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Evaluation of confirmatory data following the Article 12 MRL review for imazamox

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Abstract

The applicant BASF SE submitted a request to the competent national authority in France to evaluate the confirmatory data that were identified for imazamox in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, the applicant submitted new residue trials on rice. Since the number of trials was not sufficient, the data gap was considered only partially addressed. The remaining data gaps related to metabolism studies and analytical enforcement methods have been addressed in the framework of the renewal of the approval for imazamox. New enforcement and risk assessment residue definitions for plant commodities were derived and the toxicological reference values for imazamox were revised. The previous consumer risk assessment was updated using the residue data submitted on rice and the new revised toxicological reference values. No consumer intake concerns were identified. The current reasoned opinion is intended to give risk managers the necessary information to take a decision on the amendment of the tentative MRLs established in the EU MRL legislation. Furthermore, EFSA recommends to review all existing EU MRLs for imazamox, considering the new residue definitions derived in the framework of the peer review.

Keywords: imazamox, confirmatory data, pesticide, MRL review, risk assessment

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Amendment: Editorial corrections were carried out that do not materially affect the contents or outcome of this reasoned opinion. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request.

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Summary

In 2013, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for imazamox according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) a validated method of analysis for the determination of imazamox residues in high oil content; crops and a confirmatory method for the determination of imazamox residues in high oil content, high water content, acidic and dry crops;
2) a validated method of analysis for the determination of imazamox residues in commodities of animal origin (supported by independent laboratory validation data and a confirmatory method)
3) representative plant metabolism studies with imazamox labelled at the imidazolinone ring;
4) seven additional residues trials supporting the southern outdoor Good Agricultural Practice (GAP) on rice.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014, including footnotes related to data gaps listed above (numbers 1, 2, 3, 4), indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 29 October 2016. In 2016, following the implementation of the Codex maximum residue limit (CXL) proposals for several commodities previously assessed by the MRL review, risk managers decided to delete the footnotes related to the data gap number 2 and footnotes related to the commodities where the CXL replaced the previous tentative European Union (EU) MRL. Thus, in Commission Regulation (EU) No 2016/567, the data requirements were maintained only for peas (with pods), soybeans, maize and rice.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, BASF SE submitted an application to the competent national authority in France (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018. When assessing the evaluation report, EFSA identified points which needed further clarifications. In June 2018, the evaluating Member State (EMS) submitted a revised evaluation report which addressed the points for clarification.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[a]	Commodity	Existing MRL[b]	Proposed MRL	Conclusion/recommendation
Existing enforcement residue definition: Imazamox (sum of imazamox and its salts, expressed as imazamox) **General recommendation:** Based on the metabolism studies provided as confirmatory data, revised residue definitions for enforcement (i.e. sum of imazamox and its hydroxymethyl metabolite CL 263484 expressed as imazamox) and for risk assessment (sum of imazamox and the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215), expressed as imazamox) were derived. Thus, EFSA recommends a review of the existing MRLs, including a comprehensive risk assessment based on the revised residue definition. This review could not be performed under the current assessment, since currently only very limited information is available on the expected residue concentrations related to the new residue definitions. Considering that the analytical methods provided as confirmatory data demonstrated that a lower LOQ of 0.01 mg/kg is achievable in routine MRL enforcement for matrices with high water content, high protein content, high acid content, high oil content and high starch content, the lowering of the existing LOQ MRLs set for commodities where no uses were reported in the framework of the MRL review could be considered.				
0260030	Peas (with pods)	0.05* (ft 1)	(0.01*) risk management decision	In the framework of the MRL review, no authorised use of imazamox on peas (with pods) was reported. Thus, the footnote requesting confirmatory data for peas with pods was erroneously implemented in Regulation (EU) No 2016/567. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routine analytical methods could be considered. The footnote should be deleted

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
0401070	Soya bean	0.05* (ft 2)	(0.01*) risk management decision	The confirmatory data requirements have been sufficiently addressed. The lowering of the MRL to a lower LOQ of 0.01 mg/kg which is achievable with routine analytical methods could be considered. The previous consumer risk assessment was updated, using lower ADI and a new ARfD. No consumer intake concerns were identified
0500030	Maize/corn	0.05* (ft 1)		
0500060	Rice	0.05* (ft 3)	Risk management decision	The requested metabolism studies were provided. Additional residue trials have been submitted, which suggest a MRL of 0.05 mg/kg. However, one additional SEU trial required is still missing. The previous consumer risk assessment was updated, using lower ADI and a new ARfD. No consumer intake concerns were identified. A risk management decision to be taken whether it is appropriate to lower the MRL to the LOQ of 0.01 mg/kg due to the lack of supporting data

MRL: maximum residue level; LOQ: limit of quantification; ADI: acceptable daily intake; ARfD: acute reference dose; SEU: southern Europe.

