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Modification of the existing maximum residue levels for fluopyram in herbal infusions from leaves, herbs and flowers

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landesanstalt fuer Landwirtschaft und Gartenbau Sachsen-Anhalt submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance fluopyram in certain herbal infusions. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the herbal infusions from leaves and herbs. A risk management decision needs to be taken whether the proposed MRL is considered appropriate for herbal infusions from flowers. Adequate analytical methods for enforcement are available to control the residues of fluopyram in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the dietary intake of residues resulting from the use of fluopyram according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: fluopyram, herbal infusions, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landesanstalt fuer Landwirtschaft und Gartenbau Sachsen-Anhalt submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance fluopyram in herbal infusions from flowers, leaves and herbs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 20 June 2019. To accommodate for the intended uses of fluopyram, the EMS proposed to raise the existing MRLs for herbal infusions from flowers and leaves and herbs from 0.1 to 40 mg/kg.

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

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

The metabolism of fluopyram in primary crops following foliar application was investigated in the fruit (grapes, peppers), root (potatoes) and pulses/oilseeds (beans) crop groups and the residue definition was proposed as 'fluopyram' for enforcement and as 'sum of fluopyram and fluopyram-benzamide (M25) expressed as fluopyram' for risk assessment purposes. The metabolism of fluopyram in rotational crops and the effect of processing on the nature of the residues were assessed in the framework of the peer review and it was concluded that the residue definitions set on primary crops are applicable to rotational crops and processing commodities.

For the use supported in this MRL application, EFSA concludes that the metabolism of fluopyram is sufficiently addressed and that the derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)).

Studies investigating the effect of processing on the nature of fluopyram (hydrolysis studies) demonstrated that the active substance is stable.

Based on the available information, EFSA could not exclude that the use of fluopyram according to the proposed Good Agricultural Practice (GAP) will result in significant residues in rotational corps. Therefore, Member States should consider the need to setting specific risk mitigation measures to avoid the presence of fluopyram residues in rotational crops.

Residues of fluopyram in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.

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

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo).

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) value derived for herbal infusions; for the remaining commodities, the MRLs, the STMR values derived in previous assessments of EFSA or derived by JMPR (for crops for which the Codex maximum residue limits (CXLs) were taken over in the European Union (EU) legislation) have been used to estimate the dietary exposure, as appropriate.

The estimated long-term dietary intake accounted for up to 96.2% of the ADI for Dutch children. Herbal infusions accounted for maximum 0.8% of the ADI.

Since no consumption data are available for herbal infusions from flowers and from leaves and herbs, EFSA calculated the short-term exposure for a scenario assuming a child of 10 kg body weight consumes herbal infusions from a portion of 4 g (corresponding to one tea bag). The calculated short-term (acute) exposure for this scenario accounted for 2.1% of the ARfD.

EFSA concluded that the proposed use of fluopyram on herbal infusions from flowers and leaves and herbs will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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

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

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
0631000	Herbal infusions from flowers	0.1	40 Further risk management considerations required	No specific residue trials have been provided. EFSA derived an MRL proposal for further risk management consideration, by extrapolation from fresh herbs, applying a generic dehydration factor of 7. Since this extrapolation is not explicitly reported in the EU guidance document on extrapolations, risk managers should discuss whether this extrapolation is acceptable
0632000	Herbal infusions from leaves and herbs	0.1	40	The submitted data are sufficient to derive an MRL proposal for the NEU/SEU use. The MRL proposal is derived by extrapolation from trials on fresh herbs (chervil, parsley, sage and savoury), applying a generic dehydration factor of 7. The extrapolation from fresh herbs to herbal infusions from leaves and herbs is in line with the EU extrapolation guidance document Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for fluopyram in herbal infusions from flowers, leaves and herbs. The detailed description of the intended uses of fluopyram, which are the basis for the current MRL application, is reported in Appendix A.

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

Fluopyram was evaluated in the framework of Directive 91/414/EEC[1] with Germany designated as rapporteur Member State (RMS); the representative uses assessed were foliar applications on grapes, tomatoes and strawberries. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013). Fluopyram was approved[2] for the use as fungicide on 1 February 2014.

The EU MRLs for fluopyram are established in Annex III of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing. EFSA has issued several reasoned opinions on the modification of MRLs for fluopyram (EFSA, 2011, 2014, 2016, 2017, 2019); the proposals from these reasoned opinions have been considered in the MRL legislation. In addition, certain Codex maximum residue limits (CXLs) were implemented in the EU MRL legislation.[4]

In accordance with Article 6 of Regulation (EC) No 396/2005, Landesanstalt fuer Landwirtschaft und Gartenbau Sachsen-Anhalt submitted an application to the competent national authority in Germany (evaluating Member State, EMS) on 18 July 2016 to modify the existing maximum residue levels (MRLs for the active substance fluopyram in herbal infusions (from flowers and from leaves and herbs)). The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 20 June 2019 (Germany, 2019). To accommodate for the intended uses of fluopyram, the EMS proposed to raise the existing MRLs for herbal infusions from 0 to 40 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2019), the DAR and its addendum (Germany, 2011, 2012) prepared under Council Directive 91/414/EEC, the Commission review report on fluopyram (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance fluopyram (EFSA, 2013), JMPR reports (FAO, 2013, 2015, 2016, 2017, 2018) as well as the conclusions from previous EFSA opinions on fluopyram under Article 10 of EU Regulation 396/2005 (EFSA, 2011, 2014, 2016, 2017, 2019).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[6].

