ADI)

Assumptions made for the calculations

0.012 mg/kg bw per day (EFSA, 2013a)

Not assessed in this review

EU (Option 1):

86% of ADI (NL toddler) EU (Option 2): 100% of ADI (NL toddler)

Not assessed in this review

EU (Option 1):

The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment (see above), except for limes and chicory roots for which the EU MRL was used and assuming that the following **risk mitigations** are in place:

- indoor tomato GAP restricted to substrate,
- PBI of 120 days for cereals,
- PBI of 1 year for leafy crops and root/tuber vegetables

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation

EU (Option 2): indoor tomato GAP restricted):

The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment (see above), except for limes and chicory roots for which the EU MRL was used and assuming that the following **risk mitigation** is in place:

indoor tomato GAP restricted to substrate

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. For those commodities having an HR from rotational uses >25% higher than the highest residue levels in the primary crops, the STMR was derived by combining the STMRs from the rotational and primary uses

These calculations included residues from the authorised GAP reported in this review and the potential uptake of fluopyram residues in crops that may be grown in rotation and for which sufficient data was available from rotational field trials

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; MRL: maximum residue level; GAP: Good Agricultural Practice; PBI: plant-back interval; HR: highest residue; CF: conversion factor for enforcement residue definition to risk assessment residue definition.



Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

Metabolite(s)

ADI (mg/kg bw per day)

Intake of groundwater metabolites (% ADI)

Not assessed	in this review

Not assessed in this review

Not assessed in this review

B.3.2. Consumer risk assessment with consideration of the existing CXLs

ARfD

Highest IESTI, according to EFSA PRIMo (rev.3.1)

NESTI (% ARfD)

Assumptions made for the calculations

0.5 mg/kg bw (EFSA, 2013a)

CX1 (Option 1)/CX1 (Option 2)/CX2 (Option 1)/ CX2 (Option 2): Lettuces: 76% of ARfD

Not assessed in this review

CX1 (Option 1), CX1 (Option 2):

For those commodities having a CXL higher than the respective EU MRL proposal (EU Option 1 and EU Option 2), highest residue levels applied in the EU scenarios were replaced by the highest residue levels derived by JMPR. The same CFs were applied for CXLs as used for the EU MRL proposals. For mango, a processing factor as derived by JMPR was considered for the risk assessment

CX2 (Option 1):

The same calculation was performed as in scenario CX1a, except the highest residue levels for cattle and swine tissues were replaced by that derived from the EU scenario (EU Option 1)

CX2 (Option 2):

Since the chronic exposure considering the authorised EU uses and import tolerances and the uptake from rotational crops accounted already for 100% of the ADI, the only safe scenario could be identified disregarding from the calculation all CXLs higher that the derived EU MRL

ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; CXL: codex maximum residue limit.



ADI

TMDI according to EFSA PRIMo NTMDI, according to (to be specified) Highest IESTI, according to EFSA PRIMo (rev.3.1)

NEDI (% ADI)

Assumptions made for the calculations

0.012 mg/kg bw per day (EFSA, 2013a)

Not assessed in this review

Not assessed in this review

CX1 (Option 1): 110% ADI (NL toddler) of which major contributors: Apples: 18% ADI; Milk: 10% ADI; Banana: 9% ADI

CX1 (Option 2): 128% ADI (NL toddler) of which major contributors: Milk: 20% ADI; Apples: 18% ADI; Banana: 9% ADI

CX2 (Option 1): 92% ADI (NL toddler)

CX2 (Option 2): 100% of ADI (NL toddler)

Not assessed in this review

CX1 (Option 1), CX1 (Option 2):

For those commodities having a CXL higher than the respective EU MRL proposal (EU Option 1 and EU Option 2), median residue levels applied in the EU scenarios were replaced by the median residue levels derived by JMPR. The same CFs were applied for CXLs as used for the EU MRL proposals. For mango, a processing factor as derived by JMPR was considered for the risk assessment

Scenario CX2 (Option 1):

The same calculation was performed as in scenario CX1 (Option 1), except the median residue levels for cattle and swine commodities were replaced by that derived from the EU scenario

Scenario CX2 (Option 2):

Since the chronic exposure considering the authorised EU uses and import tolerances and the uptake from rotational crops accounted already for 100% of the ADI, the only safe scenario could be identified disregarding from the calculation all CXLs higher that the derived EU MRLs

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake; MRL: maximum residue level; CF: conversion factor for enforcement residue definition to risk assessment residue definition; CXL: codex maximum residue limit.

B.4. Proposed MRLs

				Outcome of the review					
Code number Comm	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Option 2 (Restriction on indoor tomato use)		
number			(1119/ K9)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
Enforceme	ent residue definit	ion: Fluopyram			·				
110010	Grapefruit	0.4	0.4	0.5	Recommended ^(a)	0.5	Recommended ^(a)		
110020	Oranges	0.6	0.6	0.6	Recommended ^(b)	0.5	Further consideration needed ^(c)		
110030	Lemons	1	1	1	Recommended ^(d)	0.9	Further consideration needed ^(e)		
110040	Limes	1	1	1	Further consideration needed ^(f)	1	Further consideration needed ^(f)		
110050	Mandarins	0.6	0.6	0.9	Further consideration needed ^(g)	0.9	Further consideration needed ^(g)		
120010	Almonds	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120020	Brazil nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120030	Cashew nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120040	Chestnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120050	Coconuts	0.04	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120060	Hazelnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120070	Macadamia	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120080	Pecans	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120090	Pine nuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120100	Pistachios	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
120110	Walnuts	0.05	0.04	0.04	Recommended ^(b)	0.03	Further consideration needed ^(c)		
130010	Apples	0.6	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
130020	Pears	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
130030	Quinces	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
130040	Medlar	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
130050	Loquat	0.5	0.5	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
140010	Apricots	1.5	1	1.5	Recommended ^(a)	1.5	Recommended ^(a)		
140020	Cherries	2	2	2	Recommended ^(d)	2	Recommended ^(d)		
140030	Peaches	1.5	1	1.5	Recommended ^(a)	1.5	Recommended ^(a)		
140040	Plums	0.5	0.5	0.6	Recommended ^(a)	0.6	Recommended ^(a)		

				Outcome of the review					
Code number	Commodity	Existing EU MRL (mg/kg)			1 (PBIs, restriction on indoor tomato use)	Option 2 (Option 2 (Restriction on indoor tomato use)		
number			(119/ kg)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
151010	Table grapes	1.5	2	2	Recommended ^(a)	2	Recommended ^(a)		
151020	Wine grapes	1.5	2	2	Recommended ^(b)	1.5	Further consideration needed ^(c)		
152000	Strawberries	2	0.4	2	Recommended ^(a)	2	Recommended ^(a)		
153010	Blackberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)		
153020	Dewberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)		
153030	Raspberries	5	5	5	Recommended ^(a)	5	Recommended ^(a)		
154010	Blueberries	7	7	7	Recommended ^(a)	7	Recommended ^(a)		
154020	Cranberries	3	_	4	Recommended ^(h)	4	Recommended ^(h)		
154030	Currants (red, black and white)	7	7	7	Recommended ^(b)	4	Further consideration needed ^(c)		
154040	Gooseberries	7	7	7	Recommended ^(b)	4	Further consideration needed ^(c)		
154050	Rose hips	7	7	7	Recommended ^(b)	3	Further consideration needed ^(c)		
154060	Mulberries	7	_	4	Recommended ^(h)	4	Recommended ^(h)		
154080	Elderberries	7	_	4	Recommended ^(h)	4	Recommended ^(h)		
163020	Bananas	0.8	0.8	0.8	Further consideration needed ^(g)	0.8	Further consideration needed ^(g)		
163030	Mangoes	1	1	1	Recommended ⁽ⁱ⁾	_	Further consideration needed ^(j)		
163060	Cherimoyas	0.01*	_	-	Further consideration needed ^(k)	_	Further consideration needed ^(k)		
211000	Potatoes	0.15	0.15	0.15	Recommended ^(b)	0.08	Further consideration needed ^(c)		
212010	Cassava	0.1	_	_	Further consideration needed ^(I)	0.06	Recommended ^(h)		
212020	Sweet potatoes	0.1	_	0.06	Recommended ^(h)	0.15	Recommended ^(h)		
212030	Yams	0.1	_	0.06	Recommended ^(h)	0.15	Recommended ^(h)		
212040	Arrowroot	0.1	_	-	Further consideration needed ^(I)	0.06	Recommended ^(h)		
213010	Beetroot	0.3	_	0.06	Recommended ^(h)	0.2	Recommended ^(h)		
213020	Carrots	0.4	0.4	0.4	Recommended ^(b)	0.4	Recommended ^(a)		
213030	Celeriac	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213040	Horseradish	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213050	Jerusalem artichokes	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		

				Outcome of the review					
Code number Commodity	Commodity	ommodity Existing EU Existing CXL MRL (mg/kg) (mg/kg)		Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Option 2 (Restriction on indoor tomato use)		
hamber			(MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
213060	Parsnips	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213070	Parsley root	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213080	Radishes	0.3	_	0.3	Recommended ^(h)	0.4	Recommended ^(h)		
213090	Salsify	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213100	Swedes	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
213110	Turnips	0.3	_	0.2	Recommended ^(h)	0.4	Recommended ^(h)		
220010	Garlic	0.1	0.07	0.07	Recommended ^(a)	0.07	Recommended ^(a)		
220020	Onions	0.1	0.07	0.07	Recommended ^(a)	0.07	Recommended ^(a)		
220030	Shallots	0.1	_	0.07	Recommended ^(h)	0.07	Recommended ^(h)		
220040	Spring onions	15	15	15	Recommended ^(b)	3	Further consideration needed ^(e)		
231010	Tomatoes	0.9	0.5	0.5	Further consideration needed ^(g)	0.5	Further consideration needed ^(g)		
231020	Peppers	3	3	3	Recommended ^(b)	2	Further consideration needed ^(c)		
231030	Aubergines (egg plants)	0.9	0.5	0.5	Recommended ^(b)	0.4	Further consideration needed ^(c)		
232010	Cucumbers	0.5	0.5	0.6	Recommended ^(a)	0.6	Recommended ^(a)		
232020	Gherkins	0.5	_	0.6	Recommended ^(h)	0.6	Recommendeded ^(h)		
232030	Courgettes	0.5	_	0.6	Recommended ^(h)	0.6	Recommended ^(h)		
233010	Melons	0.4	_	0.9	Further consideration needed ^(m)	0.9	Further consideration needed ^(m)		
233020	Pumpkins	0.4	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)		
233030	Watermelons	0.4	_	0.4	Further consideration needed ^(m)	0.4	Further consideration needed ^(m)		
234000	Sweet corn	0.01*	0.01*	0.01*	Recommended ^(a)	0.02	Recommended ^(a)		
241010	Broccoli	0.4	0.3	0.4	Recommended ^(a)	0.5	Recommended ^(a)		
241020	Cauliflower	0.2	0.09	0.1	Recommended ^(a)	0.3	Recommended ^(a)		
242010	Brussels sprouts	0.3	0.3	0.3	Recommended ^(a)	0.4	Recommended ^(a)		
242020	Head cabbage	0.3	0.15	0.15	Recommended ^(a)	0.3	Recommended ^(a)		
243010	Chinese cabbage	0.7	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
243020	Kale	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		
244000	Kohlrabi	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		



			Existing CXL (mg/kg)	Outcome of the review					
Code number	Commodity	Existing EU MRL (mg/kg)		Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Option 2 (Restriction on indoor tomato use)		
hamber			(9/9)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
251010	Lamb's lettuce	15	-	20	Recommended ^(h)	20	Recommended ^(h)		
251020	Lettuce	15	15	15	Recommended ^(a)	15	Recommended ^(a)		
251030	Escarole (broad-leaf endive)	1.5	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251040	Cress	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
251050	Land cress	15	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251060	Rocket, Rucola	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
251070	Redmustard	15	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
251080	Baby leaf crops	15	_	20	Recommended ^(h)	20	Recommended ^(h)		
252010	Spinach	0.2	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
252020	Purslane	20	_	20	Recommended ^(h)	20	Recommended ^(h)		
252030	Beet leaves (chard)	0.2	_	2	Further consideration needed ^(m)	2	Further consideration needed ^(m)		
254000	Watercress	0.1	_	_	Further consideration needed ^(I)	0.15	Recommended ^(h)		
255000	Witloof	0.3	0.15	0.3	Recommended ^(a)	0.3	Recommended ^(a)		
256010	Chervil	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256020	Chives	8	_	6	Recommended ^(h)	6	Recommendeded ^(h)		
256030	Celery leaves	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256040	Parsley	8	_	6	Recommended ^(h)	6	Recommendeded ^(h)		
256050	Sage	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256060	Rosemary	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256070	Thyme	8	_	6	Recommended ^(h)	6	Recommendeded ^(h)		
256080	Basil	70	70	70	Recommended ^(b)	60	Further consideration needed ^(c)		
256090	Bay leaves (laurel)	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
256100	Tarragon	8	_	6	Recommended ^(h)	6	Recommended ^(h)		
260010	Beans (fresh, with pods)	1	1	3	Recommended ^(a)	3	Recommended ^(a)		
260020	Beans (fresh, without pods)	0.2	0.2	0.2	Recommended ^(b)	0.15	Further consideration needed ^(c)		



				Outcome of the review					
Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Option 2 (Restriction on indoor tomato use)		
number		(iiig/ kg)	(1119/149)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment		
260030	Peas (fresh, with pods)	1.5	_	3	Recommended ^(h)	3	Recommended ^(h)		
260040	Peas (fresh, without pods)	0.2	0.2	0.2	Recommended ^(b)	0.15	Further consideration needed ^(c)		
260050	Lentils (fresh)	0.2	_	0.15	Recommended ^(h)	0.15	Recommended ^(h)		
270010	Asparagus	0.01*	0.01*	0.01*	Recommended ^(a)	0.01*	Recommended ^(a)		
270030	Celery	0.01*	_	20	Recommended ^(h)	20	Recommended ^(h)		
270050	Globe artichokes	0.5	0.4	4	Further consideration needed ^(g)	4	Further consideration needed ^(g)		
270060	Leek	0.7	0.15	0.8	Further consideration needed ^(g)	0.8	Further consideration needed ^(g)		
300010	Beans (dry)	0.4	0.15	0.5	Recommended ^(a)	0.5	Recommended ^(a)		
300020	Lentils (dry)	0.4	0.7	0.7	Recommended ^(b)	0.5	Further consideration needed ^(c)		
300030	Peas (dry)	0.4	0.7	0.7	Recommended ^(b)	0.5	Further consideration needed ^(c)		
300040	Lupins (dry)	0.4	0.15	0.5	Recommended ^(a)	0.5	Recommended ^(a)		
401020	Peanuts	0.2	0.2	0.2	Recommended ^(b)	0.02	Further consideration needed ^(c)		
401030	Poppy seed	0.3	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)		
401050	Sunflower seed	0.7	0.7	0.7	Recommended ^(a)	0.7	Recommended ^(a)		
401060	Rape seed	1	1	1	Recommended ^(a)	1	Recommended ^(a)		
401070	Soya bean	0.3	0.3	0.3	Recommended ^(b)	0.08	Further consideration needed ^(c)		
401080	Mustard seed	0.3	_	0.4	Recommended ^(h)	0.4	Recommended ^(h)		
401090	Cotton seed	0.8	0.8	0.8	Recommended ^(a)	0.8	Recommended ^(a)		
500010	Barley grain	0.2	0.2	0.2	Recommended ^(a)	0.2	Recommended ^(a)		
500020	Buckwheat grain	0.2	_	_	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500030	Maize grain	0.02	0.02	0.02	Recommended ^(b)	0.02	Recommended ^(a)		
500040	Millet grain	0.01*	_	-	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500050	Oats grain	0.2	0.2	0.2	Recommended ^(a)	0.2	Recommended ^(a)		
500060	Rice	0.01*	1.5	_	Further consideration needed ^(I)	0.02	Recommended ^(h)		
500070	Rye grain	0.9	0.9	0.9	Recommended ^(b)	0.07	Further consideration needed ^(c)		
500080	Sorghum grain	1.5	_	4	Recommended ^(h)	4	Recommended ^(h)		



					Outcome	of the review	
Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato use)
hamber			(1119/119)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment
500090	Wheat grain	0.9	0.9	0.9	Recommended ^(a)	0.9	Recommended ^(a)
631000	Herbal infusions (dried, flowers)	0.1	_	40	Recommended ^(h)	40	Recommended ^(h)
632000	Herbal infusions (dried, leaves)	0.1	_	40	Recommended ^(h)	40	Recommended ^(h)
633000	Herbal infusions (dried, roots)	2.5	_	-	Further consideration needed ^(I)	1	Recommended ^(h)
700000	Hops (dried)	50	50	60	Recommended ^(a)	60	Recommended ^(a)
810060	Dill seeds	70	70	70	Recommended ^(a)	70	Recommended ^(a)
840000	Spices (roots and rhizome)	-	_	_	Further consideration needed ^(I)	1	Recommended ^(h)
900010	Sugar beet (root)	0.1	0.04	0.04	Recommended ⁽ⁱ⁾	0.1	Further consideration needed ^(c)
900030	Chicory roots	0.1	_	_	Further consideration needed ^(k)	0.1	Further consideration needed ^(k)
Enforceme	ent residue definitio	n 2: Sum of fluopy	ram and fluopyrar	n-benzamide	(M25), expressed as fluopyram		
1011010	Swine muscle	0.8	1.5	0.09	Further consideration needed ^(c)	0.1	Further consideration needed ^(c)
1011020	Swine fat tissue	0.5	1.5	0.08	Further consideration needed ^(c)	0.09	Further consideration needed ^(c)
1011030	Swine liver	5	8	0.50	Further consideration needed ^(c)	0.5	Further consideration needed ^(c)
1011040	Swine kidney	0.8	8	0.08	Further consideration needed ^(c)	0.08	Further consideration needed ^(c)
1012010	Bovine muscle	0.8	1.5	0.10	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)
1012020	Bovine fat tissue	0.5	1.5	0.09	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)
1012030	Bovine liver	5	8	0.50	Further consideration needed ^(c)	0.8	Further consideration needed ^(c)
1012040	Bovine kidney	0.8	8	0.08	Further consideration needed ^(c)	0.15	Further consideration needed ^(c)
1013010	Sheep muscle	0.8	1.5	1.5	Recommendeded ^(b)	0.15	Further consideration needed ^(c)
1013020	Sheep fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)
1013030	Sheep liver	5	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)
1013040	Sheep kidney	0.8	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)
1014010	Goat muscle	0.8	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)
1014020	Goat fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)

