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Modification of the existing maximum residue levels for isofetamid in raspberries, blackberries and dewberries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ISK Biosciences Europe N.V. submitted a request to the competent national authority in Belgium to modify the existing maximum residue levels (MRLs) for the active substance isofetamid in raspberries, blackberries and dewberries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for blackberries, dewberries and raspberries. Adequate analytical methods for enforcement are available to control the residues of isofetamid 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 short-term and long-term intake of residues resulting from the use of isofetamid according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, ISK Biosciences Europe N.V. submitted an application to the competent national authority in Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance isofetamid in raspberries, blackberries and dewberries. 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 16 March 2021. To accommodate for the intended NEU uses of isofetamid, the EMS proposed to raise the existing MRLs for raspberries, blackberries and dewberries from 3 to 7 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 Regulation (EC) No 1107/2009, 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 isofetamid following foliar application was investigated in crops belonging to the groups of fruit crops (grape), leafy crops (lettuce) and pulses/oilseeds (bean). Residues were mainly composed of the parent and metabolite GPTC.

As the proposed uses of isofetamid are on permanent crops, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of isofetamid (hydrolysis studies) demonstrated that the active substance is stable. Hydrolysis studies on metabolite GPTC have not been provided, but, since it is a glucoside conjugate of isofetamid, the possible hydrolytic decomposition of GPTC to the aglycone is covered by the available hydrolysis studies on isofetamid.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and degradation products and the capabilities of the analytical methods for enforcement, the residue definitions for plant products were proposed by the EU pesticides peer review as 'isofetamid' for enforcement and 'sum of isofetamid and metabolite GPTC, expressed as isofetamid', for risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

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

Sufficiently validated analytical methods based on LC-MS/MS 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 the limit of quantification (LOQ) of 0.01 mg/kg in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 7 mg/kg for blackberries, dewberries and raspberries in support of intended NEU uses of isofetamid.

Specific studies investigating the magnitude of isofetamid residues following processing of the commodities under assessment are not available. However, processing factors (PF) derived from processing studies on grapes in the framework of the EU pesticides peer review are available and could eventually be extrapolated to blackberries, dewberries and raspberries. Further processing studies with berries under consideration are not required and were not requested.

Residues of isofetamid 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 isofetamid was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.02 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1 mg/kg bw. The metabolite included in the residue definition is of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The estimated short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The acute consumer exposure was calculated to be 4% of ARfD for blackberries, 3.5% of ARfD for raspberries, 0.7% of ARfD for dewberries and 0.4% of ARfD for raspberry juice.

The highest estimated long-term dietary intake accounted for 28% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL application to

the overall long-term exposure were 2.3% of ADI (FI (3 year) diet) for raspberries (red and yellow), 1.4% of ADI (IE adult diet) for blackberries and 0.3% of ADI (SE general diet) for dewberries.

EFSA concluded that the proposed use of isofetamid on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and, therefore, is unlikely to pose a risk to consumers' health. It is also noted that the consumer exposure is considered tentative for several commodities for which the existing EU MRL is based on the CXL, as the residue data according to the EU risk assessment residue definition are not available, and therefore, the exposure to the plant metabolite GPTC might be underestimated.

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: Isofetamid				
0153010	Blackberries	3	7	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0153020	Dewberries			
0153030	Raspberries (red and yellow)			

MRL: maximum residue level; NEU: northern 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 levels (MRL) for isofetamid in raspberries, blackberries and dewberries. The detailed description of the intended NEU uses of isofetamid, which are the basis for the current MRL application, is reported in Appendix A.

Isofetamid is the ISO common name for *N*-[1,1-dimethyl-2-(4-isopropoxy-*o*-tolyl)-2-oxoethyl]-3-methylthiophene-2-carboxamide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Isofetamid was evaluated in the framework of Regulation (EC) No 1107/2009¹ with Belgium designated as rapporteur Member State (RMS) for the representative field uses on peaches, plums, apricots, cherries, grapes, strawberries, lettuces and oilseed rapes and glasshouse uses on strawberries and lettuces. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2015). Isofetamid was approved² for the use as fungicide on 15 September 2016. The process of renewal of the first approval has not yet been initiated.

The EU MRLs for isofetamid are established in Annex II of Regulation (EC) No 396/2005³. Proposals for setting MRLs covering the representative uses according to good agricultural practices (GAP) in the EU were assessed during the approval of isofetamid under Regulation (EC) No 1107/2009 and implemented in Regulation in accordance with Article 11(2) of the Regulation (EC) 1107/2009. Since the EU pesticides peer review (EFSA, 2015), EFSA has issued one reasoned opinion on the modification of MRLs for isofetamid in several fruiting vegetables (EFSA, 2018b) and the MRL proposals assessed therein have been considered in recent MRL regulations.⁴ EFSA also has issued two scientific reports in support of preparing the EU position in the Sessions of the Codex Committee on Pesticide Residues (CCPR) (EFSA, 2017, 2019b). Codex maximum residue limits (CXLs) have also been implemented, including a CXL of 3 mg/kg for berries under consideration.^{5,6}

In accordance with Article 6 of Regulation (EC) No 396/2005, ISK Biosciences Europe N.V. submitted an application to the competent national authority in Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance isofetamid in raspberries, blackberries and dewberries. 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 16 March 2021. To accommodate for the intended NEU uses of isofetamid, the EMS proposed to raise the existing MRLs for raspberries, blackberries and dewberries from 3 to 7 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2021), the draft assessment report (DAR) and its addendum (Belgium, 2014, 2015) prepared under Regulation (EC) 1107/2009, the Commission review report on isofetamid (European Commission, 2020b), the conclusion on the peer review of the pesticide risk assessment of the active substance isofetamid (EFSA, 2015), as well as the conclusions from previous EFSA outputs on isofetamid (EFSA, 2017, 2018b, 2019b).