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] Commission Implementing Regulation (EU) No 802/2013 of 22 August 2013 approving the active substance fluopyram, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 225, 23.8.2013, p. 13–16.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. **OJ** L 70, 16.3.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN

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

[6] 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.

The evaluation report submitted by the EMS (Germany, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

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 has been investigated in the framework of EU pesticides peer review in primary crops in three crop groups, i.e. fruit, root and pulses/oilseeds crops using the radiolabelled active substance (labelled on the phenyl or the pyridyl moiety) (EFSA, 2013). After foliar application, fluopyram constitutes the major component of the radioactive residues in grapes, potato leaves and bean leaves. Fluopyram is however observed in lower proportions in potato tubers and beans (fresh and dry), where the residues are mostly composed of the metabolites resulting from the cleavage of the parent molecule, the fluopyram-benzamide (M25), fluopyram pyridyl-acetic acid (M40) and fluopyram pyridyl-carboxilic acid (M43). Similar metabolic profiles were observed in pepper following drip irrigation. In addition, metabolite M42 was detected.

1.1.2. Nature of residues in rotational crops

Since crops under consideration can grow in rotation with other crops and due to the high persistence of fluopyram in soils (DT_{50} > 300 days, DT_{90} > 1,000 days) (EFSA, 2013), the possible occurrence of residues in rotational crops had to be investigated. The metabolism of fluopyram in rotational crops (root, leafy and cereals crops categories) was assessed in the framework of the EU peer review process. The metabolism in rotational crops was shown to be similar to primary crop metabolism (EFSA, 2013).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of residues was investigated in the framework of the EU pesticides peer review. Fluopyram and fluopyram-benzamide (metabolite M25) were found to be stable under standard hydrolysis conditions (EFSA, 2013).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fluopyram residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2013). An analytical method using gas chromatography with tandem mass spectrometry (GC–MS/MS) detection was concluded to be sufficiently validated for the determination of fluopyram residues in high acid (orange), high oil (oilseed rape), high water (lettuce), dry/protein (pea) and dry/starch (wheat) commodities at the validated limit of quantification (LOQ) of 0.01 mg/kg.

Analytical methods for difficult commodities such as herbal infusions are not available. However, considering that sufficiently validated methods are available for products with high oil content and for commodities – matrices which have similar characteristics for residue analysis with the commodities under assessment – EFSA considers that the available methods are appropriate for routine enforcement of the proposed MRL for herbal infusions.

1.1.5. Storage stability of residues in plants

The stability of fluopyram and its benzamide metabolite (metabolite M25) in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2013) and additional studies were assessed in the previous EFSA reasoned opinions (EFSA, 2014, 2016). Based on the available data, it was concluded that residues of fluopyram and its metabolite M25 are stable for at least 3 years in high water (lettuce, cabbage), high starch (wheat), high protein (dry pea), high oil (rapeseeds) and in high acid matrices (orange), when stored at −18°C (EFSA, 2014).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies on primary and rotational crops, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation

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

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

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition as well as the residue definitions proposed by JMPR. The residue definitions proposed from primary crops are also applicable to processed commodities.

Based on the available information, EFSA concluded that these residue definitions are appropriate and applicable for the intended use in crops used to produce herbal infusions.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

a) Herbal infusions from flowers and leaves and herbs

To support the intended use of fluopyram in herbal infusions from flowers and leaves and herbs (application rate 1 × 200 g a.s./ha, preharvest interval (PHI) 14 days), the applicant provided in total 11 northern European (NEU) residue trials performed in different crops classified in the group of fresh herbs (two trials in chervil, four in parsley, three in sage and two in savoury). The trials were conducted in different locations in Germany in 2011–2013.

The samples were analysed for the parent compound fluopyram and the metabolite fluopyram-benzamide (M25) achieving an LOQ of 0.01 mg/kg per analyte. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Samples in the residue studies were stored deep-frozen within 24 h after sampling for 36 months; therefore, it is concluded that the residue data are valid with regard to storage stability.

According to the EU guidance document (European Commission, 1997b), any representative of the subgroup herbs and edible flowers (0256000) is suitable for extrapolation to the subgroup of herbal infusions from leaves and herbs, applying appropriate dehydration factors to recalculate the residues measured in fresh herbs to the dry products classified in the subgroup of herbal infusions from leaves and herbs.