					Outcome	of the review	,	
Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Option	1 (PBIs, restriction on indoor tomato use)	Option 2 (Restriction on indoor tomato us		
number			(1119/169)	MRL (mg/kg)	Comment	MRL (mg/kg)	Comment	
1014030	Goat liver	5	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)	
1014040	Goat kidney	0.8	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)	
1015010	Equine muscle	0.8	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)	
1015020	Equine fat tissue	0.5	1.5	1.5	Recommended ^(b)	0.15	Further consideration needed ^(c)	
1015030	Equine liver	0.7	8	8	Recommended ^(b)	0.8	Further consideration needed ^(c)	
1015040	Equine kidney	0.7	8	8	Recommended ^(b)	0.15	Further consideration needed ^(c)	
1016010	Poultry muscle	0.5	1.5	1.5	Recommended ^(b)	0.07	Further consideration needed ^(c)	
1016020	Poultry fat tissue	0.2	1	1	Recommended ^(b)	0.07	Further consideration needed ^(c)	
1016030	Poultry liver	2	5	5	Recommended ^(b)	0.3	Further consideration needed ^(c)	
1020010	Cattle milk	0.6	0.8	0.05	Recommended ^(h)	0.07	Further consideration needed ^(h)	
1020020	Sheep milk	0.6	0.8	0.05	Recommended ^(h)	0.06	Further consideration needed ^(h)	
1020030	Goat milk	0.6	0.8	0.05	Recommended ^(h)	0.06	Further consideration needed ^(h)	
1020040	Horse milk	0.6	0.8	0.05	Recommended ^(h)	0.07	Further consideration needed ^(h)	
1030000	Birds eggs	1	2	2	Recommended ^(b)	0.15	Further consideration needed ^(c)	
_	Other commodities of plant and/or animal origin	See Reg. 2019/ 1791	_	-	Further consideration needed ⁽¹⁾			

MRL: maximum residue level; CXL: codex maximum residue limit.

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination H-III in Appendix E).

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination H-VII in Appendix E).

(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a chronic risk to consumers cannot be excluded considering some (Option 1)/or all additional CXLs (Option 2) (combination H-VI/VII in Appendix E).

(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower or same tentative MRL (combination F-VII in Appendix E).

(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition; CXL is higher, supported by data but a chronic risk to consumers cannot be excluded considering some (Option 1)/or all additional CXLs (Option 2) (combination F-VI/VII in Appendix E).

(f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination D-III in Appendix E).



- (g): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
- (h): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available or CXL was not considered further due to reservations raised by the EU delegation. (combination H-I in Appendix E).
- (i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).
- (j): There are no relevant authorisations or import tolerances reported at EU level; CXL is supported by data but a chronic risk to consumers cannot be excluded considering all additional CXLs (Option 2). Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-VI in Appendix E).
- (k): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
- (I): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available or CXL was not considered further due to reservations raised by the EU delegation. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
- (m): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).



Appendix C – Pesticide Residue Intake Model (PRIMo)

• PRIMo(EU Option 1)

5	*	~			FLUOPYRAM	Λ			mput	: values		
×	0	tea		LOQs (mg/kg) range	from: 0.01	to:	0.01	Details – c	hronic risk	Supplementary re	sults –	
	••е	Sd			Toxicological reference	alues		assess	ment	chronic risk assess	ment	
		fsa		ADI (mg/kg bw per da	ay): 0.012	ARfD (mg/kg bw):	0.5	Details – a	auto riele	Details – acute	winte	
urop	ean Food	Safety Authority		Source of ADI:	EFSA	Source of ARfD:	EFSA					
EFS	A PRIMo re	vision 3.1; 2019/03/19		Year of evaluation:	2013	Year of evaluation:	2013	assessmen	t/children	assessment/ad	uits	
nts:					Defendent							
					Chronic risk assessmen	ulation mode						
						JINFR Method					1 -	
T			-	No of diets exceeding	the ADI : -	-				1	Exposure MRLs set at	
1			Expsoure	Highest contributor to		2nd contributor to			3rd contributor to		the LOQ	under a
	ulated exposure		(µg/kg bw per	MS diet	Commodity/	MS diet	Commodity/		MS diet	Commodity/	(in % of ADI)) (in %
4	(% of ADI)	MS Diet NL toddler	day)	(in % of ADI)	group of commodities	(in % of ADI)	group of commodities Milk: Cattle		(in % of ADI)	group of commodities Bananas	_	<u> </u>
i i	86% 65%	NL toddler DE child	10.36 7.81	18% 21%	Apples Apples	10% 7%	Milk: Cattle Table grapes		9% 7%	Bananas Wheat		8
	50%	NL child	5.94	10%	Apples	7%	Wheat		5%	Table grapes		
	39%	GEMS/Food G07	4.67	7%	Wheat	6%	Wine grapes		3%	Celeries		
	38%	GEMS/Food G06	4.61	11%	Wheat	5%	Table grapes		4%	Tomatoes		:
	38%	IE adult	4.54	5%	Basil and edible flowers	5%	Wine grapes		4%	Wheat		
	36% 33%	GEMS/Food G11 FR child 3–15 years	4.27 3.94	7% 7%	Celeries Wheat	6% 4%	Wheat Milk: Cattle		4% 3%	Wine grapes Oranges		
	33%	GEMS/Food G08	3.92	6%	Wheat	4%	Wine grapes		2%	Lettuces		
	32%	GEMS/Food G15	3.86	7%	Wheat	4%	Wine grapes		2%	Celeries		
	32%	GEMS/Food G10	3.82	6%	Wheat	4%	Lettuces		2%	Tomatoes		:
	30%	FR toddler 2–3 years	3.55	5%	Apples	5%	Milk: Cattle		5%	Wheat		
	29% 29%	RO general SE general	3.50 3.46	8% 5%	Wheat	6% 5%	Wine grapes Lettuces		2% 3%	Apples Bananas		
	29% 29%	SE general ES child	3.46	5% 7%	Wheat	5% 5%	Lettuces		3%	Bananas Oranges		
	27%	DK child	3.22	7%	Wheat	4%	Apples		2%	Milk: Cattle		
	27%	DE women 14-50 years	3.20	4%	Apples	3%	Wheat		3%	Wine grapes		
	27%	PT general	3.20	10%	Wine grapes	6%	Wheat		2%	Apples		1
	26%	UK toddler	3.18	6%	Wheat	3%	Milk: Cattle		3%	Apples		
	25%	IT toddler	3.02	11%	Wheat	4%	Lettuces		2% 3%	Tomatoes		
	25% 24%	DE general UK infant	2.98 2.93	4% 6%	Apples Milk: Cattle	3% 4%	Wine grapes Wheat		3%	Wheat Apples		
	24%	ES adult	2.93	6% 7%	Lettuces	4%	Wheat		2%	Wine grapes		
	22%	FR adult	2.68	9%	Wine grapes	4%	Wheat		1%	Apples		
	21%	IT adult	2.55	7%	Wheat	5%	Lettuces		1%	Tomatoes		
	21%	NL general	2.55	3%	Wheat	2%	Apples		2%	Wine grapes		-
	17% 16%	FI 3 years	2.04	2% 3%	Bananas Wheat	2% 3%	Wheat Wine groups		2% 2%	Raspberries (red and yellow) Lettuces		
	16%	UK vegetarian FR infant	1.96	3%	Apples	3%	Wine grapes Milk: Cattle		2%	Lettuces Beans (with pods)		
	15%	DK adult	1.80	4%	Wine grapes	2%	Wheat		2%	Apples		
	15%	UK adult	1.76	4%	Wine grapes	3%	Wheat		1%	Lettuces		
	13%	FI 6 years	1.57	2%	Wheat	1%	Raspberries (red and yellow)		1%	Bananas		
	10% 10%	LT adult PL general	1.18 1.17	3% 3%	Apples Apples	2% 2%	Wheat Table grapes		0.8%	Lettuces Tomatoes		
	9%	Fl adult	1.17	2%	Appres Lettuces	2%	Wine grapes		1.0%	Apples		
ł	5%	IE child	0.60	2%	Wheat	0.6%	Milk: Cattle		0.6%	Apples		
				1	1	1	1		1	1	1	1



Acute risk assessment/children

Acute risk assessment/adults/general population

Details - acute risk assessment/adults

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

Results for children No. of commodities for exceeded (IESTI):	or which ARfD/ADI is			Results for adults No. of commodities exceeded (IESTI):	for which ARfD/ADI is		
IESTI				IESTI			
Highest % of		MRL/input for RA	Exposure	Highest % of		MRL/input for RA	Exp
ARfD/ADI	Commodities Lettuces	(mg/kg)	(µg/kg bw) 381	ARfD/ADI 31%	Commodities Celeries	(mg/kg) 20/9.74	(µg/
76% 73%	Celeries	15/10 20/9.74	364	24%		20/9.74	
18%	Peaches	20/9.74 1.5/0.95	364 90	24%	Lettuces Blueberries	7/4.33	
16%	Peaches	0.8/0.6	90 82	7%	Table grapes	2/1	
15%	Sweet peppers/bell peppers	2/1.23	73	4%	Wine grapes	1.5/0.95	
15%	Table grapes	2/1.23	73	4%	Chinese cabbages/pe-tsai	2/0.84	
13%	Apples	0.8/0.6	64	4%	Sweet peppers/bell peppers	2/0.84	
10%	Bananas	0.8/0.52	64 50	4%	Escaroles/broad-leaved	2/1.23	
8%	Bananas Oranges	0.8/0.52	50 42	4% 4%	Escaroles/broad-leaved Blackberries	2/0.98	
8% 8%	•	2/0.98	42 39	4% 4%	Purslanes	5/2.39 20/10	
8% 7%	Escaroles/broad-leaved Apricots	2/0.98	39	4% 4%	Lamb's lettuce/corn salads	20/10	
6%		20/10	28	4%	Chards/beet leaves	2/0.98	
5%	Lamb's lettuce/corn salads Chinese cabbages/pe-tsai	20/10 2/0.84	28 27	4% 4%	Chards/beet leaves Pears	2/0.98	
5% 5%	Roman rocket/rucola	2/0.84 20/10	27	4% 4%	Pears Peaches	1.5/0.95	
	Roman rocket/rucola		27		Globe artichokes	4/1.37	
	Divisional and						
5% Expand/collapse list		7/4.33 fD/ADI in	20	4% Results for adults		4/1.07	
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com	mmodities exceeding the AR liets			Results for adults No of processed cor	mmodities for which ARfD/ADI	1.01	
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI):	mmodities exceeding the AR liets			Results for adults No of processed cor is exceeded (IESTI)	mmodities for which ARfD/ADI		
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com	mmodities exceeding the AR liets			Results for adults No of processed cor	mmodities for which ARfD/ADI	MRL/input	
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI):	mmodities exceeding the AR liets	fD/ADI in		Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of	mmodities for which ARfD/ADI		
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI	mmodities exceeding the AR liets	fD/ADI in		Results for adults No of processed cor is exceeded (IESTI) IESTI	mmodities for which ARfD/ADI	MRL/input	
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of	mmodities exceeding the AR liets modities for which ARfD/ADI	fD/ADI in MRL/input for RA	 Exposure	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of	nmodities for which ARfD/ADI	MRL/input for RA	(µg/
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI	nmodities exceeding the AR liets modities for which ARfD/ADI Processed commodities	fD/ADI in MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARfD/ADI	nmodities for which ARfD/ADI	MRL/input for RA (mg/kg)	(µg/
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARFD/ADI 13%	mmodities exceeding the AR liets modities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end	fD/ADI in MRL/input for RA (mg/kg) 2/0.98	Exposure (µg/kg bw) 65	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66%	nmodities for which ARfD/ADI	MRL/input for RA (mg/kg) 20/9.74	(µg)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARTD/ADI 13% 6%	mmodities exceeding the AR liets modities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98	Exposure (µg/kg bw) 65 30	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARID/ADI 66% 8%	nmodities for which ARfD/ADI Processed commodities Celeries/boiled Purslanes/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10	(µg)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARID/ADI 13% 6% 5%	modities exceeding the AR liets modities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95	 Exposure (µg/kg bw) 65 30 25	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARfD/ADI 66% 8% 4%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98	(µg/
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARTD/ADI 13% 6% 5% 4%	mmodities exceeding the AR lifets modities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2.0.98 1.5/0.95 4/0.78	 Exposure (µg/kg bw) 65 30 25 22	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98	(µg
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARtD/ADI 13% 6% 5% 4%		fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65	 Exposure (µg/kg bw) 65 30 25 22 21	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARID/ADI 66% 8% 4% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78	(µg/)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI 13% 6% 5% 4% 4%	mmodities exceeding the AR liets modifies for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35	 Exposure (µg/kg bw) 65 30 25 22 21 20	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARfD/ADI 66% 8% 4% 2% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98	(µg/)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 3%	modities exceeding the AR liets modities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaved Peaches/anned/boiled Peaches/anned/boiled Leeks/boiled Leeks/boiled	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98	Exposure (µg/kg bw) 65 30 25 22 21 20 14	Results for adults No of processed cori is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 2%	Processed commodities Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozer; boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95	(µg/ :
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI 13% 6% 5% 4% 4% 4% 4% 3%	mmodities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98 5/1.12	Exposure (µg/kg bw) 65 30 25 22 21 20 14 13	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Purslanes/boiled Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78	, (bh) ;
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI 13% 6% 5% 4% 4% 4% 4% 3% 3%	modities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98 2/1.12 0.3/0.14	 Exposure (µg/kg bw) 65 30 25 22 21 20 14 13 13	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3	(µg
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARID/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 2%	mmodities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 2/0.98 3/1.65 0.870.35 2/0.98 5/1.12 0.3/0.14 4/0.78	Exposure (µg/kg bw) 65 30 25 22 21 20 14 13 13 12	Results for adults No of processed cor is exceeded (IESTI) IESTI Highest % of ARfD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1% 1%	Processed commodities Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12	(<u>1</u> 91)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 3% 2%	mmodities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14	Exposure (µg/kg bw) 65 30 25 21 20 14 13 13 12 11	Highest % of ARD/ADI Highest % of ARD/ADI 66% 8% 4% 2% 2% 2% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67	(µ <u>g</u>)
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARfD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 2% 2%	modities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14 0.4/0.14	 Exposure (µg/kg bw) 65 30 25 22 21 20 14 13 13 12 11 11	Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled Peas (with pods)/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35	(<u>שן)</u>
5% Expand/collapse list Total number of cor children and adult d (IESTI calculation) Results for children No of processed com is exceeded (IESTI): IESTI Highest % of ARTO/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 2% 2%	mmodities exceeding the AR liets	fD/ADI in MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14 0.4/0.12 0.6/0.3	Exposure (µg/kg bw) 65 30 25 22 21 20 14 13 13 12 11 11 11	Highest % of ARtD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 1% 1% 1% 1% 1% 0.9%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled	MRL/input for RA (mg/kg) 20/9.74 20/10 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35 3/1.36	Ехц (µg/

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.