¹ 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.

² Commission Implementing Regulation (EU) 2016/1425 of 25 August 2016 approving the active substance isofetamid 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 231, 26.8.2016, p. 30–33.

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

⁴ For an overview of all MRL Regulations on this active substance, please consult: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

⁵ Commission Regulation (EU) 2018/687 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluzifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products. C/2018/2627. OJ L 121, 16.5.2018, p. 63–104.

⁶ Commission Regulation (EU) 2020/856 of 9 June 2020 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 cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products. C/2020/3608. OJ L 195, 19.6.2020, p. 9–51.

For this application, the data requirements established in Regulation (EU) No 544/2011⁷ 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, 2020a; 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 546/2011⁸.

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

The evaluation report submitted by the EMS (Belgium, 2021) 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 isofetamid in primary crops belonging to the group of fruit crops (grape), leafy crops (lettuce) and pulses/oilseeds (bean) has been investigated in the framework of the EU pesticides peer review (EFSA, 2015). In the crops tested, parent compound was the main residue, accounting for 18–73% of the total radioactive residues (TRRs), except in bean seeds at harvest, where isofetamid was only 1% of the TRR and the residues mainly composed of polar fractions representing all 22–51% TRR. In addition, metabolite GPTC was observed up to 10% TRR in grape and lettuce, all other identified metabolites being below 7% TRR. The metabolic pathway was seen to be similar in the three plant groups (EFSA, 2015).

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

1.1.2. Nature of residues in rotational crops

As the proposed uses of isofetamid are on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of isofetamid was investigated in the framework of the EU pesticides peer review (EFSA, 2015). The available hydrolysis studies showed that isofetamid is hydrolytically stable under standard processing conditions representative of pasteurisation, boiling and sterilisation. The metabolite GPTC, included together with isofetamid in the plant residue definition for risk assessment (see Section 1.1.6), is a glucoside conjugate of isofetamid, and therefore, possible hydrolytic decomposition of GPTC to the aglycone is covered by the available hydrolysis studies on isofetamid.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of residues of isofetamid and the metabolite GPTC in food/feed of plant origin were assessed during the EU pesticides peer review (EFSA, 2015). The LC-MS/MS methods allow for the quantification of residues at or above the limit of quantification (LOQ) of 0.01 mg/kg for each analyte in crops belonging to the high acid, high water content and to dry commodities (EFSA, 2015, 2018b).

The methods are sufficiently validated for the determination of residues of isofetamid and the metabolite GPTC in the crops under consideration in the present MRL application.

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

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

1.1.5. Storage stability of residues in plants

The storage stability of isofetamid and the metabolite GPTC in commodities stored under frozen conditions were investigated in the framework of the EU pesticides peer review (EFSA, 2015). It was demonstrated that for the crops assessed in the framework of this application, residues were stable for at least 12 months when stored at -20°C .

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed by the EU pesticides peer review (EFSA, 2015):

- residue definition for risk assessment: sum of isofetamid and metabolite GPTC, expressed as isofetamid;
- residue definition for enforcement: isofetamid.

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

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

Taking into account the proposed use assessed in this application, EFSA concluded that no further information is required and that the previously derived residue definitions are applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted four residue decline trials on raspberries (samples taken immediately after treatment and at the preharvest intervals (PHIs) of 1, 3 days (all trials) and 7 days (2 trials)). The trials were conducted under field conditions in Poland, over the 2018 and 2019 growing seasons, and were performed with two foliar spray applications after formation of the edible part of the plants, with an application interval of 7–8 days and a PHI of 1 day. As performed in two different locations per growing season, the trials were considered sufficiently independent.

Two residue studies from 2018 were performed at a nominal application rate of 2×480 g a.s./ha, in accordance with the intended critical good agricultural practice (cGAP) ($\pm 25\%$). The trials from 2019 were performed at a higher application rate (2×600 g a.s./ha) compared to the cGAP (2×480 g a.s./ha). The EMS proposed to scale all available residue trial endpoints to the nominal application rate of the intended cGAP (480 g a.s./ha), according to the principle of proportionality (EFSA, 2018c; Belgium, 2021). Scaling factors derived from the seasonal application rate per trial were then applied to scale the residue data.

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. The samples were analysed for the parent compound and the metabolite GPTC, in accordance with the requirements of the residue definitions for enforcement (isofetamid) and risk assessment (sum of isofetamid and GPTC, expressed as isofetamid). According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Belgium, 2021). The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

The applicant proposed to extrapolate residue data from the trials performed on raspberries to blackberries and dewberries. In accordance with the EU technical guideline on extrapolation (European Commission, 2020a), such an extrapolation is acceptable and an MRL proposal of 7 mg/kg is derived for all berries under consideration.