In the absence of specific processing studies for dried herbs, a generic dehydration factor of 7 (assuming a dry matter content of 14%) was applied to recalculate residue concentrations measured in fresh herbs to dried herbs.

Overall, the studies were considered appropriate to derive an MRL proposal of 40 mg/kg for herbal infusions from leaves and herbs (crops classified under the code 0632000) using the OECD calculator (OECD, 2011).

b) Herbal infusions from flowers

For setting MRLs for the subgroup of herbal infusions from flowers – according to the EU guidance document on extrapolation (European Commission, 2017) – residue trials on either crops classified under subgroup herbal infusions from flowers (0631000) or herbal infusions from leaves and herbs (0632000) can be used.

Although no residue trials are available for herbal infusions from flowers or from leaves, the use of residue trials on fresh herbs, taking into account a dehydration factor, could be considered by risk managers as appropriate.

1.2.2. Magnitude of residues in rotational crops

The confined rotational crop study previously evaluated (EFSA, 2013) has shown that residues of fluopyram cannot be excluded in rotational crops.

A default MRL of 0.1 mg/kg was recommended by the peer review (EFSA, 2013) for root and leafy crops and of 0.01 mg/kg for cereals, oilseed grown in rotation with crops treated with fluopyram. These proposals were derived from the field studies conducted at the exaggerated dose rate of 500 g/ha, representative for the predicted plateau concentration in soil (0.08 mg/kg soil, 20 cm depth) reached after 10 years of consecutive application (EFSA, 2013). In addition, a default MRL of 0.2 mg/kg was proposed for spinaches grown in rotation to crops treated with fluopyram (EFSA, 2014).

New rotational field studies were not submitted in the framework of the current application.

The GAP for the crops under consideration is comparable with the previously assessed uses. Thus, the new uses will not have an impact on the residues in succeeding crops grown on fields where the crops under consideration were treated according to the intended GAP.

Considering that the residue level in the crops under consideration (primary crop treatment) is significantly higher than the residues found in the rotational crops, even if a dehydration factor is taken into account, the uptake of residues from the soil will not significantly change the residue concentration for herbal infusions grown in crop rotation on fields where fluopyram was used on previous crops.

1.2.3. Magnitude of residues in processed commodities

New studies to address the effect of processing on the magnitude of fluopyram residues were not submitted in the framework of the current assessment. However, numerous processing studies were evaluated in previous assessments (EFSA, 2011, 2013) and processing factors (PFs) were proposed for a wide range of processed products.

Since herbal infusions are usually consumed only after processing (preparation of infusions with boiling water), it would be desirable to quantify the residues consumed after processing. However, considering the low contribution to the dietary intake, these studies are not essential in view of refinement of the risk assessment.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for herbal infusions from leaves and herbs (see Appendix B.1.2.1). EFSA also derived an MRL proposal for herbal infusions from flowers for further risk management consideration.

In Section 3, EFSA assessed whether the expected residues on herbal infusions resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

Residues of fluopyram in commodities of animal origin were not assessed in the framework of this application, since herbal infusions from flowers and from leaves and herbs are not fed to livestock.

3. Consumer risk assessment

The toxicological reference values for fluopyram used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU pesticides peer review (EFSA, 2013); the toxicological reference values were formally approved by Member States (European Commission, 2013). The metabolites (M02, M03 and M25) included in the risk assessment residue definitions for plant and animal commodities are considered to be of similar toxicity/not more toxic than the parent compound.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. The PRIMo model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2007).

The long-term exposure assessment was performed, taking into account the supervised trials median residue (STMR) value derived for herbal infusions[7]; for the remaining commodities, the STMR values derived in previous assessments of EFSA (2011, 2014, 2016, 2017, 2019) were selected as input values. For crops for which the CXLs were taken over in the EU legislation, the related STMR values derived by JMPR have been used to estimate the dietary exposure. For the remaining commodities, the MRLs established in most recent MRL regulation were used. The complete list of input values is presented in Appendix D.1.

The estimated long-term dietary intake accounted for up to 96.2% of the ADI for Dutch children. Herbal infusions accounted for maximum 0.8% of the ADI. EFSA concludes that the long-term intake of residues of fluopyram resulting from the existing and the intended use is unlikely to present a risk to consumer health.

[7] Since detailed consumption data are not available for the crops under consideration, EFSA used the STMR value to calculate the exposure for the whole group of commodities listed under herbal infusions, including herbal infusions from flowers, from leaves and herbs and from roots.