• PRIMo(EU Option 2 and CXL2 Option)

-	****	fsa			FLUOPYRA	м			Input	values		
	-	faa		LOQs (mg/kg) range		to:	0.01	Details – c	hronic risk	Supplementary res	ults –	
	* • e	Sdm			Toxicological reference	values		assess	sment	chronic risk assess	ment	
				ADI (mg/kg bw per da	y): 0.012	ARfD (mg/kg bw):	0.5	D - t - ile		Dataile and	-tali	
E	uropean Food	Safety Authority		Source of ADI:	EFSA	Source of ARfD:	EFSA	assessmer	acute risk ut/children	Details – acute assessment/adu		
		evision 3.1; 2019/03/19		Year of evaluation:	2013	Year of evaluation:	2013	ussessiner	it, children	ussessment/uu	110	
ommei	nts:											
					Norm	al mode						
					Chronic risk assessme	nt: JMPR method	ology (IEDI/TMDI)					
				No of diets exceeding	the ADI :							e resulting from
	Calculated exposu (% of ADI)	re 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	MRLs set at the LOQ (in % of ADI)	commodities under assess (in % of AL
	100%	NL toddler	12.00	21%	Milk: Cattle	18%	Apples		9%	Bananas		100%
	69% 57% 42%	DE child NL child GEMS/Food G07	8.27 6.81 5.01	21% 10% 7%	Apples Apples Wheat	7% 9% 6%	Milk: Cattle Milk: Cattle Wine grapes		7% 7% 3%	Table grapes Wheat Celeries		69% 57% 42%
	40%	IE adult	4.86	5% 11%	Basil and edible flowers Wheat	5% 5%	Wine grapes		4% 4%	Wheat		40% 40%
	40% 39%	GEMS/Food G06 FR child 3–15 years	4.81 4.68	11%	Wheat Milk: Cattle	5% 7%	Table grapes Wheat			Tomatoes Oranges		40%
(in o	38%	GEMS/Food G11	4.59	7%	Celeries	6%	Wheat		4%	Wine grapes		38%
npti	37% 35%	FR toddler 2–3 years GEMS/Eood G08	4.41 4.19	10% 6%	Milk: Cattle Wheat	5% 4%	Apples		5% 2%	Wheat Lettuces		37% 35%
Jsur	35%	GEMS/Food G08 GEMS/Food G15	4.19		Wheat	4% 4%	Wine grapes Wine grapes		2%	Lettuces Milk: Cattle		35%
food consumption)	34%	GEMS/Food G10	4.10	6%	Wheat	4%	Lettuces		2%	Milk: Cattle		34%
bo	34%	SE general	4.09		Wheat	5%	Lettuces		4%	Milk: Cattle		34%
e P	33%	UK infant	4.01 3.89	14% 8%	Milk: Cattle Wheat	4%	Wheat		3%	Apples Milk: Cattle		33% 32%
average 1	32% 32%	RO general ES child	3.89	8% 7%	Wheat	6% 5%	Wine grapes Lettuces		4% 4%	Milk: Cattle		32%
ave	32%	UK toddler	3.86	7%	Milk: Cattle	6%	Wheat		3%	Apples		32 %
5	30%	DK child	3.66	7%	Wheat	4%	Milk: Cattle		4%	Apples		30%
TMDI/NEDI/IEDI calculation (based	30%	DE women 14–50 years	3.59	4%	Milk: Cattle	4%	Apples		3%	Wheat		30%
g)	28% 28%	DE general PT general	3.38 3.32	4% 10%	Milk: Cattle	4% 6%	Apples Wheat		3% 2%	Wine grapes Apples		28% 28%
5	25%	IT toddler	3.04		Wine grapes Wheat	6% 4%	Lettuces		2%	Tomatoes		28%
ulat	25%	ES adult	2.99	7%	Lettuces	4%	Wheat		2%	Milk: Cattle		259
alo	24%	NL general	2.91	3%	Wheat	3%	Milk: Cattle		2%	Apples		249
5	24%	FR adult	2.86		Wine grapes	4%	Wheat		2%	Milk: Cattle		249
Ę	21%	IT adult	2.56	7%	Wheat	5%	Lettuces		1%	Tomatoes		219
Į.	19% 18%	FR infant FI 3 years	2.33 2.15	6% 2%	Milk: Cattle Bananas	3% 2%	Apples Wheat		2% 2%	Beans (with pods) Raspberries (red and yellow)		199 189
	17%	UK vegetarian	2.15		Wheat	2%	Wine grapes		2%	Lettuces		107
	17%	DK adult	2.00		Wine grapes	2%	Milk: Cattle		2%	Wheat		17
	16%	UK adult	1.92	4%	Wine grapes	3%	Wheat		1%	Lettuces		16
	14%	FI 6 years	1.66	2%	Wheat	1%	Raspberries (red and yellow)		1%	Bananas		149
	11% 10%	LT adult PL general	1.36 1.25	3% 3%	Apples Apples	2% 2%	Wheat Table grapes		1% 1%	Milk: Cattle Tomatoes		119
	10%	PL general Fl adult	1.25	3%	Apples Lettuces	2%	Vine grapes		1%	Apples		109
	6%	IE child	0.71	2%	Wheat	1%	Milk: Cattle		0.5%	Apples		6%
	Conclusion:				1						-1	
		 term dietary intake (TMDI/NEDI/IEDI) term dietary intake (TMDI/NEDI/IEDI) term dietary intake (TMDI/NEDI/IEDI) 		boolth concorn								
	The long-term intak	LE OF TESIGUES OF FLOOPTRAM IS UNIT	very to present a public	meann concern.								
	1											



Acute risk assessment/children

Acute risk assessment/adults/general population

Details - acute risk assessment/adults

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

exceeded (IESTI):	for which ARfD/ADI is			exceeded (IESTI):	for which ARfD/ADI is		
IESTI				IESTI			
		MRL/input	_			MRL/input	_
Highest % of	–	for RA	Exposure	Highest % of		for RA	Ex
ARfD/ADI 76%	Commodities Lettuces	(mg/kg) 15/10	(µg/kg bw) 381	ARfD/ADI 31%	Commodities Celeries	(mg/kg) 20/9.74	(µg
76%	Celeries		364	31% 24%	Lettuces		
18%	Peaches	20/9.74 1.5/0.95	364 90	24% 8%	Blueberries	15/10 7/4.33	
17%	Pears	0.8/0.6	83	7%	Table grapes	2/1	
15%	Sweet peppers/bell peppers	2/1.23	73	4%	Wine grapes	1.5/0.95	
15%	Table grapes	2/1.23	73	4%	Chinese cabbages/pe-tsai	2/0.84	
13%	Apples	0.8/0.6	65	4%	Sweet peppers/bell peppers	2/1.23	
10%	Bananas	0.8/0.52	50	4%	Escaroles/broad-leaved	2/0.98	
8%	Oranges	0.5/0.32	42	4%	Blackberries	5/2.39	
8%	Escaroles/broad-leaved	2/0.98	39	4%	Purslanes	20/10	
7%	Apricots	1.5/0.95	33	4%	Lamb's lettuce/corn salads	20/10	
6%	Lamb's lettuce/corn salads	20/10	28	4%	Chards/beet leaves	2/0.98	
5%	Chinese cabbages/pe-tsai	2/0.84	27	4%	Pears	0.8/0.6	
5%	Roman rocket/rucola	20/10	27	4%	Peaches	1.5/0.95	
	Blueberries	7/4.33	26	4%	Globe artichokes	4/1.37	
5% Expand/collapse list Total number of co children and adult (IESTI calculation) Results for childre No of processed co	mmodities exceeding the AR diets n mmodities for which ARfD/ADI	fD/ADI in			mmodities for which ARfD/ADI		
5% Expand/collapse list Total number of co children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI)	mmodities exceeding the AR diets n mmodities for which ARfD/ADI	fD/ADI in		No of processed con is exceeded (IESTI)			
5% Expand/collapse list Total number of co children and adult (IESTI calculation) Results for childre No of processed co	mmodities exceeding the AR diets n mmodities for which ARfD/ADI			No of processed co		MDI /input	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI	mmodities exceeding the AR diets n mmodities for which ARfD/ADI	MRL/input	 Evnosure	No of processed co is exceeded (IESTI) IESTI		MRL/input	Fr
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of	mmodities exceeding the AR diets n mmodities for which ARfD/ADI	MRL/input for RA	Exposure (ug/kg bw)	No of processed cou is exceeded (IESTI) IESTI Highest % of	:	for RA	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARtD/ADI	pommodities exceeding the AR diets in mmodities for which ARfD/ADI : Processed commodities	MRL/input for RA (mg/kg)	(µg/kg bw)	No of processed cou is exceeded (IESTI) IESTI Highest % of ARfD/ADI	Processed commodities	for RA (mg/kg)	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13%	pommodities exceeding the AR diets n mmodities for which ARfD/ADI : Processed commodities Escaroles/broad-leaved end	MRL/input for RA (mg/kg) 2/0.98	(µg/kg bw) 65	No of processed coi is exceeded (IESTI) IESTI Highest % of ARfD/ADI 66%	Processed commodities	for RA (mg/kg) 20/9.74	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARtD/ADI	pommodities exceeding the AR diets in mmodities for which ARfD/ADI : Processed commodities	MRL/input for RA (mg/kg)	(µg/kg bw)	No of processed cou is exceeded (IESTI) IESTI Highest % of ARfD/ADI	Processed commodities	for RA (mg/kg)	
5% Expand/collapse lisis Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6%	mmodities exceeding the AR diets n mmodities for which ARfD/ADI : Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned	MRL/input for RA (mg/kg) 2/0.98 2/0.98	(μg/kg bw) 65 30	No of processed coi is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8%	Processed commodities Celeries/boiled Purslanes/boiled	for RA (mg/kg) 20/9.74 20/10	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARfD/ADI 13% 6% 5%	mmodities exceeding the AR diets mmmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95	(µg/kg bw) 65 30 25	No of processed co is exceeded (IESTI) IESTI Highest % of ARID/ADI 66% 8% 4%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved	for RA (mg/kg) 20/9.74 20/10 2/0.98	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4%	pmmodities exceeding the AR diets in mmodities for which ARfD/ADI : Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78	(μg/kg bw) 65 30 25 22	No of processed col is exceeded (IESTI) IESTI Highest % of ARtD/ADI 66% 8% 4% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98	
5% Expand/collapse lists Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4%	mmodities exceeding the AR diets n mmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65	(μg/kg bw) 65 30 25 22 21	No of processed col is exceeded (IESTI) IESTI Highest % of ARtD/ADI 66% 8% 4% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4%	mmodities exceeding the AR diets nmmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35	(μg/kg bw) 65 30 25 22 21 20	No of processed col is exceeded (IESTI) IESTI Highest % of ARID/ADI 66% 8% 4% 2% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98	
5% Expand/collapse lists Total number of co- children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARID/ADI 13% 6% 5% 4% 4% 4% 4% 3%	processed commodities Processed commodities Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.35 0.5/0.23	(μg/kg bw) 65 30 25 22 21 20 18 14 13	No of processed col is exceeded (IESTI) Highest % of ARID/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95	
5% Expand/collapse list Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3%	promodities exceeding the AR diets n mmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 0.8/0.35 0.8/0.35 0.5/0.23 2/0.98 5/1.12 2/0.98	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13	No of processed co. is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12	
5% Expand/collapse lists Total number of cc children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 3% 3% 3% 3% 2%	mmodities exceeding the AR diets n mmodities for which ARfD/ADI : Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 4/0.78 3/1.65 0.8/0.32 2/0.98 5/1.12 0.3/0.14 4/0.78	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13 13 12	No of processed co is exceeded (IESTI) IESTI Highest % of ARtD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67	
5% Expand/collapse lists Total number of co- children and adult (IESTI calculation) IESTI Highest % of ARIDIADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 2%	mmodities exceeding the AR diets mmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice	MRL/input for RA (mg/kg) 2/0.98 2/0.98 3/1.65 0.5/0.23 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.12	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13 13 12 11	No of processed col is exceeded (IESTI) Highest % of ARID/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 4/0.78 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35	Ex (µg
5% Expand/collapse lisis Total number of cc children and adult (IESTI calculation) Results for children No of processed co. is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 4% 3% 3% 3% 2% 2%	mmodities exceeding the AR diets nmmodities for which ARfD/ADI Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Pumpkins/boiled Courgettes/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78 0.3/0.14	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13 12 11 11	No of processed co. is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled Cauliflowers/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35 0.3/0.14	
5% Expand/collapse lisis Total number of cc children and adult (IESTI calculation) Results for children No of processed col is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 3% 3% 3% 3% 2% 2% 2%	mmodities exceeding the AR diets n mmodities for which ARfD/ADI Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Pumpkins/boiled Courgettes/boiled Cauliflowers/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 2/0.95 3/1.65 0.8/0.32 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.78 0.4/0.12 0.6/0.23	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13 12 11 9.7	No of processed co is exceeded (IESTI) IESTI Highest % of ARtD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 1% 1% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled Cauliflowers/boiled Broccoli/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35 0.3/0.14 0.5/0.23	
5% Expand/collapse lisis Total number of cc children and adult (IESTI calculation) Results for children No of processed co. is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 6% 5% 4% 4% 4% 4% 4% 4% 3% 3% 3% 2% 2%	mmodities exceeding the AR diets mmodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Chards/beet leaves/boiled Peaches/canned Currants (red, black and wh Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Pumpkins/boiled Cauliflowers/boiled Turnips/boiled	MRL/input for RA (mg/kg) 2/0.98 2/0.98 1.5/0.95 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78 0.3/0.14	(µg/kg bw) 65 30 25 22 21 20 18 14 13 13 12 11 11	No of processed co. is exceeded (IESTI) IESTI Highest % of ARTD/ADI 66% 8% 4% 2% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Chards/beet leaves/boiled Currants (red, black and Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Pumpkins/boiled Wine grapes/wine Leeks/boiled Cauliflowers/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 2/0.98 4/0.78 2/0.98 1.5/0.95 4/0.78 0.6/0.3 0.4/0.12 1.5/0.67 0.8/0.35 0.3/0.14	



• PRIMo(CXL1 Option 1)

5	***	~			FL	.UOPYRAN	1				: values		
	×. 0	fsa		LOQs (mg/kg) range		0.01	to:	0.01	Details – cł		Supplementary re		
	E					ogical reference v			assessi	ment	chronic risk assess	ment	
с.	uropoon Food	Safety Authority		ADI (mg/kg bw per da	y):	0.012	ARfD (mg/kg bw):	0.5	Details – a	icute risk	Details – acute	risk	
		, ,		Source of ADI:		EFSA	Source of ARfD:	EFSA	assessment		assessment/ad		
men		vision 3.1; 2019/03/19		Year of evaluation:		2013	Year of evaluation:	2013					
men	ns:												
						Norma	l mode						
					Chronie	risk assessment	: JMPR methodo	logy (IEDI/TMDI)					
				No of diets exceeding	the ADI :		1				-		resulting from
			E.e.e.	I link and an adult of the			Ond contribut			Ord a stability to 1		MRLs set at the LOQ	commodities under assessr
	Calculated exposure	e	Expsoure (µg/kg bw per	Highest contributor to MS diet	Commodity/		2nd contributor to MS diet	Commodity/		3rd contributor to MS diet	Commodity/	(in % of ADI)	(in % of AD
	(% of ADI)	MS Diet	day)	(in % of ADI)	group of commodities		(in % of ADI)	group of commodities		(in % of ADI)	group of commodities		
	110%	NL toddler	13.19	18%	Apples		10%	Milk: Cattle		9%	Bananas		110%
	76% 68%	DE child NL child	9.11 8.19	21% 10%	Apples Apples		7% 7%	Table grapes Wheat		7% 5%	Wheat Table grapes		76% 68%
	60%	GEMS/Food G07	7.25	7%	Wine grapes		7%	Wheat		5%	Swine: Muscle/meat		60%
	57%	DK child	6.89	9%	Swine: Muscle/meat		9%	Rye		7%	Wheat		57%
	54%	IE adult	6.51	7%	Sheep: Liver		6%	Wine grapes		5%	Basil and edible flowers		54%
	54%	FR child 3–15 years	6.49	7%	Wheat		6%	Bovine: Muscle/meat		6%	Swine: Muscle/meat		54%
	51%	SE general	6.09	19%	Bovine: Muscle/meat		5%	Wheat		5%	Lettuces		51%
	51%	GEMS/Food G08	6.07	8%	Swine: Muscle/meat		6%	Wheat		5%	Wine grapes		51%
	50%	GEMS/Food G11	6.05	7%	Celeries		6%	Wheat		5%	Swine: Muscle/meat		50%
	50%	GEMS/Food G15	6.01	7%	Wheat		6%	Swine: Muscle/meat		5%	Wine grapes		50%
	48% 47%	ES child	5.72	7%	Wheat Wheat		6%	Bovine: Muscle/meat Lettuces		5%	Swine: Muscle/meat Bovine: Muscle/meat		48% 47%
	47%	GEMS/Food G10 FR toddler 2–3 years	5.61 5.47	6% 5%	Apples		4% 5%	Lettuces Bovine: Muscle/meat		4% 5%	Bovine: Muscle/meat Swine: Muscle/meat		47%
	40%	GEMS/Food G06	5.31	11%	Wheat		5%	Table grapes		4%	Tomatoes		40%
	44%	RO general	4.82	8%	Wine grapes		8%	Wheat		4 % 5%	Swine: Muscle/meat		44 %
	39%	UK infant	4.67	6%	Milk: Cattle		5%	Bovine: Muscle/meat		5%	Eggs: Chicken		39%
	38%	UK toddler	4.57	6%	Wheat		5%	Bovine: Muscle/meat		3%	Milk: Cattle		38%
	36%	DE women 14-50 years	4.38	4%	Apples		4%	Wine grapes		4%	Swine: Muscle/meat		36%
	36%	DE general	4.33	5%	Swine: Muscle/meat		4%	Apples		4%	Wine grapes		36%
	34%	ES adult	4.09	7%	Lettuces		4%	Wheat		3%	Bovine: Muscle/meat		34%
	33%	FR adult	4.00	11%	Wine grapes		4%	Wheat		3%	Swine: Muscle/meat		33%
	33%	NL general	3.96	4%	Swine: Muscle/meat		3%	Bovine: Muscle/meat		3%	Wheat		33%
	30% 27%	PT general DK adult	3.59 3.28	12% 5%	Wine grapes Wine grapes		6% 4%	Wheat Swine: Muscle/meat		2% 2%	Apples Bovine: Muscle/meat		30% 27%
	26%	IT toddler	3.07	5%	Wheat		4%	Leftuces		2%	Tomatoes		21%
	21%	IT adult	2.58	7%	Wheat		5%	Lettuces		1%	Tomatoes		20%
	21%	UK adult	2.55	5%	Wine grapes		3%	Bovine: Muscle/meat		3%	Wheat		21%
	20%	FR infant	2.44	3%	Apples		3%	Milk: Cattle		2%	Beans (with pods)		20%
	20%	LT adult	2.41	4%	Swine: Muscle/meat		3%	Apples		2%	Rye		20%
	19%	UK vegetarian	2.33	4%	Wine grapes		3%	Wheat		2%	Lettuces		19%
	19%	FI 3 years	2.28	2%	Bananas		2%	Wheat		2%	Raspberries (red and yellow)		19%
	15%	FI 6 years	1.75	2% 2%	Wheat		1% 1%	Raspberries (red and yellow)		1%	Bananas		15% 11%
	11% 10%	Fl adult PL general	1.33 1.23	2%	Lettuces Apples		1%	Wine grapes Table grapes		1% 1%	Rye Tomatoes		11%
	8%	IE child	0.93	2%	Wheat		0.7%	Swine: Fat tissue		0.7%	Swine: Muscle/meat		8%
-	Conclusion:							1			1		L