1.2.2. Magnitude of residues in rotational crops

As the proposed uses of isofetamid are on permanent crops, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies with the crops under assessment are not available. However, processing studies in grapes were assessed in the EU pesticides peer review and processing factors were derived

for wine, juice and raisin (EFSA, 2015). These studies demonstrated that juicing and drying processes lead to reduction and concentration of residues in the processed products, respectively (EFSA, 2015).

Results from studies on the processing of grapes into grape juice can be extrapolated to small berries and the derived processing factor (see Appendix B.1.2.3) could be applied in case of a need to refine consumer exposure assessment (OECD, 2008; Scholz et al., 2018). Further processing studies with berries under consideration are not required, since, considering the low individual contribution of residues in the commodities under assessment to the total consumer exposure, such results would not be expected to affect the outcome of the risk assessment (see Section 3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as blackberries, dewberries and raspberries are not used for feed purposes.

3. Consumer risk assessment

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

The toxicological reference values for isofetamid used in the risk assessment (i.e. acceptable daily intake (ADI) of 0.02 mg/kg bw per day and acute reference dose (ARfD) of 1 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2020b). The toxicological reference values for isofetamid are considered to be applicable to the metabolite GPTC included in the risk assessment residue definition (EFSA, 2015).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016a). The calculations were based on the highest residue (HR) values derived from supervised field trials; to account for residues in raspberry juice, a processing factor of 0.13 was applied (EFSA, 2015). The complete list of input values can be found in Appendix D.2. The estimated short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The acute consumer exposure was calculated to be 4% of ARfD for blackberries, 3.5% of ARfD for raspberries (red and yellow), 0.7% of ARfD for dewberries and 0.4% of ARfD for raspberry juice (see Appendix B.3).

Long-term (chronic) dietary risk assessment

The long-term exposure assessment was performed taking into account the median residue values (STMR) derived from supervised trials for the commodities assessed in this application. For the remaining commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review (EFSA, 2015), previous MRL application (EFSA, 2018b) and, where relevant, in the evaluations by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) were selected as input values (FAO, 2016b, 2018). Since for some plant commodities that could be fed to livestock the MRLs for isofetamid are established, the commodities of animal origin were also considered in the exposure calculation despite the fact that MRLs are set at the LOQ.

EFSA notes, that for those commodities for which the existing EU MRL is set on a basis of the CXL, the residue data according to the EU risk assessment residue definition are not available. Thus, in order to estimate the contribution of the plant metabolite GPTC, included in the EU risk assessment residue definition, EFSA applied the previously derived conversion factor (CF) for risk assessment for peaches (also used for apricots) and plums (CF 1.1) (EFSA, 2015). For other commodities – almonds, pome fruit, cherries, strawberries, cranberries, azarole, kaki, beans (with pods), peas (with pods) – a conversion factor was not available which may lead to an underestimation of residue levels. For these commodities, the risk assessment is considered tentative.

The complete list of input values is presented in Appendix D.2.

The highest estimated long-term dietary intake accounted for a maximum of 28% of the ADI (NL toddler diet). The contributions of residues expected in the commodities assessed in the present MRL application to the overall long-term exposure were 2.3% of ADI (FI (3 year) diet) for raspberries (red and yellow), 1.4% of ADI (IE adult diet) for blackberries and 0.3% of ADI (SE general diet) for dewberries (see Appendix B.3).

EFSA concluded that the long-term intake of residues of isofetamid resulting from the existing and the intended uses is unlikely to present a risk to consumer health. It is also noted that the consumer exposure is considered tentative for several commodities for which the existing EU MRL is based on the CXL, as residue data according to the EU risk assessment residue definition are not available, and therefore, the exposure to the plant metabolite GPTC might be underestimated.

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 MRL proposals for blackberries, dewberries and raspberries.

EFSA concluded that the proposed use of isofetamid on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and, therefore, is unlikely to pose a risk to consumers' health. It is also noted that the consumer exposure is considered tentative for several commodities for which the existing EU MRL is based on the CXL, as the residue data according to the EU risk assessment residue definition are not available, and therefore, the exposure to the plant metabolite GPTC might be underestimated.

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
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
CIRCA	(EU) Communication & Information Resource Centre Administrator

CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DS	powder for dry seed treatment
EDI	estimated daily intake
EMS	evaluating Member State
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
GAP	Good Agricultural Practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GS	growth stage
HR	highest residue
IEDI	international estimated daily intake
IENTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
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
SL	soluble concentrate
SP	water-soluble powder
STMR	supervised trials median residue
TAR	total applied radioactivity
TRR	total radioactive residue
UV	ultraviolet (detector)
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				PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min–max	Interval between application (days) min–max	kg A.S./HL Min–Max	Water (L/ha) min–max	Rate min–max	Unit		
Blackberries	NEU	F	Grey mould (<i>Botrytis cinerea</i> or <i>Botryotinia fuckeliana</i>); BOTRCI	SC	400 g/L	Foliar treatment – broadcast spraying	BBCH 50–89 Spring–late summer (Jun–Oct)	1–2	7–12	0.035–0.240	200–1,200	400–480	g a.i./ha	1–3	The maximal number of applications (2) is limited for reasons of specific aspect related to the active ingredient (resistance management). A full control of the pathogen is therefore not expected in all cases. In the event of multiple treatments are expected, use the product in strict alternation with different mode of action fungicides (carrying a different FRAC code).
Dewberries	NEU	F	Grey mould (<i>Botrytis cinerea</i> or <i>Botryotinia fuckeliana</i>); BOTRCI	SC	400 g/L	Foliar treatment – broadcast spraying	BBCH 50–89 Spring–late summer (Jun–Oct)	1–2	7–12	0.035–0.240	200–1,200	400–480	g a.i./ha	1–3	
Raspberries (red and yellow)	NEU	F	Grey mould (<i>Botrytis cinerea</i> or <i>Botryotinia fuckeliana</i>); BOTRCI	SC	400 g/L	Foliar treatment – broadcast spraying	BBCH 50–89 Spring–late summer (Jun–Oct)	1–2	7–12	0.035–0.240	200–1,200	400–480	g a.i./ha	1–3	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