The short-term exposure assessment was performed in accordance with the internationally agreed methodology. Since no consumption data are available for herbal infusions from flowers and from leaves and herbs, EFSA calculated the short-term exposure for a scenario assuming a child of 10 kg body weight consumes herbal infusions from a portion of 4 g; no PFs were taken into account assuming a complete transfer of residues in the dried herbal infusions to the herbal tea. The calculated short-term (acute) exposure for this scenario accounted for 2.1% of the ARfD.

Based on these calculations, EFSA concluded that the proposed use of fluopyram on the crop assessed is unlikely to pose a risk for the consumers.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for herbal infusions from flowers and from leaves and herbs. Additional risk management considerations are however required for herbal infusions from flowers.

EFSA concluded that the proposed use of fluopyram on crops used for producing herbal infusions (listed under crop codes 0631000 and 0632000), will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS/MS	gas chromatography with tandem mass spectrometry

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern Europe
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
WHO	World Health Organization

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

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Chamomile	NEU	F	Fungal leaf spot diseases, powdery mildew	SC	200 g/L	Foliar treatment – broadcast spraying	At the beginning of infestation and/or when first symptoms become visible, from 50% ground coverage onwards	1	n.a.	200–400		200	g/ha	14	
Rose	NEU	F	Fungal leaf spot diseases, powdery mildew	SC	200 g/L	Foliar treatment – broadcast spraying	At the beginning of infestation and/or when first symptoms become visible, from 50% ground coverage onwards	1	n.a.	200–400		200	g/ha	14	Use requested for herbal infusions from several crops (e.g. 0631030-009, -022, -024, -031, -036) Extrapolation to the whole group to set a group MRL

Crop and/or situation	NEU, SEU, MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			Unit	PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate			
Strawberry leaves	NEU	F	Fungal leaf spot diseases, powdery mildew	SC	200 g/L	Foliar treatment – broadcast spraying	At the beginning of infestation and/or when first symptoms become visible, from 50% ground coverage onwardbs	1	n.a.	200–400		200	g/ha	14	Use requested for herbal infusions from several crops (e.g. 0632010-001, -017, -021, -060, -065, -077) Extrapolation to whole group to set a group MRL

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate; MRL: maximum residue level.
(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 formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Grapes	Foliar, 1× 100 + 2× 200 g/ha	18–19	Radiolabelled active substance: phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: EFSA (2013)
	Fruit crops	Peppers	Drip irrigation, 5 and 20 mg/plant	33–97	Radiolabelled active substance: phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: EFSA (2013)
	Root crops	Potatoes	Foliar, 3× 167 g/ha	51	Radiolabelled active substance: phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: EFSA (2013)
	Pulses/ oilseeds	Beans	Foliar, 2× 250 g/ha	4–29	Radiolabelled active substance: phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: EFSA (2013)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root	Turnips	Bare soil, 1× 534 g/ha	30, 139, 280	Phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: Germany (2011; EFSA (2013)
	Leafy	Swiss chard	Bare soil, 1× 534 g/ha	30, 139, 280	Phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: Germany (2011); EFSA (2013)
	Cereal (small grain)	Wheat	Bare soil, 1× 534 g/ha	30, 139, 280	Phenyl-UL-^{14}C and pyridyl-2,6-^{14}C Reference: Germany (2011); EFSA (2013)
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2013)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2013)
	Sterilisation (20 min, 120°C, pH 6)		Yes		EFSA (2013)
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	Yes
Rotational crop and primary crop metabolism similar?	Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring (RD-Mo)	Fluopyram
Plant residue definition for risk assessment (RD-RA)	Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, GC–MS, LOQ 0.01 mg/kg (EFSA, 2013; EFSA, 2016; EFSA, 2019)

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry LOQ: limit of quantification.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability period**		**Compounds covered**	**Comment/ Source**
				Value	**Unit**		
	High water content	Lettuces, cabbages	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
	High oil content	Rapeseeds	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
	Dry/High starch	Dry peas/wheat	−18°C	36	Months	Fluopyram, M25	EFSA (2014)
	High acid content	Oranges	−18°C	36	Months	Fluopyram, M25	EFSA (2014)

B.1.2. Magnitude of residues in plants

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

Commodity	Region/ indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Herbal infusions from leaves and herbs	NEU	Chervil, fresh: Mo: 0.083, 0.38 RA: 0.084, 0.39 Parsley, fresh: Mo: 0.31, 0.39, 0.54, 0.64 RA: 0.32, 0.40, 0.55, 0.67 Sage, fresh: Mo: 0.13, 0.31, 0.32 RA: 0.14, 0.32, 0.33 Savoury, fresh: Mo: 0.11, 3.6 RA: 0.12, 3.7 All trials on fresh herbs; results recalculated to dried products: Mo: 0.58, 0.77, 0.91, 2× 2.17, 2.24, 2.66, 2.73, 3.78, 4.48, 25.2 RA: 0.59, 0.84, 0.98, 2× 2.24, 2.31, 2.73, 2.8, 3.85, 4.69, 25.9	Residue trials on chervil, parsley, sage and savoury compliant with GAP for herbal infusions from flowers and leaves and herbs Extrapolation from fresh herbs to herbal infusions from leaves and herbs is possible, after correction of results by applying a dehydration factor (default dehydration factor) MRL OECD: 32.43/40	40	Mo: 25.2 RA: 25.9	Mo: 2.24 RA: 2.31	1.03
Herbal infusions from flowers	NEU	See comment	No residue trials available for crops classified under herbal infusions from flowers EFSA derived the MRL proposal and the risk assessment values by extrapolation from herbal infusions from leaves and herbs (see above)	**40**	Mo: 25.2 RA: 25.9	Mo: 2.24 RA: 2.31	1.03