Acute risk assessment/children

Acute risk assessment/adults/general population

Details - acute risk assessment/adults

60/0.1

3.6

Hops/beer

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

		r which ARfD/ADI is			Results for adults No. of commodities t exceeded (IESTI):	for which ARfD/ADI is		
IESTI					IESTI			
			MRL/input				MRL/input	
	est % of		for RA	Exposure	Highest % of		for RA	Exposur
ARf	D/ADI	Commodities	(mg/kg)	(µg/kg bw)	ARfD/ADI	Commodities	(mg/kg)	(µg/kg b
7	6%	Lettuces	15/10	381	31%	Celeries	20/9.74	156
7	3%	Celeries	20/9.74	364	24%	Lettuces	15/10	121
2	3%	Spring onions/green onions	15/7.3	115	8%	Blueberries	7/4.33	39
1	8%	Peaches	1.5/0.95	90	7%	Table grapes	2/1	34
1	7%	Sweet peppers/bell peppers	3/1.4	83	7%	Spring onions/green onions	15/7.3	33
1	6%	Pears	0.8/0.6	82	6%	Currants (red, black and	7/4.9	32
1	5%	Table grapes	2/1	73	6%	Bovine: Liver	8/7.4	30
1		Apples	0.8/0.6	64	5%	Wine grapes	2/1	24
		Bovine: Liver	8/7.4	60	5%	Sweet peppers/bell peppers	3/1.4	23
		Bananas	0.8/0.52	50	4%	Gooseberries (green, red	7/4.9	22
		Oranges	0.6/0.37	49	4%	Chinese cabbages/pe-tsai	2/0.84	21
		Escaroles/broad-leaved	2/0.98	39	4%	Sheep: Liver	8/7.4	21
		Currants (red, black and	7/4.9	39	4%	Escaroles/broad-leaved	2/0.98	20
		Mangoes	1/0.48	38	4%	Blackberries	5/2.39	20
		Apricots	1.5/0.95	33	4%	Purslanes	20/10	19
	ollapse list	Apricots	1.5/0.95	33	4%	Pursianes	20/10	19
children a	and adult die	modities exceeding the AR ets	ID/ADI in					
children a (IESTI cal	and adult die Iculation) or children	ets	ID/ADI in		Results for adults			
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children a (IESTI cal Results for No of proo is exceede	and adult die Iculation) or children	ets	D/ADI in		No of processed con is exceeded (IESTI):	modities for which ARfD/ADI		
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children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf	and adult die Iculation) or children cessed comm ed (IESTI): est % of D/ADI	nodities for which ARfD/ADI	MRL/input for RA (mg/kg)	(µg/kg bw)	No of processed con is exceeded (IESTI): IESTI Highest % of ARfD/ADI	Processed commodities	for RA (mg/kg)	(µg/kg l
children a (IESTI cal Results fr No of proc is exceede IESTI Highe ARf	and adult die lculation) or children cessed comm ed (IESTI): est % of D/ADI 3%	ets nodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end	MRL/input for RA (mg/kg) 2/0.98	(µg/kg bw) 65	No of processed con is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66%	Processed commodities Celeries/boiled	for RA (mg/kg) 20/9.74	(µg/kg b 329
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf	and adult die lculation) or children cessed comm ed (IESTI): est % of D/ADI 3% 7%	ets nodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Currants (red, black and wh	MRL/input for RA (mg/kg) 2/0.98 7/1.15	(µg/kg bw) 65 33	No of processed con is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66% 8%	Processed commodities Celeries/boiled Purslanes/boiled	for RA (mg/kg) 20/9.74 20/10	(µg/kg t 329 41
children a (IESTI cal No of proc is exceeded IESTI Highe ARf	and adult die lculation) or children cessed comm ad (IESTI): ast % of D/ADI 3% 3% 5%	ets nodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98	(µg/kg bw) 65 33 30	No of processed con is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66% 8% 4%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved	for RA (mg/kg) 20/9.74 20/10 2/0.98	(µg/kg t 329 41 20
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf	and adult die lculation) or children cessed comm ed (IESTI): ast % of D/ADI 3% 7% 5%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95	(μg/kg bw) 65 33 30 25	No of processed con is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66% 8% 4% 3%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15	(μg/kg t 329 41 20 15
children a (IESTI cal No of pro- is exceeded IESTI Highe ARf	and adult die lculation) or children cessed comm ad (IESTI): ast % of D/ADI 3% 7% 5% 5% 4%	ets nodities for which ARfD/ADI Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 3/1.65	(µg/kg bw) 65 33 30 25 21	No of processed con is exceeded (IESTI): Highest % of ARID/ADI 66% 8% 4% 3% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98	(μg/kg b 329 41 20 15 12
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf	and adult die lculation) or children cessed commed (IESTI): est % of D/ADI 3% 7% 3% 5% 5% 4%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 3/1.65 0.8/0.35	(µg/kg bw) 65 33 30 25 21 20	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98	(µg/kg t 329 41 20 15 12 8.1
children a (IESTI cal No of proc is exceeded IESTI Highe ARf 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6 6	and adult die culation or children zessed comm ad (IESTI): bst % of D/ADI 3% 7% 5% 4% 5% 4% 5%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 3/1.65 0.8/0.35 2/0.98	(μg/kg bw) 65 33 30 25 21 20 14	No of processed con is exceeded (IESTI): IESTI Highest % of ARIDIADI 66% 8% 4% 3% 2% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95	(µg/kg t 329 41 20 15 12 8.1 7.8
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf 1 7 6 8 8 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	and adult die lculation) or children zessed comm ad (IESTI): b D/ADI 3% 7% 5% 5% 4% 4% 4% 4% 4% 4% 4% 3%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled Raspberries/juice	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 0.8/0.35 2/0.98 5/1.12	(μg/kg bw) 65 33 30 25 21 20 14 13	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78	(µg/kg t 329 41 20 15 12 8.1 7.8 7.2
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARR	and adult die culation) or children ressed comme ed (IESTI): st % of D/ADI S% 7% 3% 7% 3% 7% 3% 4% 4% 3% 3%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.98 1.5/0.95 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14	(µg/kg bw) 65 33 30 25 21 20 14 13 13	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78 0.6/0.3	(µg/kg t 329 41 20 15 12 8.1 7.8 7.2 6.9
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children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARf	and adult die culation or children cessed comm ad (IESTI): bst % of D/ADI 3% 7% 3% 3% 3% 4% 4% 4% 4% 3% 3% 3% 3% 3% 3% 3% 3% 3% 3% 3% 3% 3%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods/boiled Leeks/boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Broccoli/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.95 3/1.65 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78	(µg/kg bw) 65 33 30 25 21 20 14 13 13 12 11	No of processed con is exceeded (IESTI): Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/rozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12	(μg/kg b 329 41 20 15 12 8.1 7.8 7.2 6.9 6.7 6.6
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARR	and adult die culation) or children ressed comm ad (IESTI): stf % of D/ADI s% f% f% f% f% f% f% f% f% f%	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled Elderberries/juice Broccoil/boiled Pumpkins/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 2/0.98 5/1.12 2/0.98 5/1.12 2/0.98 5/1.12 2/0.98 5/1.12	(µg/kg bw) 65 33 30 25 21 20 14 13 13 12 11 11	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.98 1.5/0.98 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35	41 20 15 12 8.1 7.8 7.2 6.9 6.7 6.6 6.1
children a (IESTI cal Results fr No of proc is exceeded IESTI Highe ARR 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	and adult die culation) or children 2005 childre	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Broccoli/boiled Elderberieis/juice Broccoli/boiled Courgettes/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.15 0.8/0.35 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.12 0.6/0.3	(µg/kg bw) 65 33 25 21 20 14 13 13 12 11 11 11	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 1% 1% 1% 1% 1% 1% 1% 0.9%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled Peas (with pods)/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35 3/1.36	(µg/kg t 329 41 20 15 12 8.1 7.8 7.2 6.9 6.9 6.6 6.6 6.1 4.7
children a (IESTI cal No of proc is exceeded IESTI Highe ARf	and adult die culation) or children cessed comm ad (IESTI): st % of D/ADI 3% 7% 3% 3% 3% 3% 2% 2% 2% 2	Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled Elderberries/juice Broccoil/boiled Pumpkins/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 2/0.98 5/1.12 2/0.98 5/1.12 2/0.98 5/1.12 2/0.98 5/1.12	(µg/kg bw) 65 33 30 25 21 20 14 13 13 12 11 11	No of processed con is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.98 1.5/0.98 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35	(μg/kg t 329 41 20 15 12 8.1 7.2 6.9 6.7 6.6 6.1

Conclusion:

2%

Expand/collapse list

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.

0.15/0.08

0.7%

Potatoes/fried



• PRIMo(CXL1 Option 2)

1	*	-			FL	UOPYRAN					: values	$ \rightarrow $	
1	* ^	tea		LOQs (mg/kg) range	from:	0.01	to:	1.5	Details – c	hronic risk	Supplementary re	sults –	
	* • -	Sdm			Toxicolo	gical reference v	alues		assess	ment	chronic risk asses	sment	
	-	fsa		ADI (mg/kg b per day):	0.012	ARfD (mg/kg bw):	0.5					
Eι	Jropean Food	Safety Authority		Source of ADI:		EFSA	Source of ARfD:	EFSA	Details – a		Details – acute		
	FESA PRIMo re	vision 3.1; 2019/03/19		Year of evaluation:		2013	Year of evaluation:	2013	assessmen	t/children	assessment/ad	ults	
nent													
						Norma	I mode						
					Chronic			ology (IEDI/TMDI)					
				No of diets exceeding			1					Exposure	resulting fro
Т												MRLs set at	commodities
			Expsoure	Highest contributor to			2nd contributor to			3rd contributor to		the LOQ (in % of ADI)	under assess (in % of Al
1	Calculated exposur (% of ADI)	MS Diet	(µg/kg bw per day)	MS diet (in % of ADI)	Commodity/ group of commodities		MS diet (in % of ADI)	Commodity/ group of commodities		MS diet (in % of ADI)	Commodity/ group of commodities	(III % OF ADI)	
+	(% of ADI) 128%	NS Diet NL toddler	day) 15.39	(in % of ADI) 20%	group of commodities Milk: Cattle		(in % of ADI) 18%	Apples		(in % of ADI) 9%	group of commodities Bananas		128%
	83%	DE child	9.96	21%	Apples		7%	Table grapes		7%	Wheat		83%
	75%	NL child	8.96	10%	Apples		8%	Milk: Cattle		7%	Wheat		75%
	66%	GEMS/Food G07	7.96	7%	Wine grapes		7%	Wheat		5%	Swine: Muscle/meat		66%
	65%	GEMS/Food G06	7.75	19%	Rice		11%	Wheat		5%	Table grapes		65%
	64%	GEMS/Food G10	7.66	16%	Rice		6%	Wheat		4%	Lettuces		64%
	64%	FR child 3–15 years	7.65	8%	Milk: Cattle		7%	Wheat		6%	Bovine: Muscle/meat		64%
	63% 59%	DK child	7.61 7.09	9% 7%	Swine: Muscle/meat		9% 6%	Rye		7% 5%	Wheat Basil and edible flowers		63% 59%
	59%	IE adult SE general	7.09	7% 19%	Sheep: Liver Bovine: Muscle/meat		6% 5%	Wine grapes Wheat		5% 5%	Basil and edible flowers Lettuces		59%
	58%	FR toddler 2–3 years	7.00	10%	Milk: Cattle		7%	Rice		5%	Apples		58%
	56%	ES child	6.70	7%	Wheat		6%	Rice		6%	Apples Bovine: Muscle/meat		56%
	56%	GEMS/Food G15	6.69	7%	Wheat		6%	Swine: Muscle/meat		5%	Wine grapes		56%
	55%	GEMS/Food G11	6.66	7%	Celeries		6%	Wheat		5%	Swine: Muscle/meat		55%
	55%	GEMS/Food G08	6.65	8%	Swine: Muscle/meat		6%	Wheat		5%	Wine grapes		55%
	54%	UK infant	6.43	13%	Milk: Cattle		8%	Rice		5%	Bovine: Muscle/meat		54%
	49%	UK toddler	5.87	7%	Rice		7%	Milk: Cattle		6%	Wheat		49%
	46%	RO general	5.49	8%	Wine grapes		8%	Wheat		5%	Swine: Muscle/meat		46%
	40%	PT general	4.80	12%	Wine grapes		10%	Rice		6%	Wheat		40%
	39% 38%	DE women 14-50 years	4.65	4%	Apples Swine: Muscle/meat		4%	Milk: Cattle Milk: Cattle		4%	Wine grapes		39% 38%
	/-	DE general	4.61	5% 7%			4% 4%	Milk: Cattle Wheat		4% 3%	Apples		
1	38% 36%	ES adult NL general	4.56 4.36	4%	Lettuces Swine: Muscle/meat		4% 3%	Wheat Bovine: Muscle/meat		3%	Bovine: Muscle/meat Wheat		38% 36%
	36%	FR adult	4.35	4%	Wine grapes		3% 4%	Wheat		3%	Swine: Muscle/meat		36%
I	29%	DK adult	3.53	5%	Wine grapes		4%	Swine: Muscle/meat		2%	Bovine: Muscle/meat		29%
	28%	IT toddler	3.37	11%	Wheat		4%	Lettuces		2%	Rice		28%
I	26%	UK adult	3.17	5%	Wine grapes		5%	Rice		3%	Bovine: Muscle/meat		26%
I	26%	FI 3 years	3.16	7%	Rice		2%	Bananas		2%	Wheat		26%
I	25%	UK vegetarian	2.99	5%	Rice		4%	Wine grapes		3%	Wheat		25%
I	24%	FR infant	2.92	6%	Milk: Cattle		3%	Apples		2%	Beans (with pods)		24%
I	24%	IT adult	2.86	7%	Wheat		5%	Lettuces		2%	Rice		24%
1	23% 20%	LT adult	2.82 2.42	4% 5%	Swine: Muscle/meat Rice		3%	Apples Wheat		3% 1%	Rice		23% 20%
	20% 13%	FI 6 years FI adult	2.42	5% 2%	Rice Lettuces		2% 2%	Wheat Rice		1% 1%	Raspberries (red and yellow) Wine grapes		20%
	12%	IE child	1.46	4%	Rice		2%	Wheat		1%	Milk: Cattle		13%
	11%	PL general	1.27	3%	Apples		2%	Table grapes		1%	Tomatoes		11%
\pm	Conclusion:						1	I		1			
		I/NEDI/IEDI was in the range of 0 – 1											