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

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

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

(d): PHI – minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and 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	3 × 750 g/ha foliar spray, 13–14 days interval, BBCH 67–69, 71–75 and 77–79	43 DALA	Radiolabelled active substance: [¹⁴ C-phenyl]-isofetamid or [¹⁴ C-(C2)-thiophene]-isofetamid (EFSA, 2015)
	Leafy crops	Lettuce	3 × 750 g/ha foliar spray, 14-day interval	18 DALA	Radiolabelled active substance: [¹⁴ C-phenyl]-isofetamid or [¹⁴ C-(C2)-thiophene]-isofetamid (EFSA, 2015)
	Pulses/oilseeds	French bean	3 × 750 g/ha foliar spray, 8-day interval, first application at BBCH 60–61	0, 14, 68 DALA	Radiolabelled active substance: [¹⁴ C-phenyl]-isofetamid or [¹⁴ C-(C2)-thiophene]-isofetamid (EFSA, 2015)
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)	Comment/Source
	Root/tuber crops	Carrot	1 × ca 2150 g/ha, bare soil application	30, 120 and 365	Radiolabelled active substance: [¹⁴ C-phenyl]-isofetamid (EFSA, 2015)
	Leafy crops	Lettuce			
	Cereal (small grain)	Wheat			
Processed commodities (hydrolysis study)	Conditions			Stable?	Comment/Source
	Pasteurisation (20 min, 90°C, pH 4)			Yes	EFSA (2015)
	Baking, brewing and boiling (60 min, 100°C, pH 5)			Yes	EFSA (2015)
	Sterilisation (20 min, 120°C, pH 6)			Yes	EFSA (2015)

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	Rotational crop metabolism similar but more extensive with further conjugation than in primary crops (EFSA, 2015).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	Isofetamid stable under standard hydrolysis conditions (EFSA, 2015).

	The metabolite GPTC is a glucoside conjugate of isofetamid, and therefore, possible hydrolytic decomposition of GPTC to the aglycone is covered by the available hydrolysis studies on isofetamid (EFSA, 2018b).
Plant residue definition for monitoring (RD-Mo)	Isofetamid
Plant residue definition for risk assessment (RD-RA)	Sum of isofetamid and metabolite GPTC, expressed as isofetamid
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Isofetamid and metabolite GPTC: Matrices with high water content, high acid content and dry matrices: LC–MS/MS, LOQ = 0.01 mg/kg (individually), ILV available (EFSA, 2015).

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; DALA: days after last treatment; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.

B.1.1.2. Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Lettuces	–20	12	Month	Isofetamid, GPTC	EFSA (2015)
	High water content/ high starch content	Potatoes	–20	12	Month	Isofetamid, GPTC	EFSA (2015)
	High oil content	Almonds	–20	12	Month	Isofetamid, GPTC	EFSA (2015)
	High oil content	Oilseed rape	–20	12	Month	Isofetamid, GPTC	EFSA (2015)
	High protein content	Beans	zz–20	12	Month	Isofetamid, GPTC	EFSA (2015)
	High acid content	Grapes	–20	12	Month	Isofetamid, GPTC	EFSA (2015)

B.1.2. Magnitude of residues in plants

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

Commodity	Region ^(a)	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR ^(b) (mg/kg)	STMR ^(c) (mg/kg)	CF ^(d)
Raspberries	NEU	Measured (unscaled) residues: Mo: 1.17 ^(e) ; 2.19; 3.45 ^(e) ; 3.78 RA: 1.22 ^(e) ; 2.25; 3.46 ^(e) ; 3.88 Scaled residues: Mo: 0.93; 2.14; 2.69; 3.65 RA: 0.97; 2.20; 2.70; 3.75	Residue trials on raspberries. All residue trials were scaled to match the intended cGAP application rate (2 × 480 g a.s./ha) to avoid bias. Extrapolation to blackberries and dewberries is possible.	7	Mo: 3.65 RA: 3.75	Mo: 2.42 RA: 2.45	1.03

MRL: maximum residue level; cGAP: critical Good Agricultural Practice; Mo: monitoring; RA: risk assessment; a.s.: active substance.