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development.
(a): Region/Indoor: NEU: outdoor trials performed in northern Europe.
(b): Highest residue.
(c): Supervised trials median residue.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Besidues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes
Residues in rotational and succeeding crops expected based on field rotational crop study?	Yes A default MRL of 0.1 mg/kg was recommended by the peer review (EFSA, 2013) for root and leafy crops and of 0.01 mg/kg for cereals, oilseed grown in rotation with crops treated with fluopyram. These proposals were derived from the field studies conducted at the exaggerated dose rate of 500 g/ha, representative for the predicted plateau concentration in soil (0.08 mg/kg soil, 20 cm depth) reached after 10 years of consecutive application (EFSA, 2013) In addition, a default MRL of 0.2 mg/kg was proposed for spinaches grown in rotation to crops treated with fluopyram (EFSA, 2014) New rotational field studies were not submitted in the framework of the current application

MRL: maximum residue level.

B.1.2.3. Processing factors

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

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD	0.5 mg/kg bw (European Commission, 2013)
Highest IESTI, according to EFSA PRIMo	2.1% of ARfD
Assumptions made for the calculations	Since no consumption data are available for herbal infusions from flowers and from leaves and herbs, EFSA calculated the short-term exposure for a scenario assuming a child of 10 kg body weight consumes herbal infusions from a portion of 4 g; no processing factors were taken into account assuming a complete transfer of residues in the dried herbal infusions to the herbal tea Calculations performed with PRIMo revision 2

ADI	0.012 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	96.2% ADI (Dutch child) Contribution of herbal infusions: 0.83% of ADI
Assumptions made for the calculations	The calculation is based on the STMR value for herbal infusions; for the remaining commodities, the STMR values derived in previous assessments of EFSA or the STMR values derived by JMPR (for crops for which the CXLs were taken over in the EU legislation) were used to estimate the dietary exposure. For the remaining commodities, the MRLs established in most recent MRL regulation were used Calculations performed with PRIMo revision 2

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue; CXL: codex maximum residue limit; MRL: maximum residue level.

B.4. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: fluopyram				
0631000	Herbal infusions from flowers	0.1	40 Further risk management considerations required	No specific residue trials have been provided. EFSA derived an MRL proposal for further risk management consideration, by extrapolation from fresh herbs, applying a generic dehydration factor of 7. Since this extrapolation is not explicitly reported in the EU guidance document on extrapolations, risk managers should discuss whether this extrapolation is acceptable
0632000	Herbal infusions from leaves and herbs	0.1	40	The submitted data are sufficient to derive an MRL proposal for the NEU/SEU use. The MRL proposal is derived by extrapolation from trials on fresh herbs (chervil, parsley, sage and savoury), applying a generic dehydration factor of 7. The extrapolation from fresh herbs to herbal infusions from leaves and herbs is in line with the EU extrapolation guidance document Risk for consumers unlikely

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Appendix C – Pesticide Residue Intake Model (PRIMo)

Fluopyram			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.012**	ARfD (mg/kg bw):	**0.5**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2013**	Year of evaluation:	**2013**