Acute risk assessment/children

Details - acute risk assessment/children

Acute risk assessment/adults/general population

Details - acute risk assessment/adults

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

Results for children No. of commodities exceeded (IESTI):	en for which ARfD/ADI is			Results for adults No. of commodities exceeded (IESTI):	for which ARfD/ADI is		
IESTI				IESTI			
-		MRL/input				MRL/input	
Highest % of		for RA	Exposure	Highest % of		for RA	Exposu
ARfD/ADI	Commodities	(mg/kg)	(µg/kg bw)	ARfD/ADI	Commodities	(mg/kg)	(µg/kg b
76%	Lettuces	15/10	381	31%	Celeries	20/9.74	156
73%	Celeries	20/9.74	364	24%	Lettuces	15/10	121
23%	Spring onions/green onions	15/7.3	115	8%	Blueberries	7/4.33	39
18%	Peaches	1.5/0.95	90	7%	Table grapes	2/1	34
17%	Sweet peppers/bell peppers	3/1.4	83	7%	Spring onions/green onions	15/7.3	33
16%	Pears	0.8/0.6	82	6%	Currants (red, black and	7/4.9	32
15%	Table grapes	2/1	73	6%	Bovine: Liver	8/7.4	30
13%	Apples	0.8/0.6	64	5%	Wine grapes	2/1	24
12%	Bovine: Liver	8/7.4	60	5%	Sweet peppers/bell peppers	3/1.4	23
10%	Bananas	0.8/0.52	50	4%	Gooseberries (green, red	7/4.9	22
10%	Oranges	0.6/0.37	49	4%	Chinese cabbages/pe-tsai	2/0.84	21
8%	Escaroles/broad-leaved	2/0.98	39	4%	Sheep: Liver	8/7.4	21
8%	Currants (red, black and	7/4.9	39	4%	Escaroles/broad-leaved	2/0.98	20
8%	Mangoes	1/0.48	39	4%	Blackberries	5/2.39	20
7%	Apricots	1.5/0.95	33	4%	Purslanes	20/10	19
	Apricois	1.0/0.90	55	4 /0	Pursianes	20/10	10
Expand/collapse lis	ommodities exceeding the ARf diets	fD/ADI in					
Expand/collapse liss Total number of co children and adult (IESTI calculation) Results for childre No of processed co	ommodities exceeding the ARf diets) an mmodities for which ARfD/ADI	fD/ADI in			nmodities for which ARfD/ADI		
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Expand/collapse liss Total number of cr children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI	ommodities exceeding the ARf	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	No of processed cor is exceeded (IESTI): IESTI Highest % of ARfD/ADI	Processed commodities	for RA (mg/kg)	Exposi (µg/kg
Expand/collapse liss Total number of co children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARID/ADI 13%	ommodities exceeding the ARf is diets an mmodities for which ARfD/ADI by: Processed commodities Escaroles/broad-leaved end	MRL/input for RA (mg/kg) 2/0.98	Exposure (µg/kg bw) 65	No of processed cor is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66%	Processed commodities Celeries/boiled	for RA (mg/kg) 20/9.74	Exposi (µg/kg 329
Expand/collapse liss Total number of c. children and adult (IESTI calculation) Results for children No of processed co is exceeded (IESTI) IESTI Highest % of ARID/ADI 13% 7%	ommodities exceeding the ARf is diets an mmodities for which ARfD/ADI p: Processed commodities Escaroles/broad-leaved end Currants (red, black and wh	MRL/input for RA (mg/kg) 2/0.98 7/1.15	Exposure (µg/kg bw) 65 33	No of processed cor is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66% 8%	Processed commodities Celeries/boiled Purslanes/boiled	for RA (mg/kg) 20/9.74 20/10	Expose (µg/kg 329 41
Expand/collapse liss Total number of c. children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARfD/ADI 13% 7% 6%	ommodities exceeding the ARf idiets in mmodities for which ARfD/ADI ; Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98	Exposure (µg/kg bw) 65 33 30	No of processed cor is exceeded (IESTI): IESTI Highest % of ARfD/ADI 66% 8% 4%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved	for RA (mg/kg) 20/9.74 20/10 2/0.98	Expos (µg/kg 329 41 20
Expand/collapse liss Total number of co children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 7% 6% 5%	ommodities exceeding the ARf i diets en mmodities for which ARfD/ADI): Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95	Exposure (µg/kg bw) 65 33 30 25	No of processed cor is exceeded (IESTI): IESTI Highest % of ARtD/ADI 66% 8% 4% 3%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15	Expos (µg/kg 329 41 20 15
Expand/collapse liss Total number of c. children and adult (IESTI calculation) Results for children No of processed co is exceeded (IESTI) IESTI Highest % of ARID/ADI 13% 7% 6% 5% 4%	ommodities exceeding the ARf is diets an mmodities for which ARfD/ADI is: Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 3/1.65	Exposure (µg/kg bw) 65 33 30 25 21	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/AD 66% 8% 4% 3% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98	Exposi (µg/kg 329 41 20 15 12
Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARfD/ADI 13% 7% 6% 5% 4%	ommodities exceeding the ARf idiets idiets immodities for which ARfD/ADI i: Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 3/1.65 0.8/0.35	Exposure (µg/kg bw) 65 33 30 25 21 20	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 4% 3% 2% 2%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98	Expos (µg/kg 329 41 20 15 12 8.1
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Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARID/ADI 13% 7% 6% 5% 4% 4% 4% 3%	ommodities exceeding the ARf is diets an mmodities for which ARfD/ADI is: Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/bee/teaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Berocoli/boiled Spinaches/frozen; boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 7/1.15 2/0.98 3/1.65 0.8/0.35 0.5/0.23 0.5/0.23	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78	Exposi (µg/kg 329 41 20 15 12 8.1 7.8 7.2
Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARTD/ADI 13% 7% 6% 5% 4% 4% 4% 3%	ommodities exceeding the ARf idiets idiets n mmodities for which ARfD/ADI ; Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 0.5/0.23 2/0.98 5/1.12	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14 13	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 2% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78 0.6/0.3	Exposi (µg/kg 329 41 20 15 12 8.1 7.8 7.2 6.9
Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARID/ADI 13% 7% 6% 5% 4% 4% 4% 3%	ommodities exceeding the ARf is diets an mmodities for which ARfD/ADI is: Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/bee/teaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Berocoli/boiled Spinaches/frozen; boiled	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 7/1.15 2/0.98 3/1.65 0.8/0.35 0.5/0.23 0.5/0.23	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78	Expos (μg/kg 329 41 20 15 12 8.1 7.8 7.2 6.9
Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARID/ADI 13% 7% 6% 5% 4% 4% 4% 4% 3% 3% 3% 2%	ommodities exceeding the ARf is diets in mmodities for which ARfD/ADI is Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Leeks/boiled Beroccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 3/1.65 0.8/0.35 0.5/0.23 2/0.98 5/1.12 0.3/0.12	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14 13 13 12	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 2/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12	Exposs (µg/kg) 329 41 20 15 12 8.1 7.8 7.2 6.9 6.7 6.6
Expand/collapse liss Total number of c: children and adult (IESTI calculation) Results for childre No of processed co is exceeded (IESTI) IESTI Highest % of ARTD/ADI 13% 7% 6% 5% 4% 4% 4% 3% 3%	ommodities exceeding the ARf indicates indicat	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 0.8/0.35 0.8/0.35 2/0.98 5/1.12 2/0.98 5/1.12	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14 13 13	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7	Exposs (µg/kg 329 41 20 15 12 8.1 7.8 7.2 6.9 6.7
Expand/collapse liss Total number of c: children and adult (IESTI calculation) Results for children No of processed co is exceeded (IESTI) IESTI Highest % of ARfD/ADI 13% 6% 6% 5% 4% 4% 4% 3% 3% 3% 3% 2% 2%	ommodities exceeding the ARf is diets mmodities for which ARfD/ADI is Processed commodities Escaroles/broad-leaved end Currants (red, black and wh Chards/beet leaves/boiled Peaches/canned Beans (with pods)/boiled Broccoli/boiled Broccoli/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Pumpkins/boiled Courgettes/boiled	MRL/input for RA (mg/kg) 2/0.98 1.5/0.95 3/1.65 0.8/0.35 0.8/0.35 5/1.12 2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.12	Exposure (µg/kg bw) 65 33 25 21 20 18 14 13 13 12 11 11	No of processed cor is exceeded (IESTI): IESTI Highest % of ARTD/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled Cauliflowers/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35 0.3/0.14	Expose (µg/kg] 329 41 20 15 12 8.1 7.8 7.2 6.9 6.7 6.6 6.1 5.8
Expand/collapse liss Total number of c. children and adult (IESTI calculation) IESTI Highest % of ARTD/ADI 13% 7% 6% 5% 4% 4% 4% 3% 3% 3% 2%	ommodities exceeding the ARf cliets c	MRL/input for RA (mg/kg) 2/0.98 7/1.15 2/0.98 1.5/0.95 0.8/0.35 0.5/0.23 2/0.98 5/1.12 0.3/0.14 4/0.78 4/0.74	Exposure (µg/kg bw) 65 33 30 25 21 20 18 14 13 13 13 12 11	No of processed cor is exceeded (IESTI): IESTI Highest % of ARID/ADI 66% 8% 4% 3% 2% 2% 2% 2% 2% 2% 1% 1% 1%	Processed commodities Celeries/boiled Purslanes/boiled Escaroles/broad-leaved Currants (red, black and Chards/beet leaves/boiled Spinaches/frozen; boiled Peaches/canned Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled	for RA (mg/kg) 20/9.74 20/10 2/0.98 7/1.15 2/0.98 1.5/0.98 1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35	Expose (µg/kg l 329 41 20 15 12 8.1 7.8 7.2 6.9 6.7 6.6 6.1

Conclusion:

2% Expand/collapse list

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.



• PRIMo(CXL2 Option 1)

Comments

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calculation (based

(NEDI/IEDI

[MDI/

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elsa
European Food Safety Authority

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	-			LOQs (mg/kg) range	from:	0.01	to:	0.01	Details – o	hronic risk	Supplementary resu	lts –	
	··· P	fsa			Toxicological	reference va	alues		assess		chronic risk assessn		
	L			ADI (mg/kg bw per da	ay):	0.012	ARfD (mg/kg bw):	0.5	<u> </u>		\succ	$ \longrightarrow $	
F	Iropean Food	Safety Authority							Details –	acute risk	Details – acute ri	sk	
-	aropean rood	Survey / lacitority		Source of ADI:		EFSA	Source of ARfD:	EFSA	assessmen	t/children	assessment/adul	ts	
	EFSA PRIMo rev	vision 3.1; 2019/03/19		Year of evaluation:		2013	Year of evaluation:	2013		,			
ner	ts:												
					Re	fined calc	ulation mode						
							JMPR methodo						
				T		assessment:	JWPR methodo	iogy (IEDI/ I MDI)				1	
				No of diets exceeding	the ADI :								resulting from
												MRLs set at	commodities not under assessmer
			Expsoure	Highest contributor to			2nd contributor to			3rd contributor to		the LOQ (in % of ADI)	(in % of ADI)
	Calculated exposure		(µg/kg bw per		Commodity/		MS diet	Commodity/		MS diet	Commodity/	(iii % 01 ADI)	
	(% of ADI)	MS Diet	day)	(in % of ADI)	group of commodities		(in % of ADI)	group of commodities		(in % of ADI)	group of commodities	├ ──┤	00%
	92%	NL toddler	11.07	18%	Apples		10%	Milk: Cattle		9%	Bananas		92%
	72%	DE child	8.66 6.59	21%	Apples		7%	Table grapes		7%	Wheat		72%
	55% 51%	NL child IE adult	6.59	10% 7%	Apples Sheep: Liver		7% 6%	Wheat Wine grapes		5% 5%	Table grapes Basil and edible flowers		55% 51%
	45%			7%			7%	Wheat		3%			45%
	45% 41%	GEMS/Food G07 GEMS/Food G06	5.38 4.97	7% 11%	Wine grapes Wheat			Wheat Table grapes			Celeries Tomatoes		45% 41%
	41%	FR child 3–15 years	4.97	7%	Wheat			Eggs: Chicken			Oranges		41%
	39%	GEMS/Food G11	4.79	7%	Celeries			Wheat		4 % 5%	Wine grapes		39%
	39%	DK child	4.69	9%	Rye			Wheat			Apples		39%
	37%	GEMS/Food G08	4.46	6%	Wheat			Wine grapes		2%	Lettuces		37%
	36%	GEMS/Food G15	4.31	7%	Wheat			Wine grapes		2%	Celeries		36%
	35%	GEMS/Food G10	4.25	6%	Wheat			Lettuces		2%	Poultry: Muscle/meat		35%
	34%	RO general	4.10	8%	Wine grapes		8%	Wheat		2%	Eggs: Chicken		34%
	34%	FR toddler 2–3 years	4.09	5%	Apples			Milk: Cattle		5%	Wheat		34%
	34%	ES child	4.07	7%	Wheat		5%	Lettuces		3%	Eggs: Chicken		34%
	33%	SE general	3.91	5%	Wheat		5%	Lettuces		3%	Eggs: Chicken		33%
	31%	UK toddler	3.76	6%	Wheat			Milk: Cattle		3%	Eggs: Chicken		31%
	31%	DE women 14-50 years	3.67	4%	Apples			Wine grapes			Wheat		31%
	30%	UK infant	3.63	6%	Milk: Cattle			Eggs: Chicken		4%	Wheat		30%
	30%	PT general	3.59	12%	Wine grapes			Wheat			Apples		30%
	29%	DE general	3.44	4%	Apples		4%	Wine grapes			Wheat		29%
	27%	FR adult	3.25	11%	Wine grapes		4%	Wheat			Eggs: Chicken		27%
	27%	ES adult	3.23	7%	Lettuces			Wheat			Wine grapes		27%
	26%	IT toddler	3.07	11%	Wheat		4%	Lettuces		2%	Tomatoes		26%
	24%	NL general	2.92	3%	Wheat			Wine grapes		2%	Apples		24%
	21%	IT adult	2.58	7%	Wheat		5%	Lettuces		1%	Tomatoes		21%
	19%	UK vegetarian	2.31	4%	Wine grapes		3%	Wheat		2%	Lettuces		19%
	19%	FI 3 years	2.28	2%	Bananas			Wheat		2%	Raspberries (red and yellow)		19%
	18%	DK adult	2.21	5%	Wine grapes		2%	Wheat		2%	Apples		18%
	18%	UK adult	2.15	5%	Wine grapes		3%	Wheat		1%	Lettuces		18%
	17%	FR infant	2.05	3%	Apples			Milk: Cattle			Beans (with pods)		17%
	15%	FI 6 years	1.75	2%	Wheat		1%	Raspberries (red and yellow		1%	Bananas		15%
	13%	LT adult	1.59	3%	Apples			Rye		2%	Wheat		13%
	11%	Fladult	1.32	2%	Lettuces			Wine grapes		1%	Rye		11%
	10%	PL general	1.23	3%	Apples		2%	Table grapes		1%	Tomatoes		10%
	6%	IE child	0.73	2%	Wheat		0.6%	Eggs: Chicken		0.6%	Milk: Cattle		6%

105

FLUOPYRAM

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.

Input values



Acute risk assessment/children

Acute risk assessment/adults/general population

Details - acute risk assessment/adults

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

l ArtD/ADI 76% 73% 23% 18% 17% 16% 15% 13% 13% 10% 10% 8%	Commodities Lettuces Celeries Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples Bananas	MRL/input for RA (mg/kg) 15/10 20/9.74 15/7.3 1.5/0.95 3/1.4 0.8/0.6 2/1	Exposure (µg/kg bw) 381 364 115 90 83	Highest % of ARfD/ADI 31% 24% 8% 7% 7%	Commodities Celeries Lettuces Blueberries Table grapes	MRL/input for RA (mg/kg) 20/9.74 15/10 7/4.33 2/1	(μg/kg 156 12 ⁻ 39
ĂRfD/ADI 76% 73% 23% 18% 17% 16% 15% 13% 10% 10%	Lettuces Celeries Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples	for RA (mg/kg) 15/10 20/9.74 15/7.3 1.5/0.95 3/1.4 0.8/0.6	(μg/kg bw) 381 364 115 90 83	ARfD/ADI 31% 24% 8% 7%	Celeries Lettuces Blueberries	for RA (mg/kg) 20/9.74 15/10 7/4.33	156
ĂRfD/ADI 76% 73% 23% 18% 17% 16% 15% 13% 10% 10%	Lettuces Celeries Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples	(mg/kg) 15/10 20/9.74 15/7.3 1.5/0.95 3/1.4 0.8/0.6	(μg/kg bw) 381 364 115 90 83	ARfD/ADI 31% 24% 8% 7%	Celeries Lettuces Blueberries	(mg/kg) 20/9.74 15/10 7/4.33	(μg/kg 156 121 39
76% 73% 23% 18% 17% 16% 15% 13% 10%	Lettuces Celeries Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples	15/10 20/9.74 15/7.3 1.5/0.95 3/1.4 0.8/0.6	381 364 115 90 83	31% 24% 8% 7%	Celeries Lettuces Blueberries	20/9.74 15/10 7/4.33	156 121 39
73% 23% 18% 17% 16% 15% 13% 10% 10%	Celeries Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples	20/9.74 15/7.3 1.5/0.95 3/1.4 0.8/0.6	364 115 90 83	24% 8% 7%	Lettuces Blueberries	15/10 7/4.33	121 39
23% 18% 17% 16% 15% 13% 10% 10%	Spring onions/green onions Peaches Sweet peppers/bell peppers Pears Table grapes Apples	15/7.3 1.5/0.95 3/1.4 0.8/0.6	115 90 83	8% 7%	Blueberries	7/4.33	39
18% 17% 16% 15% 13% 10% 10%	Peaches Sweet peppers/bell peppers Pears Table grapes Apples	1.5/0.95 3/1.4 0.8/0.6	90 83	7%			
17% 16% 15% 13% 10% 10%	Sweet peppers/bell peppers Pears Table grapes Apples	3/1.4 0.8/0.6	83		Table grapes	2/1	
16% 15% 13% 10% 10%	Pears Table grapes Apples	0.8/0.6					
15% 13% 10% 10%	Table grapes Apples				Spring onions/green onions	15/7.3	33
13% 10% 10%	Apples	2/1	82	6%	Currants (red, black and	7/4.9	32
10% 10%			73	5%	Wine grapes	2/1	24
10%	Bananas	0.8/0.6	64	5%	Sweet peppers/bell peppers	3/1.4	23
		0.8/0.52	50	4%	Gooseberries (green, red	7/4.9	22
8%	Oranges	0.6/0.37	49	4%	Chinese cabbages/pe-tsai	2/0.84	21
	Escaroles/broad-leaved	2/0.98	39	4%	Sheep: Liver	8/7.4	21
8%	Currants (red, black and	7/4.9	39	4%	Escaroles/broad-leaved	2/0.98	20
8%	Mangoes	1/0.48	38	4%	Blackberries	5/2.39	20
							19
	Gooseberries (green, red	7/4.9	29	4%	Lamb's lettuce/corn salads	20/10	19
	nmodities for which ARfD/ADI						
		MRL/input		IESTI		MRI /input	
lighest % of			Exposure	Highest % of			Expos
	Processed commodities				Processed commodities		(µg/kg
13%							329
							41
							20
5%	Peaches/canned	1.5/0.95	25	3%	Currants (red, black and	7/1.15	15
	Beans (with pods)/boiled	3/1.65	21	2%	Chards/beet leaves/boiled	2/0.98	12
4%			20	2%	Spinaches/frozen; boiled	2/0.98	8.1
4% 4%	· · · /	0.8/0.35					
4%	Leeks/boiled	0.8/0.35			Peaches/canned		
4% 3%	Leeks/boiled Spinaches/frozen; boiled	2/0.98	14	2%	Peaches/canned	1.5/0.95	7.8
4% 3% 3%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice	2/0.98 5/1.12	14 13	2% 1%	Elderberries/juice	1.5/0.95 4/0.78	7.8 7.2
4% 3% 3% 3%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled	2/0.98 5/1.12 0.3/0.14	14 13 13	2% 1% 1%	Elderberries/juice Courgettes/boiled	1.5/0.95 4/0.78 0.6/0.3	7.8 7.2 6.9
4% 3% 3% 3% 2%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled Elderberries/juice	2/0.98 5/1.12 0.3/0.14 4/0.78	14 13 13 12	2% 1% 1% 1%	Elderberries/juice Courgettes/boiled Wine grapes/wine	1.5/0.95 4/0.78 0.6/0.3 2/0.7	7.8 7.2 6.9 6.7
4% 3% 3% 3% 2% 2%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Broccoli/boiled	2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14	14 13 13 12 11	2% 1% 1% 1% 1%	Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled	1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12	7.8 7.2 6.9 6.7 6.6
4% 3% 3% 2% 2% 2% 2%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled Elderberries/juice Broccoli/boiled Pumpkins/boiled	2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14 0.4/0.12	14 13 13 12 11 11	2% 1% 1% 1% 1% 1%	Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled	1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35	7.8 7.2 6.9 6.7 6.6 6.1
4% 3% 3% 2% 2% 2% 2%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Wittoofs/boiled Elderberries/juice Broccoli/boiled Pumpkins/boiled Courgettes/boiled	2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14 0.4/0.12 0.6/0.3	14 13 13 12 11 11 11	2% 1% 1% 1% 1% 1% 0.9%	Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled Peas (with pods)/boiled	1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35 3/1.36	7.8 7.2 6.9 6.7 6.6 6.1 4.7
4% 3% 3% 2% 2% 2% 2%	Leeks/boiled Spinaches/frozen; boiled Raspberries/juice Witloofs/boiled Elderberries/juice Broccoli/boiled Pumpkins/boiled	2/0.98 5/1.12 0.3/0.14 4/0.78 0.4/0.14 0.4/0.12	14 13 13 12 11 11	2% 1% 1% 1% 1% 1%	Elderberries/juice Courgettes/boiled Wine grapes/wine Pumpkins/boiled Leeks/boiled	1.5/0.95 4/0.78 0.6/0.3 2/0.7 0.4/0.12 0.8/0.35	7.8 7.2 6.9 6.7 6.6 6.1
	I calculation) Its for children processed con eeded (IESTI): Iighest % of ARTD/ADI 13% 7% 6%	6% Gooseberries (green, red d/collapse list number of commodities exceeding the AR ren and adult diets I calculation) Its for children processed commodities for which ARfD/ADI eeded (IESTI): Iighest % of ARfD/ADI Processed commodities 13% Escaroles/broad-leaved end 7% Currants (red, black and wh 6% Chards/beet leaves/boiled	6% Gooseberries (green, red 7/4.9 d/collapse list number of commodities exceeding the ARfD/ADI in ren and adult diets I calculation) Its for children processed commodities for which ARfD/ADI eeded (IESTI): MRL/input lighest % of for RA ARfD/ADI Processed commodities (mg/kg) 13% Escaroles/broad-leaved end 2/0.98 7% Currants (red, black and wh 7/1.15 6% Chards/beet leaves/boiled 2/0.98	6% Gooseberries (green, red 7/4.9 29 d/collapse list number of commodities exceeding the ARfD/ADI in ren and adult diets I calculation) Its for children processed commodities for which ARfD/ADI eeded (IESTI): Iighest % of for RA Exposure ARfD/ADI Processed commodities (mg/kg) (µg/kg bw) 13% Escaroles/broad-leaved end 2/0.98 65 7% Currants (red, black and wh 7/1.15 33 6% Chards/beel teaves/boiled 2/0.98 30	6% Gooseberries (green, red 7/4.9 29 4% d/collapse list number of commodities exceeding the ARfD/ADI in ren and adult diets I calculation)	6% Gooseberries (green, red 7/4.9 29 4% Lamb's lettuce/corn salads d/collapse list number of commodities exceeding the ARfD/ADI in ren and adult diets I calculation)	6% Gooseberries (green, red 7/4.9 29 4% Lamb's lettuce/com salads 20/10 d/collapse list number of commodities exceeding the ARfD/ADI in ren and adult diets I calculation)