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

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

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

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

(e): Overdosed residue trials performed with ca. 2 × 600 g/ha.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	Following soil application of isofetamid at ca 2,150 g/ha, parent isofetamid in succeeding crops was detected in lower amounts and proportions than in primary crops and the residues mainly composed of the GPTC and GPTC-malonyl metabolites accounting together up to ca 40% TRR in carrot roots (0.02 mg/kg) and up to ca 60% TRR in lettuce (0.06 mg/kg) at the 120-day plant-back interval (EFSA, 2015).
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Field rotational crop studies demonstrated that no significant residues (residues of isofetamid and GPTC below 0.01 mg/kg and residues of GPTC-malonyl at or below 0.02 mg/kg) are expected in the edible parts of succeeding crops (spinach, radish and winter barley) planted in soil following foliar applications to primary crop (lettuce) treated at 2 × 400 g a.s./ha (EFSA, 2015).

TRR: total radioactive residue; a.s.: active substance.

B.1.2.3. Processing factors

Processing studies with the berries under consideration were not submitted in the framework of the present MRL application.

Processing studies in grapes were assessed in the EU pesticide peer review (EFSA, 2015) and results can be extrapolated to blackberries, dewberries and raspberries (Scholz et al., 2018).

Processed commodity	Number of valid studies ^(a)	Processing Factor (PF)		CF _p ^(b)	Comment/Source
		Individual values	Median PF		
Grapes/juice	5	0.60; 0.17; 0.12; 0.11; 0.13	0.13	1.12	EFSA (2015)
Grapes/raisins	5	4.64; 1.48; 2.31; 1.13; 2.28	2.28	1.04	EFSA (2015)

PF: processing factor.

(a): Studies with residues in the raw agricultural commodity (RAC) at or close to the limit of quantification (LOQ) were disregarded (unless concentration may occur).

(b): $CF_p = \frac{[\text{Residue level in processed fraction (expressed according to RD-RA)}]}{[\text{Residue level in processed fraction (expressed according to RD-Mo)}]}$ median of the individual conversion factors for each processing trial.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD

1 mg/kg bw (European Commission, 2020b)

Highest IESTI, according to EFSA PRIMo

Blackberries: 4% of ARfD
Dewberries: 0.7% of ARfD
Raspberries (red and yellow): 3.5% of ARfD
Raspberries/juice: 0.4% of ARfD

Assumptions made for the calculations

Calculations performed with PRIMo revision 3.1.
The calculation is based on the highest residue levels expected in raw agricultural commodities under assessment (HR values). In order to estimate consumer

	<p>exposure from the intake of raspberry juice, the processing factor of 0.13 was applied to the input value (STMR).</p>
ADI	0.02 mg/kg bw per day (EC, 2020b)
Highest IEDI, according to EFSA PRIMo	<p>28% ADI (NL toddler diet)</p> <p>Contribution of crops assessed: Blackberries: 1.43% of ADI (IE adult diet) Dewberries: 0.33% of ADI (SE general diet) Raspberries (red and yellow): 2.27% of ADI (FI (3 year diet))</p>
Assumptions made for the calculations	<p>Calculations performed with PRIMo revision 3.1. The calculation is based on the median residue levels derived for raw agricultural commodities (STMR values) according to the risk assessment residue definition.</p> <p>For the remaining commodities covered by the MRL regulation, the STMR values derived in the EU pesticides peer review, in previous MRL application and, where relevant, in the evaluations by the JMPR were selected as input values. Since for some plant commodities that could be fed to livestock MRLs for isofetamid are established, the commodities of animal origin were also considered in the exposure calculation despite the fact that MRLs are set at the LOQ.</p> <p>For those commodities, for which the existing EU MRLs is set on the basis of CXLs, the residue data according to the EU risk assessment residue definition are not available. Thus, in order to estimate the contribution of the plant metabolite GPTC, EFSA applied the previously derived conversion factor (CF) for risk assessment for peaches (also used for apricots) and plums (CF 1.1) (EFSA, 2015). For other commodities - almonds, pome fruit, cherries, strawberries, cranberries, azarole, kaki, beans (with pods), peas (with pods) - a conversion factor was not available which may lead to an underestimation of residue levels. For these commodities the risk assessment is considered tentative.</p> <p>The crops on which no uses have been reported in the EU pesticides peer review or in subsequent EFSA outputs, were not included in the exposure calculation.</p>

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

B.4. Recommended MRLs

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Isofetamid				
0153010	Blackberries	3	7	The submitted data are sufficient to derive an MRL proposal for the NEU use. Risk for consumers unlikely.
0153020	Dewberries			
0153030	Raspberries (red and yellow)			

MRL: maximum residue level; NEU: northern Europe.