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI minimum – maximum	
12	96
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	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	pTMRLs at LOQ (in % of ADI)
96.2	NL child	29.3	Milk and cream	12.2	Apples	6.6	Swine: Meat	0.2
81.9	DE child	23.2	Apples	14.3	Milk and cream	6.3	Table grapes	0.2
78.3	FR toddler	39.6	Milk and cream	5.7	Bovine: Meat	5.0	Apples	0.1
69.1	UK Infant	38.7	Milk and cream	8.4	Sugar beet (root)	5.2	Birds' eggs	0.2
60.7	UK Toddler	20.7	Milk and cream	19.1	Sugar beet (root)	3.4	Birds' eggs	0.1
60.6	WHO Cluster diet B	7.9	Lettuce	5.1	Tomatoes	4.2	Poultry: Meat	1.0
59.1	ES child	12.5	Milk and cream	9.1	Lettuce	6.0	Bovine: Meat	0.3
56.9	IE adult	7.2	Sheep: Liver	5.3	Basil	3.0	Sweet potatoes	0.8
49.8	FR infant	25.7	Milk and cream	4.8	Apples	2.5	Bovine: Meat	0.1
46.1	WHO regional European diet	8.3	Lettuce	5.4	Swine: Meat	4.8	Milk and cream	0.3
39.8	DK child	12.6	Milk and cream	4.5	Apples	4.0	Bovine: Liver	0.1
39.4	ES adult	11.7	Lettuce	5.0	Milk and cream	3.2	Bovine: Meat	0.2
38.2	WHO cluster diet E	4.3	Poultry: Meat	3.0	Bovine: Meat	3.0	Milk and cream	0.3
37.7	WHO Cluster diet F	6.6	Lettuce	4.9	Swine: Meat	4.0	Milk and cream	0.1
33.4	NL general	6.6	Milk and cream	3.9	Swine: Meat	3.0	Bovine: Meat	0.1
31.2	SE general population 90th percentile	12.4	Milk and cream	3.4	Birds' eggs	2.6	Bananas	0.2
28.6	WHO cluster diet D	5.0	Milk and cream	2.5	Bovine: Meat	1.7	Poultry: Meat	0.3
26.1	FR all population	4.2	Other lettuce and other salad plants	2.7	Milk and cream	2.6	Poultry: Meat	0.1
22.9	LT adult	4.1	Swine: Meat	4.0	Milk and cream	3.6	Apples	0.0
22.3	IT adult	8.3	Lettuce	3.5	Other lettuce and other salad plants	1.9	Tomatoes	0.2
21.5	IT kids/toddler	6.4	Lettuce	2.4	Other lettuce and other salad plants	2.4	Tomatoes	0.2
19.7	UK vegetarian	3.3	Milk and cream	3.1	Sugar beet (root)	3.1	Lettuce	0.1
18.0	DK adult	5.4	Milk and cream	2.4	Bovine: Meat	1.7	Bovine: Liver	0.1
17.2	UK Adult	3.3	Sugar beet (root)	3.0	Milk and cream	2.6	Lettuce	0.1
16.4	FI adult	5.7	Milk and cream	1.7	Lettuce	1.6	Other other small fruit & berries	0.0
13.0	PT General population	2.0	Apples	1.5	Tomatoes	1.4	Table grapes	0.2
11.6	PL general population	3.9	Apples	1.6	Table grapes	1.5	Tomatoes	0.1

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Fluopyram is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations				Acute risk assessment/adults/general population – refined calculations			

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1 *)		**)	**IESTI 2** *)		**)	**IESTI 1** *)		**)	**IESTI 2** *)		**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
2.1	Camomille flowers	25.9/-	2.1	Camomille flowers	25.9/-						
No of critical MRLs (IESTI 1) ---			**No of critical MRLs (IESTI 2)** ---								

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
***)						***)					
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
22.4	Elderberry juice	7/-				1.2	Orange juice	0.6/-			
14.2	Cuurant juice	7/-				1.2	Wine	1.5/-			
12.0	Raspberries juice	5/-				0.8	Bread/pizza	0.9/-			
10.2	Blueberries	7/-				0.8	Apple juice	0.6/-			
9.9	Grape juice	1.5/-				0.6	Peach preserved with syrup	1.5/-			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:

For Fluopyram IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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