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



Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

	Residues from primary crops only (Option 1)				Residues from primary uses and rotational crops (Option 2)				
	Media	Median dietary burden		Maximum dietary burden		Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Risk assessment re	esidue defi	inition: sum of fluopyr	am and fluo	pyram-benzamide (M2	5), expresse	d as fluopyram			
Grapefruits, dried pulp	0.12	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.12	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.12	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.12	STMR $ imes$ PF (0.93) $ imes$ CF (1.1) ^(a)	
Oranges, dried pulp	0.12	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.12	$\begin{array}{l} STMR\timesPF\\ (0.93)\timesCF\;(1.1)^{(a)} \end{array}$	0.12	$\begin{array}{l} STMR\timesPF\\ (0.93)\timesCF\;(1.1)^{(a)} \end{array}$	0.12	STMR $ imes$ PF (0.93) $ imes$ CF (1.1) ^(a)	
Lemons, dried pulp	0.30	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.30	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.30	$\begin{array}{l} STMR\timesPF\\ (0.93)\timesCF\;(1.1)^{(a)} \end{array}$	0.30	STMR \times PF (0.93) \times CF (1.1) ^(a)	
Mandarins, dried pulp	0.30	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.30	$\begin{array}{l} STMR\timesPF\\ (0.93)\timesCF\;(1.1)^{(a)} \end{array}$	0.30	$\begin{array}{l} STMR \times PF \\ (0.93) \times CF \ (1.1)^{(a)} \end{array}$	0.30	STMR \times PF (0.93) \times CF (1.1) ^(a)	
Apple, pomace, wet	0.48	STMR \times PF (2.26) \times CF (1.05)	0.48	STMR \times PF (2.26) \times CF (1.05)	0.48	STMR \times PF (2.26) \times CF (1.05)	0.48	STMR \times PF (2.26) \times CF (1.05)	
Potato, culls	0.01	STMR	0.07	HR	0.03	STMR ^(b)	0.07	HR ^(b)	
Potato, process waste	0.20	STMR \times default PF (20)	0.20	STMR \times default PF (20)	0.60	$STMR^{(b)} \times default PF$ (20)	0.60	$STMR^{(b)} \times default PF (20)$	
Potato, dried pulp	0.38	STMR \times default PF (38)	0.38	STMR \times default PF (38)	1.14	$STMR^{(b)} \times default PF$ (38)	1.14	$\text{STMR}^{(b)} \times \text{default PF}$ (38)	
Cassava/tapioca, roots	_	-	-	-	0.02	STMR ^(b)	0.02	HR ^(b)	
Carrot, culls	0.06	STMR	0.13	HR	0.10	STMR ^(b)	0.18	HR ^(b)	
Swede, roots	0.05	STMR	0.13	HR	0.10	STMR ^(b)	0.18	HR ^(b)	
Turnip, roots	0.05	STMR	0.13	HR	0.10	STMR ^(b)	0.18	HR ^(b)	
Cabbage, heads, leaves	0.01	STMR	0.08	HR	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 \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	
Cowpea, seed	0.04	STMR \times CF (1.3)	0.04	STMR $\times \times$ CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	



	Residues from primary crops only (Option 1)				Residues from primary uses and rotational crops (Option 2)			
Feed commodity	Median dietary burden		Maximum dietary burden		Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pea (Field pea), seed (dry)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)
Lupin, seed	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)	0.04	STMR \times CF (1.3)
Lupin seed, meal	0.05	STMR \times default PF (1.1) \times CF (1.3)	0.05	STMR \times default PF (1.1) \times CF (1.3)	0.05	STMR \times default PF (1.1) \times CF (1.3)	0.05	STMR \times default PF (1.1) \times CF (1.3)
Peanut, meal	0.02	STMR \times default PF (2) \times CF (1.2)	0.02	STMR \times default PF (2) CF (1.2)	0.02	STMR \times default PF (2) \times CF (1.2)	0.02	STMR \times default PF (2) \times CF (1.2)
Sunflower, meal	0.15	STMR \times default PF (2)	0.15	STMR \times default PF (2)	0.15	STMR \times default PF (2)	0.15	STMR \times default PF (2)
Canola (Rape seed), meal	0.32	$\begin{array}{l} STMR \times PF \\ (0.73) \times CF \ (1.29) \end{array}$	0.32	$\begin{array}{l} STMR \times PF \\ (0.73) \times CF \ (1.29) \end{array}$	0.32	$\begin{array}{l} STMR \times PF \\ (0.73) \times CF \mbox{ (1.29)} \end{array}$	0.32	STMR \times PF (0.73) \times CF (1.29)
Rape, meal	0.32	STMR \times PF (0.73) \times CF (1.29)	0.32	$\begin{array}{l} STMR \times PF \\ (0.73) \times CF \ (1.29) \end{array}$	0.32	STMR \times PF (0.73) \times CF (1.29)	0.32	STMR \times PF (0.73) \times CF (1.29)
Soybean, seed	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)
Soybean, meal	0.00	STMR \times PF (0.047) \times CF (1.2)	0.00	STMR × PF (0.047) × CF (1.2)	0.00	STMR \times PF (0.047) \times CF (1.2)	0.00	STMR \times PF (0.047) \times CF (1.2)
Soybean, hulls	0.02	$\begin{array}{l} STMR \times PF \\ (1.31) \times CF \ (1.2) \end{array}$	0.02	$\begin{array}{l} STMR \times PF \\ (1.31) \times CF \ (1.2) \end{array}$	0.02	$\begin{array}{l} STMR \times PF \\ (1.31) \times CF \ (1.2) \end{array}$	0.02	STMR \times PF (1.31) \times CF (1.2)
Cotton, undelinted seed	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)
Cotton, meal	0.09	STMR \times default PF (1.25) \times CF (1.2)	0.09	STMR \times default PF (1.25) \times CF (1.2)	0.09	STMR \times default PF (1.25) \times CF (1.2)	0.09	STMR \times default PF (1.25) \times CF (1.2)
Barley, grain	0.02	STMR	0.02	STMR	0.02	STMR	0.02	STMR
Brewer's grain, dried	0.07	STMR \times default PF (3.3)	0.07	STMR \times default PF (3.3)	0.07	STMR \times default PF (3.3)	0.07	STMR \times default PF (3.3)
Corn, field (Maize), grain	0.01*	STMR	0.01*	STMR	0.01*	STMR	0.01*	STMR
Corn, pop, grain	0.01*	STMR	0.01*	STMR	0.01*	STMR	0.01*	STMR



	Re	sidues from primar	y crops only	(Option 1)	Residues from primary uses and rotational crops (Option 2)				
	Media	n dietary burden	Maximum	dietary burden	Media	n dietary burden	Ma	aximum dietary burden	
Feed commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Corn, field, milled by-pdts	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	
Corn, field, hominy meal	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	
Corn, field, distiller's grain (dry)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	
Corn, field, gluten feed	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	
Corn, field, gluten, meal	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	0.01*	STMR ^(c)	
Millet, grain	-	-	-	_	0.01	STMR	0.01	STMR	
Oat, grain	0.02	STMR	0.02	STMR	0.02	STMR	0.02	STMR	
Rye, grain	0.01	STMR	0.01	STMR	0.01	STMR	0.01	STMR	
Sorghum, grain	0.36	STMR	0.36	STMR	0.36	STMR	0.36	STMR	
Triticale, grain	0.19	STMR	0.19	STMR	0.19	STMR	0.19	STMR	
Wheat, grain	0.19	STMR	0.19	STMR	0.19	STMR	0.19	STMR	
Wheat, distiller's grain (dry)	0.63	STMR \times default PF (3.3)	0.63	STMR \times default PF (3.3)	0.63	STMR \times default PF (3.3)	0.63	STMR \times default PF (3.3)	
Wheat gluten, meal	0.34	STMR \times default PF (1.8)	0.34	STMR \times default PF (1.8)	0.34	STMR \times default PF (1.8)	0.34	STMR \times default PF (1.8)	
Wheat, milled by- pdts	1.33	STMR \times default PF (7)	1.33	STMR \times default PF (7)	1.33	STMR \times default PF (7)	1.33	STMR × default PF (7)	
Beet, sugar, dried pulp	-	-	-	_	0.18	$STMR^{(b)} \times default PF$ (18)	0.18	$STMR^{(b)} \times default PF (18)$	
Beet, sugar, ensiled pulp	-	-	-	_	0.03	$STMR^{(b)} \times default PF$ (3)	0.03	$STMR^{(b)} \times default PF (3)$	
Beet, sugar, molasses	_	_	-	_	0.28	$STMR^{(b)} \times default PF$ (28)	0.28	$STMR^{(b)} \times default PF$ (28)	
Barley, forage	_	-	_	_	0.17	$STMR^{(b)} \times CF (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)	



	Re	esidues from prima	ry crops only	y (Option 1)	Residues from primary uses and rotational crops (Option 2)					
	Media	n dietary burden	Maximum	dietary burden	Media	n dietary burden	Ma	aximum dietary burden		
Feed commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment		
Barley, silage	_	-	-	-	0.21	$\begin{array}{l} STMR^{(b)} \times \text{ default PF} \\ (1.3) \times CF (1.5) \end{array}$	0.55	$HR^{(b)}$ × default PF (1.3) × CF (1.5)		
Millet, forage	_	-	_	-	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Corn, field, forage/ silage	_	-	-	_	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Oat, forage	_	-	-	_	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Oat, hay	_	-	-	-	0.50	STMR ^(b) \times default PF (3) \times CF (1.5)	1.26	$HR^{(b)}$ × default PF (3) × CF (1.5)		
Rye, forage (greens)	_	-	-	_	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Sorghum, grain, forage	-	-	-	-	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Sorghum, grain, silage	_	-	_	-	0.10	$\begin{array}{l} STMR^{(b)} \times \text{ default PF} \\ (0.6) \times CF \ (1.5) \end{array}$	0.25	$\rm HR^{(b)} \times$ default PF (0.6) \times CF (1.5)		
Triticale, forage	_	_	_	_	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Triticale, hay	_	-	_	-	0.48	$\begin{array}{l} STMR^{(b)} \times \text{ default PF} \\ (2.9) \times CF \ (1.5) \end{array}$	1.22	HR ^(b) \times default PF (2.9) \times CF (1.5)		
Wheat, forage	_	-	_	_	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.5)$	0.42	$HR^{(b)} \times CF$ (1.5)		
Wheat, hay (fodder dry)	_	-	_	-	0.58	$\begin{array}{l} STMR^{(b)} \times \text{ default PF} \\ (3.5) \times CF \ (1.5) \end{array}$	1.47	$\rm HR^{(b)} \times$ default PF (3.5) \times CF (1.5)		
Barley, straw	0.15	STMR \times CF (1.1)	1.21	HR \times CF (1.1)	0.15	$\text{STMR}^{(b)} \times \text{CF} (1.1)$	1.21	${\sf HR}^{(b)} imes {\sf CF}$ (1.1)		
Corn, field, stover (fodder)	0.42	STMR	1.70	HR	0.42	STMR	1.70	HR		
Corn, pop, stover	0.42	STMR	1.70	HR	0.42	STMR	1.70	HR		
Oat, straw	0.15	STMR \times CF (1.1)	1.21	HR \times CF (1.1)	0.15	$\text{STMR}^{(b)} \times \text{CF} (1.1)$	1.21	${\sf HR}^{(b)} imes {\sf CF}$ (1.1)		
Rye, straw	0.17	STMR \times CF (1.1)	1.21	HR \times CF (1.1)	0.17	$\text{STMR}^{(b)} \times \text{CF} (1.1)$	1.21	${\sf HR}^{(b)} imes {\sf CF}$ (1.1)		
Triticale, straw	0.17	STMR \times CF (1.1)	1.21	HR \times CF (1.1)	0.17	$STMR^{(b)} imes CF (1.1)$	1.21	${\sf HR}^{(b)} imes {\sf CF}$ (1.1)		
Wheat, straw	0.17	STMR \times CF (1.1)	1.21	HR \times CF (1.1)	0.17	$STMR^{(b)} imes CF$ (1.1)	1.21	${\sf HR}^{(b)} imes {\sf CF}$ (1.1)		
Beet, mangel, roots	_	_	_	-	0.01	STMR ^(b)	0.01	HR ^(b)		



	Residues from primary crops only (Option 1)				Resi	Residues from primary uses and rotational crops (Option 2)			
Feed commodity	Median dietary burden		Maximum	Maximum dietary burden		Median dietary burden		aximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
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. In the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

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

(a): Tentative PF, based on only 1 value.

(b): The STMR and HR values reflect the combined residues from both primary and rotational crops (sum of the HR/STMR values).

(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.