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

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

Isofetamid

LOQs (mg/kg) range from: **0.01** to: **0.05**

Toxicological reference values

ADI (mg/kg bw per day): **0.02** ARID (mg/kg bw): **1**

Source of ADI: **EC** Source of ARID: **EC**

Year of evaluation: **2020** Year of evaluation: **2020**

Input values

Details – chronic risk assessment

Supplementary results – chronic risk assessment

Details – acute risk assessment/children

Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	No of diets exceeding the ADI: ---			Exposure resulting from MRLs set at commodities not under assessment (in % of ADI)				
				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 commodities not under assessment (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/IEDI calculation (based on average food consumption)	28%	NL toddler	5.58	7%	Apples	5%	Table grapes	3%	Milk: Cattle	3%	28%
	26%	DE child	5.15	8%	Apples	5%	Table grapes	2%	Tomatoes	1%	26%
	19%	GEMS/Food G06	3.79	9%	Tomatoes	4%	Table grapes	1%	Sweet peppers/bell peppers	0.2%	19%
	17%	RO general	3.34	6%	Wine grapes	5%	Tomatoes	1%	Sweet peppers/bell peppers	0.7%	17%
	17%	NL child	3.30	4%	Apples	4%	Table grapes	2%	Raspberries (red and yellow)	1%	17%
	15%	PT general	3.08	9%	Wine grapes	2%	Tomatoes	1%	Peaches	0.5%	15%
	13%	GEMS/Food G15	2.65	4%	Wine grapes	3%	Tomatoes	2%	Sweet peppers/bell peppers	0.5%	13%
	13%	IE adult	2.58	4%	Wine grapes	1%	Blackberries	1%	Peaches	0.3%	13%
	13%	GEMS/Food G07	2.50	5%	Wine grapes	3%	Tomatoes	1%	Table grapes	0.5%	13%
	12%	FR adult	2.46	8%	Wine grapes	1%	Tomatoes	0.5%	Peaches	0.3%	12%
	12%	GEMS/Food G08	2.46	4%	Wine grapes	3%	Tomatoes	1%	Table grapes	0.5%	12%
	11%	DE women 14-50 yr	2.30	3%	Wine grapes	2%	Tomatoes	2%	Apples	0.7%	11%
	11%	GEMS/Food G11	2.14	4%	Wine grapes	2%	Tomatoes	1%	Table grapes	0.6%	11%
	11%	DE general	2.13	3%	Wine grapes	2%	Apples	2%	Tomatoes	0.7%	11%
	10%	FR child 3 15 yr	1.99	2%	Tomatoes	2%	Wine grapes	1%	Table grapes	1%	10%
	10%	GEMS/Food G10	1.96	3%	Tomatoes	1%	Wine grapes	1%	Table grapes	0.5%	10%
	8%	IT toddler	1.62	3%	Tomatoes	1%	Peaches	0.6%	Apples	0.6%	8%
	8%	FI 3 yr	1.56	2%	Raspberries (red and yellow)	1%	Tomatoes	0.9%	Strawberries	0.8%	8%
	8%	DK adult	1.53	3%	Wine grapes	1%	Tomatoes	0.6%	Apples	0.4%	8%
	8%	FR toddler 2 3 yr	1.52	2%	Apples	1%	Milk: Cattle	1%	Tomatoes	2%	8%
	8%	DK child	1.52	2%	Apples	1%	Tomatoes	1%	Cucumbers	0.9%	8%
	8%	UK toddler	1.51	1%	Tomatoes	1%	Raspberries (red and yellow)	1%	Apples	1%	8%
	7%	NL general	1.48	2%	Wine grapes	1%	Tomatoes	1.0%	Apples	0.5%	7%
	7%	IT adult	1.47	3%	Tomatoes	2%	Peaches	0.5%	Apples	0.5%	7%
	7%	ES adult	1.42	2%	Tomatoes	1%	Wine grapes	0.9%	Peaches	0.4%	7%
	7%	SE general	1.39	2%	Tomatoes	0.7%	Apples	0.6%	Milk: Cattle	0.9%	7%
	7%	ES child	1.36	2%	Tomatoes	0.8%	Peaches	0.8%	Apples	0.9%	7%
	6%	UK vegetarian	1.28	3%	Wine grapes	1%	Tomatoes	0.4%	Apples	0.2%	6%
	6%	UK infant	1.26	2%	Milk: Cattle	1%	Apples	0.0%	Tomatoes	2%	6%
	6%	UK adult	1.25	4%	Wine grapes	1%	Tomatoes	0.3%	Apples	0.2%	6%
6%	PL general	1.24	2%	Tomatoes	1%	Apples	1%	Table grapes	0.6%	6%	
6%	FI 6 yr	1.17	2%	Raspberries (red and yellow)	1%	Tomatoes	0.7%	Strawberries	0.7%	6%	
5%	FI adult	0.91	1%	Tomatoes	1%	Wine grapes	0.5%	Raspberries (red and yellow)	0.5%	5%	
4%	LT adult	0.80	1%	Tomatoes	1%	Apples	0.3%	Cucumbers	0.3%	4%	
4%	FR infant	0.77	1%	Apples	0.8%	Milk: Cattle	0.4%	Strawberries	0.9%	4%	
1%	IE child	0.20	0.2%	Apples	0.2%	Table grapes	0.2%	Milk: Cattle	0.2%	1%	

Conclusion:
The estimated long-term dietary intake (TMDI/IEDI) was below the ADI.
The long-term intake of residues of Isofetamid is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