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

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

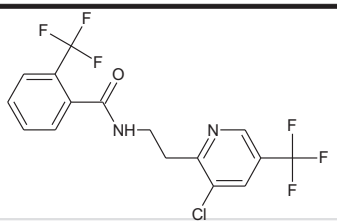
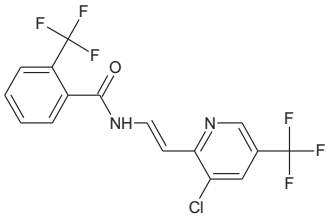
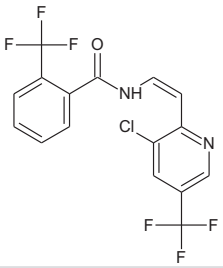
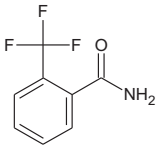
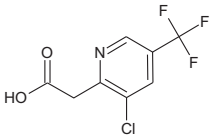
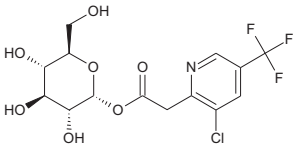
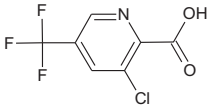
Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Sum of fluopyram and fluopyram-benzamide (M25), expressed as fluopyram						
Herbal infusions	40	Proposed MRL	2.31	STMR	25.9	HR
Grapefruits	0.4	FAO (2017)	0.14	STMR-RAC	Acute risk assessment was performed only for the commodities under assessment	
Oranges	0.6	FAO (2017)	0.15	STMR-RAC		
Lemons	1	FAO (2017)	0.325	STMR-RAC		
Limes	1	FAO (2017)	0.325	STMR-RAC		
Mandarins	0.6	FAO (2017)	0.15	STMR-RAC		
Tree nuts (except coconuts)	0.05	EFSA (2011)	0.011	STMR-RAC		
Coconuts	0.04	FAO (2013)	0.01	STMR-RAC		
Pome fruit	0.6/0.5	EFSA (2011)	0.231	STMR-RAC		
Apricots	1.5	EFSA (2016)	0.36	STMR-RAC		
Cherries (sweet)	2	FAO (2017)	0.57	STMR-RAC		
Peaches	1.5	EFSA (2014)	0.26	STMR-RAC		
Plums	0.5	EFSA (2014)	0.2	STMR-RAC		
Table grapes	1.5	EFSA (2011)	0.6	STMR-RAC		
Wine grapes	1.5	EFSA (2011)	0.065	STMR-RAC		
Strawberries	2	EFSA (2011)	0.44	STMR-RAC		
Cane fruit	5	FAO (2017)	0.83	STMR-RAC		
Blueberries	7	FAO (2017)	1.15	STMR-RAC		
Cranberries	3	EFSA (2014)	0.83	STMR-RAC		
Currants (red, black and white)	7	FAO (2017)	1.15	STMR-RAC		
Gooseberries (green, red and yellow)	7	FAO (2017)	1.15	STMR-RAC		
Rose hips	7	FAO (2017)	1.15	STMR-RAC		
Mulberries (black and white)	7	FAO (2017)	1.15	STMR-RAC		
Elderberries	7	FAO (2017)	1.15	STMR-RAC		
Bananas	0.8	FAO (2013)	0.175	STMR-RAC		
Mangoes	1	FAO (2017)	0.02	STMR-RAC		
Potatoes	0.15	FAO (2017)	0.021	STMR-RAC		
Root and tuber vegetables (except carrots)	0.3	EFSA (2014)	0.1	STMR-RAC		
Carrots	0.4	FAO (2013)	0.09	STMR-RAC		
Bulb vegetables (except spring onions)	0.1	EFSA (2014)	0.02	STMR-RAC		
Spring onions/green onions and Welsh onions	15	FAO (2017)	5.1	STMR-RAC		
Tomatoes	0.9	EFSA (2011)	0.2	STMR-RAC		
Sweet peppers/bell peppers	3	FAO (2017)	0.14	STMR-RAC		
Aubergines/egg plants	0.9	EFSA (2014)	0.2	STMR-RAC		

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Cucurbits - edible peel	0.5	EFSA (2011)	0.15	STMR-RAC		
Cucurbits - inedible peel	0.4	EFSA (2011)	0.0117	STMR-RAC		
Cauliflowers	0.2	EFSA (2011)	0.0117	STMR-RAC		
Broccoli	0.3	EFSA (2019)	0.04	STMR-RAC		
Brussels sprouts	0.3	FAO (2014)	0.06	STMR-RAC		
Head cabbages	0.3	EFSA (2011)	0.03	STMR-RAC		
Chinese cabbages/pe-tsai	0.7	EFSA (2011)	0.18	STMR-RAC		
Lettuces (except escaroles)	15	EFSA (2011)	2.63	STMR-RAC		
Spinaches	0.2	EFSA (2014)	0.09	STMR-RAC		
Purslanes	20	EFSA et al. (2017, 2019)	1.61	STMR-RAC		
Chards/beet leaves	0.2	EFSA (2016)	0.2	STMR-RAC		
Witloofs/Belgian endives	0.3	EFSA (2016)	0.14	STMR-RAC		
Herbs (except basil)	8	EFSA (2016)	1.19	STMR-RAC		
Basil and edible flowers	70	FAO (2017)	19	STMR-RAC		
Beans (with pods)	1	FAO (2015)	0.2	STMR-RAC		
Beans (without pods)	0.2	FAO (2015)	0.03	STMR-RAC		
Peas (with pods)	1.5	EFSA (2016)	0.15	STMR-RAC		
Peas (without pods)	0.2	FAO (2015)	0.03	STMR-RAC		
Lentils (fresh)	0.2	EFSA (2016)	0.05	STMR-RAC		
Globe artichokes	0.5	EFSA (2011)	0.18	STMR-RAC		
Leeks	0.7	EFSA (2011)	0.14	STMR-RAC		
Pulses	0.4	EFSA (2011)	0.045	STMR-RAC		
Linseeds	0.3	EFSA (2014)	0.12	STMR-RAC		
Peanuts/groundnuts	0.2	FAO (2017)	0.033	STMR-RAC		
Sesame seeds	0.3	EFSA (2016)	0.12	STMR-RAC		
Sunflower seeds	0.7	FAO (2017)	0.066	STMR-RAC		
Rapeseeds/canola seeds	1	FAO (2014)	0.33	STMR-RAC		
Soya beans	0.3	FAO (2017)	0.0205	STMR-RAC		
Cotton seeds	0.8	FAO (2017)	0.0585	STMR-RAC		
Other minor oil seeds	0.3	EFSA (2016)	0.12	STMR-RAC		
Barley	0.2	EFSA (2016)	0.03	STMR-RAC		
Buckwheat and other pseudo-cereals	0.2	EFSA (2016)	0.03	STMR-RAC		
Maize/corn	0.02	EFSA (2011)	0.011	STMR-RAC		
Oat	0.2	EFSA (2016)	0.03	STMR-RAC		
Rye	0.9	FAO (2017)	0.19	STMR-RAC×PF		
Sorghum	1.5	EFSA (2011)	0.429	STMR-RAC		
Wheat	0.9	FAO (2017)	0.19	STMR-RAC×PF		
Herbal infusions (dried roots)	2.5	EFSA (2014)	0.72	STMR-RAC		
HOPS (dried)	50	FAO (2017)	10.35	STMR-RAC		
Dill seed	70	FAO (2017)	19	STMR-RAC		