D.2. Consumer risk assessment without consideration of the existing CXLs, and no risk mitigation implemented to avoid residues from rotational use

			Option 1			Opti	on 2	
	Chronic risk assessment		Ac	ute risk assessment	Chronic ris	sk assessment	Acute risk assessme	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment res	idue definiti	ion 1: sum of fluopyram	and fluopyran	n-benzamide (M25), expressed	as fluopyram			
Grapefruits, oranges	0.12	STMR	0.32	HR	0.12	STMR	0.32	HR
Lemons, mandarins	0.29	STMR (tentative)	0.32	HR (tentative)	0.29	STMR (tentative)	0.32	HR (tentative)
Limes	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL
Treenuts	0.01	STMR	0.03	HR	0.01	STMR	0.03	HR
Pome fruits	0.20	STMR	0.60	HR	0.20	STMR	0.60	HR
Apricots	0.33	STMR	0.95	HR	0.33	STMR	0.95	HR
Cherries (sweet)	0.56	STMR (tentative)	1.10	HR (tentative)	0.56	STMR (tentative)	1.10	HR (tentative)
Peaches	0.34	STMR	0.95	HR	0.34	STMR	0.95	HR
Plums	0.19	STMR	0.27	HR	0.19	STMR	0.27	HR



		0	ption 1		Option 2					
	Chron	ic risk assessment	Ac	ute risk assessment	Chronic ris	sk assessment	Acute	risk assessment		
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment		
Table grapes	0.59	STMR	1.00	HR	0.59	STMR	1.00	HR		
Wine grapes	0.46	STMR	0.95	HR	0.46	STMR	0.95	HR		
Strawberries	0.43	STMR	1.01	HR	0.43	STMR	1.01	HR		
Cane fruits	1.12	STMR	2.39	HR	1.12	STMR	2.39	HR		
Blueberries	1.14	STMR	4.33	HR	1.14	STMR	4.33	HR		
Other small fruits and berries, except rose hips and azaroles	0.78	STMR	2.10	HR	0.78	STMR	2.10	HR		
Rose hips	0.69	STMR	1.58	HR	0.69	STMR	1.58	HR		
Bananas	0.19	STMR (tentative)	0.52	HR (tentative)	0.19	STMR (tentative)	0.52	HR (tentative)		
Cherimoyas	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL		
Potatoes	0.01	STMR	0.07	HR	0.03 ^(a)	STMR	0.07	HR		
Cassava roots/manioc Arrowroots	n.r.	n.r.	n.r.	n.r.	0.02 ^(b)	STMR	0.02 ^(b)	HR		
Sweet potatoes Yams	0.02	STMR	0.03	HR	0.04 ^(a)	STMR	0.05 ^(a)	HR		
Beetroot	0.02	STMR	0.04	HR	0.07 ^(a)	STMR	0.1 ^(a)	HR		
Carrots, radishes	0.06	STMR	0.13	HR	0.07 ^(a)	STMR	0.18 ^(a)	HR		
other root and tuber vegetables except radishes, carrots, beetroots and sugar beets	0.05	STMR	0.13	HR	0.07 ^(a)	STMR	0.18 ^(a)	HR		
Onions, garlic, shallots	0.01	STMR	0.04	HR	0.01	STMR	0.04	HR		
Spring onions/green onions and Welsh onions	0.56	STMR (tentative) × CF (1.1)	1.32	HR (tentative) \times CF (1.1)	0.56	STMR (tentative) × CF (1.1)	1.32	HR (tentative) × CF (1.1)		
Tomatoes	0.14	STMR \times CF (1.3)	0.29	HR \times CF (1.3)	0.14	STMR \times CF (1.3)	0.29	HR \times CF (1.3)		
Aubergines	0.12	STMR	0.23	HR	0.12	STMR	0.23	HR		



			Option 1		Option 2				
	Chron	ic risk assessment	Ac	ute risk assessment	Chronic ris	sk assessment	Acute	risk assessment	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Sweet peppers/bell peppers	0.29	STMR	1.23	HR	0.29	STMR	1.23	HR	
Cucumbers, gherkins, courgettes	0.14	STMR	0.30	HR	0.14	STMR	0.30	HR	
Melons	0.19	STMR (tentative)	0.44	HR (tentative)	0.19	STMR (tentative)	0.44	HR (tentative)	
Watermelons	0.05	STMR (tentative)	0.12	HR (tentative)	0.05	STMR (tentative)	0.12	HR (tentative)	
Pumpkins, watermelons	0.05	STMR	0.12	HR	0.05	STMR	0.12	HR	
Sweet corn	0.01*	STMR	0.01*	HR	0.01	STMR ^(a)	0.01	HR ^(a)	
Broccoli	0.04	STMR	0.14	HR	0.06	STMR ^(a)	0.19	HR ^(a)	
Cauliflowers	0.01	STMR	0.05	HR	0.03	STMR ^(a)	0.10	HR ^(a)	
Brussels sprouts	0.04	STMR	0.14	HR	0.06	STMR ^(a)	0.19	HR ^(a)	
Head cabbages	0.01	STMR	0.08	HR	0.04	STMR ^(a)	0.17	HR ^(a)	
Chinese cabbages/pe- tsai	0.36	STMR (tentative)	0.84	HR (tentative)	0.36	STMR (tentative)	0.84	HR (tentative)	
Kales, kohlrabies, watercresses	n.r.	n.r.	n.r.	n.r.	0.03 ^(b)	STMR	0.09 ^(b)	HR	
Lamb's lettuces, Cresses, Roman rocket, purslanes, baby leaf crops	1.60	STMR	10.00	HR	1.60	STMR	10.00	HR	
Lettuces	1.50	STMR	10.00	HR	1.50	STMR	10.00	HR	
Escaroles, land cresses, red mustard, spinaches, chards/beet leaves	0.37	STMR (tentative)	0.98	HR (tentative)	0.37	STMR (tentative)	0.98	HR (tentative)	
Witloofs/Belgian endives	0.12	STMR \times CF (1.2)	0.14	HR \times CF (1.2)	0.12	STMR \times CF (1.2)	0.14	HR \times CF (1.2)	
Herbs, and edible flowers, except basil	0.38	STMR	3.65	HR	0.38	STMR	3.65	HR	
Basil	19.12	STMR	30.08	HR	19.12	STMR	30.08	HR	



		0	ption 1		Option 2				
	Chron	ic risk assessment	Ac	ute risk assessment	Chronic ri	sk assessment	Acute	risk assessment	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Beans/peas (with pods)	0.45	STMR (tentative) × CF (1.1)	1.65	HR (tentative) \times CF (1.1)	0.45	STMR (tentative) × CF (1.1)	1.65	HR (tentative) × CF (1.1)	
Beans/peas (without pods), lentils (fresh)	0.05	STMR \times CF (1.3)	0.09	HR \times CF (1.3)	0.05	STMR \times CF (1.3)	0.09	HR \times CF (1.3)	
Asparagus	0.01*	STMR	0.01*	HR	0.01*	STMR	0.01*	HR	
Celeries	3.03	STMR	9.74	HR	3.03	STMR	9.74	HR	
Globe artichokes	1.27	STMR (tentative)	1.37	HR (tentative)	1.27	STMR (tentative)	1.37	HR (tentative)	
Leeks	0.24	STMR (tentative) × CF (1.1)	0.35	HR (tentative) × CF (1.1)	0.24	STMR (tentative) × CF (1.1)	0.35	HR (tentative) × CF (1.1)	
Pulses (dry)	0.05	STMR \times CF (1.4)	0.05	STMR \times CF (1.4)	0.05	STMR \times CF (1.4)	0.05	STMR \times CF (1.4)	
Peanuts/groundnuts	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	
Poppy seeds, mustard seeds	0.12	STMR \times CF (1.2)	0.12	STMR \times CF (1.2)	0.12	STMR \times CF (1.2)	0.12	STMR \times CF (1.2)	
Sunflower seeds	0.08	STMR	0.08	STMR	0.08	STMR	0.08	STMR	
Rapeseeds/canola seeds	0.40	STMR \times CF (1.2)	0.40	STMR \times CF (1.2)	0.40	STMR \times CF (1.2)	0.40	STMR \times CF (1.2)	
Soya beans	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	0.01	STMR \times CF (1.2)	
Cotton seeds	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)	
Barley, oat grains	0.02	STMR	0.02	STMR	0.02	STMR	0.02	STMR	
Buckwheat, millet, rice grains	n.r.	n.r.	n.r.	n.r.	0.01 ^(b)	STMR	0.01 ^(b)	STMR	
Maize/corn grains, rye grains	0.01	STMR	0.01	STMR	0.01	STMR	0.01	STMR	
Sorghum grains	0.36	STMR	0.36	STMR	0.36	STMR	0.36	STMR	
Wheat grains	0.19	STMR	0.19	STMR	0.19	STMR	0.19	STMR	
Herbal infusions (dried flowers and leaves)	2.31	STMR (EFSA, 2019d)	25.9	HR (EFSA, 2019d)	2.31	STMR (EFSA, 2019d)	25.9	HR (EFSA, 2019d)	



			Option 1		Option 2				
	Chron	ic risk assessment	Ac	ute risk assessment	Chronic ris	sk assessment	Acute	risk assessment	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Herbal infusions (dried roots)	n.r.	n.r.	n.r.	n.r.	0. 1 ^(b)	STMR \times default DF(10)	0. 1 ^(b)	HR \times default DF (10)	
Hops	12.13	STMR \times CF (1.2)	30.48	HR \times CF (1.2)	12.13	STMR \times CF (1.2)	30.48	HR \times CF (1.2)	
Seed spices	22.50	STMR	29.60	HR	22.50	STMR	29.60	HR	
Spices (roots or rhizome)	n.r.	n.r.	n.r.	n.r.	0.2 ^(b)	STMR \times default DF(10)	0.5 ^(b)	HR	
Sugar beet (root)	n.r.	n.r.	n.r.	n.r.	0.02 ^(b)	STMR	0.05 ^(b)	HR	
Chicory roots	0.1	EU MRL	0.1	EU MRL	0.1	EU MRL	0.1	EU MRL	
Risk assessment resi	due definiti	ion 2: sum of fluopyram	, fluopyram-be	enzamide (M25), and fluopy	ram- <i>E/Z</i> -olefine (M	02/M03), expresse	d as fluopyr	am	
Swine muscle	0.02	STMR	0.09	HR	0.02	STMR	0.09	HR	
Swine fat tissue	0.03	STMR \times CF (1.4)	0.11	HR \times CF (1.4)	0.03	STMR \times CF (1.4)	0.11	HR \times CF (1.4)	
Swine liver	0.26	STMR	0.44	HR	0.32 ^(a)	STMR	0.49 ^(a)	HR	
Swine kidney	0.02	STMR	0.07	HR	0.03 ^(a)	STMR	0.08 ^(a)	HR	
Bovine, equine muscle	0.02	STMR	0.09	HR	0.07 ^(a)	STMR	0.13 ^(a)	HR	
Bovine, equine fat tissue	0.03	STMR \times CF (1.4)	0.12	HR \times CF (1.4)	0.07 ^(a)	STMR \times CF (1.4)	0.16 ^(a)	HR \times CF (1.4)	
Bovine, equine liver	0.27	STMR	0.48	HR	0.51 ^(a) /0.27	STMR	0.71 ^(a)	HR	
Bovine, equine kidney	0.02	STMR	0.08	HR	0.06 ^(a) /0.02	STMR	0.11 ^(a)	HR	
Sheep, goat muscle	0.05	STMR	0.1	HR	0.07 ^(a) /0.05	STMR	0.13 ^(a)	HR	
Sheep, goat fat tissue	0.05	STMR \times CF (1.4)	0.12	HR \times CF (1.4)	0.07 ^(a)	STMR \times CF (1.4)	0.15 ^(a)	HR \times CF (1.4)	
Sheep, goat liver	0.37	STMR	0.53	HR	0.53 ^(a)	STMR	0.7 ^(a)	HR	
Sheep, goat kidney	0.04	STMR	0.09	HR	0.06 ^(a)	STMR	$0.11^{(a)}$	HR	
Poultry fat tissue	0.04	STMR \times CF (1.25)	0.08	HR \times CF (1.25)	0.07 ^(a)	STMR \times CF (1.25)	0.08 ^(a)	HR × CF (1.25)	
Poultry liver	0.20	STMR	0.24	HR	0.21 ^(a)	STMR	0.26 ^(a)	HR	
Cattle, horse milk	0.02	STMR	0.02	STMR	0.04 ^(a)	STMR	0.04 ^(a)	STMR	
Sheep, goat milk	0.02	STMR	0.02	STMR	0.05 ^(a)	STMR	0.05 ^(a)	STMR	
Birds eggs	0.10	STMR	0.13	HR	0.10 ^(a)	STMR	0.13 ^(a)	HR	



STMR: supervised trials median residue; HR: highest residue; CF: Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

n.r.: not registered for use on primary crops.

DF: drying factor.

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

(a): The STMR and HR values reflect the combined residues from both primary and rotational crops (sum of the HR/STMR values).

(b): The STMR and HR values reflect the residues from rotational crops.

D.3. Consumer risk assessment with consideration of the existing CXLs

		Opt	ion 1			Optio	n 2	
	Chroni	c risk assessment	Acute	risk assessment	Chronic	risk assessment	Acute risk assessment	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment	residue defi	nition: sum of fluopyra	am and fluopy	vram-benzamide (M25), expressed as flue	opyram		
Grapefruits	0.12	STMR	0.32	HR	0.12	STMR	0.32	HR
Oranges	0.15	STMR (CXL)	0.37	HR (CXL)	0.15/0.12	STMR (CXL/EU)	0.37/0.32	HR (CXL/EU)
Mandarins	0.29	STMR (tentative)	0.32	HR (tentative)	0.29	STMR (tentative)	0.32	HR (tentative)
Lemons	0.33	STMR (CXL)	0.51	HR (CXL)	0.33/0.29	STMR (CXL)/STMR (tentative)	0.51/0.32	HR (CXL)/HR (tentative)
Limes	0.33	STMR (CXL)	0.51	HR (CXL)	0.33/0.01	STMR (CXL)/EU MRL	0.51/0.01	HR (CXL)/EU MRL
Treenuts	0.01	STMR (CXL)	0.04	HR (CXL)	0.01/0.01	STMR (CXL/EU)	0.04/0.03	HR (CXL/EU)
Pome fruits	0.20	STMR	0.60	HR	0.20	STMR	0.60	HR
Apricots	0.33	STMR	0.95	HR	0.33	STMR	0.95	HR
Cherries (sweet)	0.56	STMR (tentative)	1.10	HR (tentative)	0.56	STMR (tentative)	1.10	HR (tentative)
Peaches	0.34	STMR	0.95	HR	0.34	STMR	0.95	HR
Plums	0.19	STMR	0.27	HR	0.19	STMR	0.27	HR
Table grapes	0.59	STMR	1.00	HR	0.59	STMR	1.00	HR
Wine grapes	0.58	STMR (CXL)	1.00	HR (CXL)	0.58/0.46	STMR (CXL)/	1.00/0.95	HR (CXL/EU)
Strawberries	0.43	STMR	1.01	HR	0.43	STMR	1.01	HR
Cane fruits	1.12	STMR	2.39	HR	1.12	STMR	2.39	HR
Blueberries	1.14	STMR	4.33	HR	1.14	STMR	4.33	HR
Cranberries, elderberries	0.78	STMR	2.10	HR	0.78	STMR	2.10	HR



		Opt	ion 1			Optio	n 2	
	Chron	ic risk assessment	Acute	risk assessment	Chronic	risk assessment	Acute r	isk assessment
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Currants, gooseberries	1.15	STMR (CXL)	4.90	HR (CXL)	1.15/0.79	STMR (CXL/EU)	4.90/2.10	HR (CXL/EU)
Rose hips	1.15	STMR (CXL)	4.90	HR (CXL)	1.15/0.69	STMR (CXL/EU)	4.90/1.58	HR (CXL)
Mulberries (black and white)	0.79	STMR	2.10	HR	0.79	STMR	2.10	HR
Bananas	0.19	STMR (tentative)	0.52	HR (tentative)	0.19	STMR (tentative)	0.52	HR (tentative)
Mangoes	0.02	STMR (CXL) × PF(0.11)	0.05	HR (CXL) × PF (0.11)	0.02/n.r.	STMR (CXL) \times PF (0.11)/n.r.	0.05	HR (CXL) × PF (0.11)/n.r.
Cherimoyas	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL	0.01	EU MRL
Potatoes	0.02	STMR (CXL)	0.08	HR (CXL)	0.02/0.03 ^(a)	STMR (CXL/EU)	0.08/0.07	HR (CXL/EU)
Cassava roots/ Arrowroots	n.r.	n.r.	n.r.	n.r.	0.02 ^(b)	STMR	0.02 ^(b)	HR
Sweet potatoes, yams	0.02	STMR	0.03	HR	0.04 ^(a)	STMR	0.05 ^(a)	HR
Beetroot	0.02	STMR	0.04	HR	0.07 ^(a)	STMR	0.1 ^(a)	HR
Carrots	0.09	STMR (CXL)	0.19	HR (CXL)	0.07 ^(a)	STMR	0.18 ^(a)	HR
other root and tuber vegetables except carrots, beetroots and sugar beets	0.05	STMR	0.13	HR	0.07 ^(a)	STMR	0.1 ^(a)	HR
Onions, garlic, shallots	0.01	STMR	0.04	HR	0.01	STMR	0.04	HR
Spring onions/green onions and Welsh onions	5.6	STMR (CXL/EU) \times CF (1.1)	8	HR (CXL/EU) \times CF (1.1)	5.6/0.56	$\frac{\text{STMR(CXL/EU)} \times \text{CF}}{(1.1)}$	8/1.32	HR (CXL/EU) × CF (1.1))
Tomatoes	0.14	STMR \times CF (1.3)	0.29	HR \times CF (1.3)	0.12	STMR	0.23	HR
Aubergines	0.11	STMR (CXL)	0.37	HR (CXL)	0.11/0.12	STMR (CXL/EU)	0.37/0.23	HR (CXL/EU)
Sweet peppers/bell peppers	0.14	STMR (CXL)	1.4	HR (CXL)	0.14/0.29	STMR (CXL/EU)	1.4/1.23	HR(CXL/EU)