Acute risk assessment /children				Acute risk assessment/adults/general population				
Details – acute risk assessment /children				Details – acute risk assessment/adults				
<p>The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.</p> <p>The calculation is based on the large portion of the most critical consumer group.</p>								
Show results of IESTI calculation only for crops with GAPs under assessment								
Unprocessed commodities	Results for children No. of commodities for which ARID/ADI is exceeded (ESTI): ---				Results for adults No. of commodities for which ARID/ADI is exceeded (ESTI): ---			
	IESTI				IESTI			
	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	4%	Blackberries	7/3.75	40	2%	Apricots	3/1.87	20
	3%	Raspberries (red and Dewberries)	7/3.75	35	2%	Cucumbers	1/0.56	16
0.7%		7/3.75	6.6	0.3%	Medlar	0.6/0.42	2.9	
Expand/collapse list								
Total number of commodities exceeding the ARID/ADI in children and adult diets (IESTI calculation)								
Processed commodities	Results for children No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---				Results for adults No. of processed commodities for which ARID/ADI is exceeded (IESTI): ---			
	IESTI				IESTI			
	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARID/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
	35%	Chards/beet leaves/boiled	20/11.38	354	14%	Chards/beet leaves/boiled	20/11.38	142
	16%	Spinaches/frozen; boiled	20/11.38	158	9%	Spinaches/frozen; boiled	20/11.38	94
	5%	Peaches/canned	3/1.87	49	5%	Purslanes/boiled	20/11.38	47
	3%	Wine grapes/juice	4/0.71	31	3%	Wine grapes/wine	4/3.13	30
	2%	Courgettes/boiled	1/0.56	20	2%	Table grapes/raisins	4/14.71	18
	1%	Peaches/juice	3/0.84	14	2%	Peaches/canned	3/1.87	15
	1%	Gherkins/pickled	1/0.56	13	1%	Wine grapes/juice	4/0.71	15
	0.9%	Tomatoes/juice	1.5/0.48	9.1	1%	Courgettes/boiled	1/0.56	13
	0.7%	Apples/juice	0.6/0.14	7.3	0.4%	Apples/juice	0.6/0.14	4.5
	0.5%	Tomatoes/sauce/puree	1.5/0.48	4.6	0.4%	Tomatoes/sauce/puree	1.5/0.48	3.9
	0.5%	Beans (with pods)/boiled	0.6/0.36	4.5	0.3%	Okra, lady's fingers/boiled	3/1.06	2.7
	0.4%	Pears/juice	0.6/0.14	4.4	0.1%	Pears (with pods)/boiled	0.6/0.36	1.2
0.4%	Raspberries/juice	7/0.32	3.7	0.04%	Cranberries/dried	4/0.49	0.37	
0.3%	Cranberries/juice	4/0.49	2.8	0.02%	Quinces/jam	0.6/0.14	0.17	
0.2%	Plums/juice	0.8/0.19	1.8	#NUM!	#NUM!	#NUM!	#NUM!	
Expand/collapse list								
Conclusion: No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Isofetamid 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

Not relevant to the present MRL application.

D.2. Consumer risk assessment

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment ^(a)
Risk assessment residue definition: Sum of isofetamid and metabolite GPTC, expressed as isofetamid						
Blackberries	7	Proposed MRL	2.450	STMR-RAC	3.750	HR-RAC
Dewberries	7	Proposed MRL	2.450	STMR-RAC	3.750	HR-RAC
Raspberries (red and yellow)	7	Proposed MRL	2.450	STMR-RAC	3.750	HR-RAC
Raspberries/juice	n/a	n/a	n/a	n/a	0.319	STMR-RAC (2.450) × PF (0.13) (grape juice; EFSA, 2015)
Almonds	0.01*	FAO (2016b)	0.01	STMR-RAC ^(b)	0.01	HR-RAC ^(b)
Apples	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Pears	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Quinces	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Medlar	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Loquats/Japanese medlars	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Other pome fruit	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Apricots	3	FAO (2018)	0.836	STMR-RAC (0.760) × CF (1.1) (EFSA, 2015)	1.870	HR-RAC (1.700) × CF (1.1) (EFSA, 2015)
Cherries (sweet)	4	FAO (2018)	1.100	STMR-RAC ^(b)	3.400	HR-RAC ^(b)
Peaches	3	FAO (2018)	0.836	STMR-RAC (0.760) × CF (1.1) (EFSA, 2015)	1.870	HR-RAC (1.700) × CF (1.1) (EFSA, 2015)
Plums	0.8	FAO (2018)	0.193	STMR-RAC (0.175) × CF (1.1) (EFSA, 2015)	0.429	STMR-RAC (0.390) × CF (1.1) (EFSA, 2015)
Table grapes	4	EFSA (2015)	0.710	STMR-RAC	3.130	HR-RAC
Wine grapes	4	EFSA (2015)	0.710	STMR-RAC	3.130	HR-RAC
Strawberries	4	FAO (2016b)	0.490	STMR-RAC ^(b)	3.100	HR-RAC ^(b)
Other cane fruit	3	FAO (2018)	0.680	STMR-RAC ^(b)	1.200	HR-RAC ^(b)
Cranberries	4	FAO (2016b)	0.490	STMR-RAC ^(b)	3.100	HR-RAC ^(b)
Azarole/ Mediterranean medlar	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Kaki/Japanese persimmons	0.6	FAO (2018)	0.135	STMR-RAC ^(b)	0.420	HR-RAC ^(b)
Tomatoes	1.5	EFSA (2018)	0.480	STMR-RAC	0.940	HR-RAC
Sweet peppers/ bell peppers	3	EFSA (2018)	0.570	STMR-RAC	1.660	HR-RAC