Commodity	Existing/ proposed MRL	Source/type of MRL	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spices (roots)	0.3	EFSA (2014)	0.72	STMR-RAC		
Risk assessment residue definition (animal products): Sum fluopyram and metabolites M02, M03, M25, expressed as fluopyram						
Mammalians (all species) Muscle/meat	1.5	FAO (2017)	0.51	STMR-RAC		
Mammalians (all species) Fat tissue	1.5	FAO (2017)	0.67	STMR-RAC		
Mammalians (all species) Liver	8	FAO (2017)	3.8	STMR-RAC		
Mammalians (all species) Kidney	8	FAO (2017)	0.6	STMR-RAC		
Mammalians (all species) Edible offals (other than liver and kidney)	8	FAO (2017	0.67	STMR-RAC		
Poultry: Muscle/meat	1.5	FAO (2017)	0.51	STMR-RAC		
Poultry: Fat tissue	1	FAO (2017)	0.67	STMR-RAC		
Poultry: Liver	5	FAO (2017)	3.8	STMR-RAC		
Poultry: Kidney	5	FAO (2017)	0.6	STMR-RAC		
Poultry: Edible offals (other than liver and kidney)	5	FAO (2017)	0.67	STMR-RAC		
Milk (all species)	0.6	FAO (2015)	0.12	STMR-RAC		
Eggs (all species)	2	FAO (2017)	0.46	STMR-RAC		
Wild terrestrial vertebrate animals	1.5	FAO (2017)	0.51	STMR-RAC		
Other crops/ commodities	MRL	Regulation (EC) 396/2005				

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; RAC: raw agricultural commodity.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Fluopyram	*N*-{2-[3-chloro-5-(trifluoromethyl)-2-pyridyl]ethyl}-α,α,α-trifluoro-*o*-toluamide FC(F)(F)c1ccccc1C(=O)NCCc2ncc(cc2Cl)C(F)(F)F KVDJTXBXMWJJEF-UHFFFAOYSA-N	
M02 fluopyram-E-olefine	*N*-{(*E*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(=O)N\C=C\c2ncc(cc2Cl)C(F)(F)F ZBXOWVYWCBPUPM-AATRIKPKSA-N	
M03 fluopyram-Z-olefine	*N*-{(*Z*)-2-[3-chloro-5-(trifluoromethyl)pyridin-2-yl]vinyl}-2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(=O)N\C=C/c2ncc(cc2Cl)C(F)(F)F ZBXOWVYWCBPUPM-WAYWQWQTSA-N	
M25 fluopyram-benzamide	2-(trifluoromethyl)benzamide FC(F)(F)c1ccccc1C(N)=O QBAYIBZITZBSFO-UHFFFAOYSA-N	
M40 Fluopyram-pyridyl-acetic acid Fluopyram-PAA	[3-chloro-5-(trifluoromethyl)pyridin2-yl]acetic acid OC(=O)Cc1ncc(cc1Cl)C(F)(F)F ZCMWOZJSLGQSQV-UHFFFAOYSA-N	
M42 Fluopyram pyridyl-acetic-acid-glycoside	1-*O*-{[3-chloro-5-(trifluoromethyl)pyridin-2-yl]acetyl}-α-D-glucopyranose O=C(O[C@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)Cc1ncc(cc1Cl)C(F)(F)F WLNHNRBMWFDQSH-KABOQKQYSA-N	
M43 Fluopyram pyridylcarboxylic acid Fluopyram-PCA (AE C657188)	3-chloro-5-(trifluoromethyl)pyridine-2-carboxylic acid Clc1cc(cnc1C(O)=O)C(F)(F)F HXRMCZBDTDCCOP-UHFFFAOYSA-N	

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).