		Opt	ion 1			Optio	on 2	
	Chron	ic risk assessment	Acute	risk assessment	Chronic	risk assessment	Acute r	isk assessment
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucumbers, gherkins, courgettes	0.14	STMR	0.30	HR	0.14	STMR	0.30	HR
Melons	0.19	STMR (tentative)	0.44	HR (tentative)	0.19	STMR (tentative)	0.44	HR (tentative)
Watermelons	0.05	STMR (tentative)	0.12	HR (tentative)	0.05	STMR (tentative)	0.12	HR (tentative)
Pumpkins, watermelons	0.05	STMR	0.12	HR	0.05	STMR	0.12	HR
Sweet corn	0.01	STMR	0.01	HR	0.01	STMR	0.01	HR
Broccoli	0.04	STMR	0.14	HR	0.06	STMR ^(a)	0.19	HR ^(a)
Cauliflowers	0.01	STMR	0.05	HR	0.03	STMR ^(a)	0.10	HR ^(a)
Brussels sprouts	0.04	STMR	0.14	HR	0.06	STMR ^(a)	0.19	HR ^(a)
Head cabbages	0.01	STMR	0.08	HR	0.04	STMR ^(a)	0.17	HR ^(a)
Chinese cabbages/ pe-tsai	0.36	STMR (tentative)	0.84	HR (tentative)	0.36	STMR (tentative)	0.84	HR (tentative)
Kales, kohlrabies, watercress	0.1	EU MRL	0.1	EU MRL	0.03 ^(b)	STMR	0.09 ^(b)	HR
Lamb's lettuces; Cresses; Roman rocket, purslanes, baby leaf crops	1.60	STMR	10.00	HR	1.60	STMR	10.00	HR
Lettuces	1.50	STMR	10.00	HR	1.50	STMR	10.00	HR
Escaroles, land cresses, red mustard, spinaches, chards/beet leaves	0.37	STMR (tentative)	0.98	HR (tentative)	0.37	STMR (tentative)	0.98	HR (tentative)
Witloofs/Belgian endives	0.12	STMR \times CF (1.2)	0.14	HR \times CF (1.2)	0.12	STMR \times CF (1.2)	0.14	HR \times CF (1.2)
Herbs, and edible flowers, except basil	0.38	STMR	3.65	HR	0.38	STMR	3.65	HR
Basil	19	STMR (CXL)	32	HR (CXL)	19/19.12	STMR (CXL/EU)	32/30.08	HR (CXL/EU)



		Optio	on 1			Optio	n 2	
	Chron	ic risk assessment	Acute	risk assessment	Chronic	risk assessment	Acute r	isk assessment
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beans/peas (with pods)	0.45	STMR (tentative) × CF (1.1)	1.65	HR (tentative) \times CF (1.1)	0.45	STMR (tentative) × CF (1.1)	1.65	HR (tentative) \times CF (1.1)
Beans/peas (without pods)	0.04	STMR (CXL) \times CF (1.3)	0.16	HR (CXL) \times CF (1.3)	0.04/0.05	STMR (CXL/EU) × CF (1.3)	0.16/0.09	HR (CXL/EU) \times CF (1.3)
Lentils (fresh)	0.05	STMR \times CF (1.3)	0.09	HR \times CF (1.3)	0.05	STMR \times CF (1.3)	0.09	HR \times CF (1.3)
Asparagus	0.01*	STMR	0.01*	HR	0.01*	STMR	0.01*	HR ^(a)
Celeries	3.03	STMR	9.74	HR	3.03	STMR	9.74	HR
Globe artichokes	1.27	STMR (tentative)	1.37	HR (tentative)	1.27	STMR (tentative)	1.37	HR (tentative)
Leeks	0.24	STMR (tentative) \times CF (1.1)	0.35	HR (tentative) \times CF (1.1)	0.24	STMR (tentative) \times CF (1.1)	0.35	HR (tentative) \times CF (1.1)
Lentils, peas (dry)	0.08	STMR (CXL) \times CF (1.4)	0.49	HR (CXL) \times CF (1.4)	0.08/0.05	STMR (CXL/EU) × CF (1.4)	0.49/0.05	HR (CXL/EU) \times CF (1.4)
Lupins (dry)	0.05	STMR \times CF (1.4)	0.49	HR \times CF (1.4)	0.05	STMR \times CF (1.4)	0.49	HR \times CF (1.4)
Peanuts/groundnuts	0.04	STMR (CXL) \times CF (1.2)	0.16	$\begin{array}{l} STMR \times CF(CXL) \\ (1.2) \end{array}$	0.04/0.01	STMR (CXL/EU) × CF (1.2)	0.16/0.01	$STMR \times CF(CXL/EU)$ (1.2)
Poppy seeds, mustard seeds	0.12	STMR \times CF (1.2)	0.31	HR \times CF (1.2)	0.12	STMR \times CF (1.2)	0.12	STMR \times CF (1.2)
Sunflower seeds	0.08	STMR	0.38	HR	0.08	STMR	0.08	STMR
Rapeseeds/canola seeds	0.40	STMR \times CF (1.2)	0.73	HR \times CF (1.2)	0.40	STMR \times CF (1.2)	0.40	STMR \times CF (1.2)
Soya beans	0.02	STMR (CXL) \times CF (1.2)	0.25	HR (CXL) \times CF (1.2)	0.02/0.01	$STMR \times CF(CXL/EU)$ (1.2)	0.25/0.01	$HR \times CF(CXL/EU)$ (1.2)
Cotton seeds	0.07	STMR \times CF (1.2)	0.56	HR \times CF (1.2)	0.07	STMR \times CF (1.2)	0.07	STMR \times CF (1.2)
Barley, oat grains	0.02	STMR	0.02	STMR	0.02	STMR	0.11	STMR
Buckwheat, millet, rice grains	n.r.	n.r.	n.r.	n.r.	n.r./0.01 ^(b)	n.r./STMR	n.r./0.01 ^(b)	n.r./STMR
Maize/corn grains	0.01	STMR (CXL)	0.02	STMR (CXL)	0.01/0.01	STMR (CXL/EU)	0.01/0.01	STMR (CXL/EU)
Rye grains	0.62	STMR (CXL)	2.7	HR (CXL)	0.62/0.01	STMR (CXL/EU)	0.62/0.01	STMR (CXL/EU)
Sorghum grains	0.36	STMR	0.36	STMR	0.36	STMR	0.36	STMR



	Option 1				Option 2			
Commodity	Chronic risk assessment		Acute risk assessment		Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat grains	0.19	STMR	0.19	STMR	0.19	STMR	0.19	STMR
Herbal infusions (dried flowers and leaves)	2.31	STMR	25.9	HR	2.31	STMR	25.9	HR
Herbal infusions (dried roots)	n.r.	n.r.	n.r.	n.r.	0. 1 ^(b)	STMRxdefault DF(10)	0. 1 ^(b)	HR xdefault DF(10)
Hops	12.13	STMR \times CF (1.2)	30.48	HR \times CF (1.2)	12.13	STMR \times CF (1.2)	30.48	HR \times CF (1.2)
Seed spices	22.50	STMR	29.60	HR	22.50	STMR	29.60	HR
Spices (roots or rhizome)	n.r.	n.r.	n.r.	n.r.	0.2 ^(b)	STMRxdefault DF(10)	0.5 ^(b)	HR
Sugar beet (root)	0.01	STMR (CXL)	0.01	HR (CXL)	0.02 ^(b)	STMR	0.05 ^(b)	HR
Chicory roots	0.1	EU MRL	0.1	EU MRL	0.1	EU MRL	0.03	EU MRL
Risk assessment r	esidue defi	nition 2: sum of fluopy	ram, fluopyra	am-benzamide (M25), a	nd fluopyram-E/2	Z-olefine (M02/M03), exp	ressed as fluopy	/ram
Swine muscle	0.51/0.02	STMR (CXL/EU)	1.0/0.09	HR (CXL/EU)	0.51/0.02	STMR (CXL/EU)	1.0/0.09	HR (CXL/EU)
Swine fat tissue	0.67/0.03	STMR (CXL/EU) \times CF (1.4)	1.5/0.08	HR (CXL) \times CF (1.4)	0.67/0.03	STMR (CXL/EU) \times CF (1.4)	1.5/0.11	HR (CXL/EU) \times CF (1.4)
Swine liver	3.8/0.26	STMR (CXL/EU)	7.4/0.44	HR (CXL/EU)	3.8/0.32 ^(a)	STMR (CXL/EU)	7.4/0.49 ^(a)	HR (CXL/EU)
Swine kidney	3.8/0.02	STMR (CXL/EU)	7.4/0.07	HR (CXL/EU)	3.8/0.03 ^(a)	STMR (CXL/EU)	7.4/0.08 ^(a)	HR (CXL/EU)
Bovine muscle	0.51/0.02	STMR (CXL/EU)	1.0/0.09	HR (CXL/EU)	0.51/0.07 ^(a)	STMR (CXL/EU)	1.0/0.13 ^(a)	HR (CXL/EU)
Bovine fat tissue	0.67/0.03	STMR (CXL/EU) \times CF (1.4)	1.5/0.08	HR (CXL/EU) \times CF (1.4)	0.67/0.07 ^(a)	STMR (CXL/EU) \times CF (1.4)	1.5/0.16 ^(a)	HR (CXL/EU) \times CF (1.4)
Bovine liver	3.80/0.27	STMR (CXL/EU)	7.4/0.49	HR (CXL/EU)	0.51 ^(a) /0.27	STMR (CXL/EU)	7.4/0.71 ^(a)	HR (CXL/EU)
Bovine kidney	3.80/0.02	STMR (CXL/EU)	7.4/0.08	HR (CXL/EU)	0.06 ^(a) /0.02	STMR (CXL/EU)	7.4/0.11 ^(a)	HR (CXL/EU)
Sheep, goat muscle	0.51/0.05	STMR (CXL/EU)	1.0	HR (CXL/EU)	0.51/0.07 ^(a)	STMR (CXL/EU)	1.0/0.13 ^(a)	HR (CXL/EU)
Sheep, goat fat tissue	0.67/0.05	STMR (CXL/EU) \times CF (1.4)	1.5	HR (CXL) \times CF (1.4)	0.67/0.07 ^(a)	STMR (CXL/EU) \times CF (1.4)	1.5/0.15 ^(a)	HR (CXL/EU) \times CF (1.4)
Sheep, goat liver	3.80/0.37	STMR (CXL/EU)	7.4	HR (CXL)	3.8/0.53 ^(a)	STMR (CXL/EU)	7.4/0.7 ^(a)	HR (CXL/EU)
Sheep, goat kidney	3.80/0.04	STMR (CXL/EU)	7.4	HR (CXL)	3.8/0.06 ^(a)	STMR (CXL/EU)	7.4/0.11 ^(a)	HR (CXL/EU)
Equine muscle	0.51	STMR (CXL)	1.0	HR (CXL)	0.51/0.07 ^(a)	(CXL/EU)STMR	1.0/0.08 ^(a)	HR (CXL/EU)

	Option 1				Option 2				
	Chroni	c risk assessment	Acute	risk assessment	Chronic	Chronic risk assessment		Acute risk assessment	
Commodity	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment	
Equine fat tissue	0.67	STMR (CXL) \times CF (1.4)	1.5	HR (CXL) \times CF (1.4)	0.67/0.21 ^(a)	STMR (CXL/EU) × CF (1.4)	1.5/0.26 ^(a)	HR (CXL/EU) \times CF (1.4)	
Equine liver	3.80	STMR (CXL)	7.4	HR (CXL)	3.8/0.04 ^(a)	STMR (CXL/EU)	7.4/0.04 ^(a)	HR (CXL/EU)	
Equine kidney	3.80	STMR (CXL)	7.4	HR (CXL)	3.8/0.05 ^(a)	STMR (CXL/EU)	7.4/0.05 ^(a)	HR (CXL/EU)	
Poultry muscle	0.19	STMR (CXL)	1.0	HR (CXL)	0.19/0.10 ^(a)	STMR (CXL/EU)	1.0/0.13 ^(a)	HR (CXL/EU)	
Poultry fat tissue	0.28	STMR (CXL) \times CF (1.25)	0.9	HR (CXL) × CF (1.25)	0.28/0.02 ^(a)	STMR (CXL/EU) × CF (1.3)	0.9/0.09 ^(a)	HR (CXL/EU) \times CF (1.3)	
Poultry liver	0.88	STMR (CXL)	3.0	HR	0.88/0.03 ^(a)	STMR (CXL/EU)	3/0.11 ^(a)	HR (CXL/EU)	
Cattle, horse milk	0.02	STMR	0.02	STMR	0.04 ^(a)	STMR (EU)	0.04 ^(a)	STMR (EU)	
Sheep, goat milk	0.02	STMR	0.02	STMR	0.05 ^(a)	STMR (EU)	0.05 ^(a)	STMR (EU)	
Birds eggs	0.46	STMR (CXL)	1.4	HR (CXL)	0.46/0.1 ^(a)	STMR (CXL/EU)	1.4/0.13 ^(a)	HR (CXL/EU)	

STMR: supervised trials median residue; HR: highest residue; CF: Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment; PF: peeling factor.

n.r.: not registered for use on primary crops.

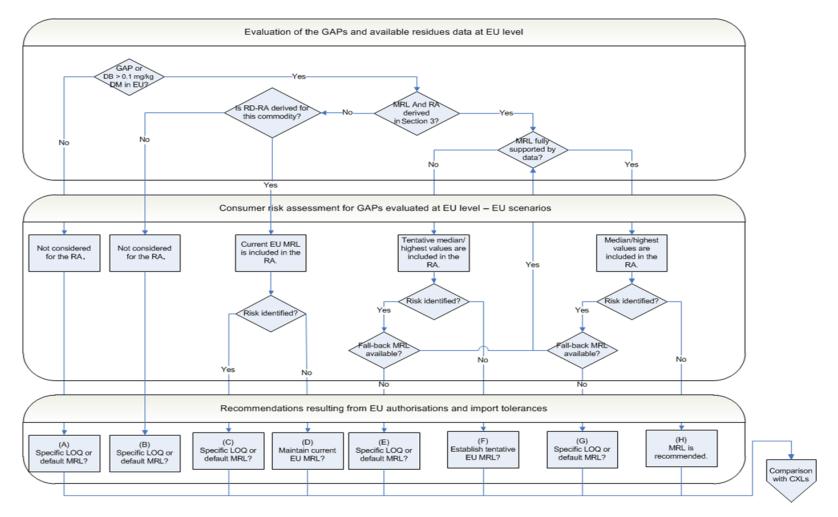
*: Indicates that the input value is proposed at the limit of quantification.

(a): The STMR and HR values reflect the residues from rotational crops.

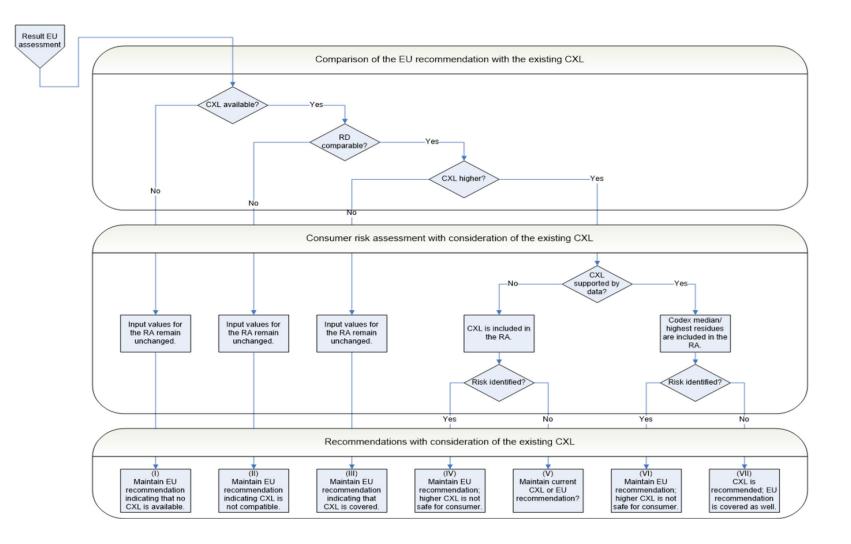
(b): The STMR and HR values reflect the combined residues from both primary and rotational crops (sum of the HR/STMR values).

(c): Tentative as no data on NEU authorised use, and therefore it is not known whether the combined primary and rotational crops use is higher than the STMR and HR values derived from the import tolerance.

Appendix E – **Decision tree for deriving MRL recommendations**









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	F F O
	KVDJTXBXMWJJEF-UHFFFAOYSA-N	
M02 fluopyram- <i>E</i> -olefine	<i>N</i> -{(<i>E</i>)-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 O
	(F)F ZBXOWVYWCBPUPM-AATRIKPKSA-N	
M03 fluopyram- <i>Z</i> -olefine	$N-{(Z)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl] vinyl}-2-(trifluoromethyl)benzamide$	F F C
	FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F) (F)F	NH
	ZBXOWVYWCBPUPM-WAYWQWQTSA-N	
M08 fluopyram-7-hydroxy	<i>N</i> -{2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]-2- hydroxyethyl}-2-(trifluoromethyl)benzamide	F
	Clc1cc(cnc1C(O)CNC(=O)c1ccccc1C(F)(F)F)C(F) (F)F	
	LZWQFTDQXOXRHG-UHFFFAOYSA-N	
M25	2-(trifluoromethyl)benzamide	F
fluopyram-benzamide	FC(F)(F)c1ccccc1C(N)=O	FF O
	QBAYIBZITZBSFO-UHFFFAOYSA-N	NH ₂
M40 fluopyram-pyridyl-acetic	[3-chloro-5-(trifluoromethyl)pyridin2-yl]acetic acid	F F
acid fluopyram-PAA	OC(=O)Cc1ncc(cc1Cl)C(F)(F)F	O N → F
	ZCMWOZJSLGQSQV-UHFFFAOYSA-N	HO
M42 fluopyram pyridyl-	$1-O-\{[3-chloro-5-(trifluoromethyl)pyridin-2-yl] a cetyl\}-\alpha-D-glucopyranose$	HO,
acetic-acid-glycoside	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	ё́н сі

Appendix F – Used compound codes



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

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 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).