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment ^(a)
Aubergines/egg plants	1.5	EFSA (2018)	0.480	STMR-RAC	0.940	HR-RAC
Okra/lady's fingers	3	EFSA (2018)	0.570	STMR-RAC	1.660	HR-RAC
Cucumbers	1	EFSA (2018)	0.130	STMR-RAC	0.560	HR-RAC
Gherkins	1	EFSA (2018)	0.130	STMR-RAC	0.560	HR-RAC
Courgettes	1	EFSA (2018)	0.130	STMR-RAC	0.560	HR-RAC
Other cucurbits – edible peel	1	EFSA (2018)	0.130	STMR-RAC	0.560	HR-RAC
Lettuces	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Spinaches	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Purslanes	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Chards/beet leaves	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Other spinach and similar	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Chervil	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Chives	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Celery leaves	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Parsley	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Sage	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Rosemary	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Thyme	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Basil and edible flowers	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Laurel/bay leaves	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Tarragon	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Other herbs	20	EFSA (2015)	0.047	STMR-RAC	11.380	HR-RAC
Beans (with pods)	0.6	FAO (2018)	0.096	STMR-RAC ^(b)	0.360	HR-RAC ^(b)
Peas (with pods)	0.6	FAO (2018)	0.096	STMR-RAC ^(b)	0.360	HR-RAC ^(b)
Linseeds	0.01*	EFSA (2015)	0.017	STMR-RAC	0.017	HR-RAC
Poppy seeds	0.01*	EFSA (2015)	0.017	STMR-RAC	0.017	HR-RAC
Rapeseeds/canola seeds	0.015	FAO (2016b)	0.017	STMR-RAC	0.017	HR-RAC
Mustard seeds	0.01*	EFSA (2015)	0.017	STMR-RAC	0.017	HR-RAC
Gold of pleasure seeds	0.01*	EFSA (2015)	0.017	STMR-RAC	0.017	HR-RAC

Risk assessment residue definition: Sum of isofetamid and PPA, expressed as isofetamid

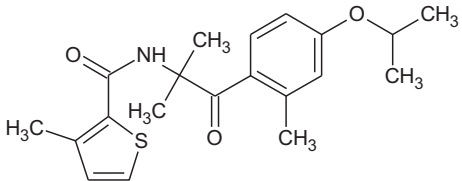
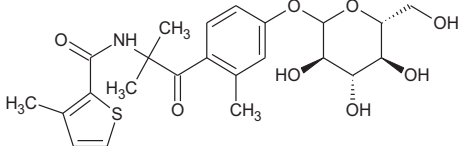
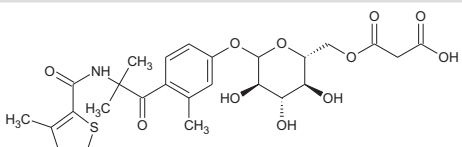
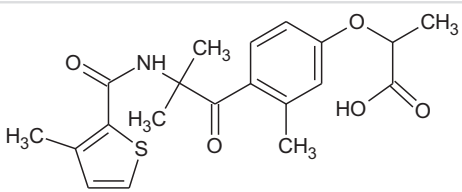
Commodities of animal origin	0.01*	MRL (Reg. (EU) 2017/171)	n/a	n/a	n/a	n/a
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STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PF: processing factor; CF: conversion factor for enforcement to risk assessment residue definition; n/a: not available.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

(b): Input values derived according to the JMPR risk assessment residue definition. A conversion factor to estimate the contribution of the plant metabolite GPTC, included in the EU risk assessment residue definition, is not available. This may lead to an underestimation of residue levels.

Appendix E – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/InChIKey ^(a)	Structural formula ^(b)
Isofetamid IKF-5411	<i>N</i> -[1,1-dimethyl-2-(4-isopropoxy- <i>o</i> -tolyl)-2-oxoethyl]-3-methylthiophene-2-carboxamide <chem>O=C(NC(C)(C)C(=O)c1ccc(OC(C)C)cc1C)c2sccc2C</chem> WMKZDPFZIZQROT-UHFFFAOYSA-N	
GPTC	<i>N</i> -{1-[4-(D-glucopyranosyloxy)-2-methylphenyl]-2-methyl-1-oxopropan-2-yl}-3-methylthiophene-2-carboxamide <chem>O=C(NC(C)(C)C(=O)c2ccc(O[C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)cc2C)c3sccc3C</chem> AJMFCWXRIDCDDN-XHCNLMPIISA-N	
GPTC-malonyl	3-methyl-4-[2-methyl- <i>N</i> -(3-methylthiophene-2-carbonyl)alanyl]phenyl 6- <i>O</i> -(carboxyacetyl)-D-glucopyranoside <chem>O=C(NC(C)(C)C(=O)c2ccc(OC1O[C@H](COC(=O)CC(=O)O)[C@@H](O)[C@H](O)[C@H]1O)cc2C)c3sccc3C</chem> HAKKTWCXWDYAPF-VVHFXJRLSA-N	
PPA	(2 <i>RS</i>)-2-{3-methyl-4-[2-methyl- <i>N</i> -(3-methylthiophene-2-carbonyl)alanyl]phenoxy}propanoic acid <chem>O=C(NC(C)(C)C(=O)c1ccc(OC(C)C(=O)O)cc1C)c2sccc2C</chem> CFZWEHRXSMYLPD-UHFFFAOYSA-N	

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

(a): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

(b): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).