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: EFSA identified some information on plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 3).

ft 2: EFSA identified some information on analytical methods and plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 1 and 3).

ft 3: EFSA identified some information on residue trials and plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 3 and 4).

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Assessment

The review of existing maximum residue levels (MRLs) for the active substance imazamox according to Article 12 of Regulation (EC) No 396/2005[1] (MRL review) has been performed in 2013 (EFSA, 2013). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The following data gaps were identified by EFSA:

1) a validated method of analysis for the determination of imazamox residues in high oil content crops and a confirmatory method for the determination of imazamox residues in high oil content, high water content, acidic and dry crops
2) a validated method of analysis for the determination of imazamox residues in commodities of animal origin (supported by independent laboratory validation data and a confirmatory method)
3) representative plant metabolism studies with imazamox labelled at the imidazolinone ring
4) seven additional residues trials supporting the southern outdoor Good Agricultural Practice (GAP) on rice.

The MRL modifications proposed following the MRL review have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014[2], including footnotes implementing the data gaps identified by EFSA points (1), (2), (3) and (4) above as confirmatory data requirements. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 29 October 2016.

In 2016, following the implementation of the Codex maximum residue limit (CXL) proposals for imazamox in several commodities previously assessed by the MRL review (EFSA, 2015), risk managers decided to delete the footnotes on confirmatory data related to data gap number 2 and footnotes related to the commodities where the CXL replaced the previous tentative European Union (EU) MRL. Thus, in Commission Regulation (EU) No 2016/567[3], the data requirements were maintained only for peas (with pods), soybeans, maize and rice. The tentative MRLs were confirmed for beans (with pods), peas (without pods), dry beans, peas, rapeseed and food commodities of animal origin; higher MRLs were enforced for dry lentils and sunflower seeds. The confirmation and/or modification of the existing tentative MRLs was based on the JMPR assessment of new metabolism studies and residue trials, which were not available at the time of the MRL review and considered as a data gap. The JMPR confirmed the enforcement residue definition as parent imazamox (FAO, 2014). It is noted, however, that in 2016 the peer review on the renewal of the approval of imazamox assessed the same metabolism studies and proposed a wider enforcement residue definition, including metabolite CL 263284 (EFSA, 2016). This residue definition has not been implemented in the EU MRL legislation so far.

EFSA also noted that there is no authorised use of imazamox on peas (with pods) according to the MRL review. Thus, for this crop, a request for confirmatory data is not justified.

In accordance with the specific provisions, the applicant BASF SE submitted an application to the competent national authority in France (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided a set of residue trials on rice.

The RMS France assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 26 April 2018 (France, 2018a). The evaluation of confirmatory data was performed in accordance with the procedure set out in the Commission Staff Working Document SANTE/10235/2016 (European Commission, 2016). During the detailed assessment, EFSA identified some points which required further clarifications. In June 2018, the RMS submitted a revised evaluation report which included studies addressing the general data gaps related

[1] 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, 16.03.2005, p. 1–16.

[2] Commission Regulation (EU) No 1146/2014 of 23 October 2014 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulfuric acid in or on certain products. OJ L 308, 29.10.2014, p. 3–60.

[3] Commission Regulation (EU) 2016/567 of 6 April 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, cyflumetofen, cyprodinil, dimethomorph, dithiocarbamates, fenamidone, fluopyram, flutolanil, imazamox, metrafenone, myclobutanil, propiconazole, sedaxane and spirodiclofen in or on certain products. OJ L 100, 15.4.2016, p. 1–60.

to metabolism studies and analytical enforcement methods, which had been assessed previously by the peer review for the renewal of the approval of imazamox but not explicitly mentioned so in the EFSA conclusion (EFSA, 2016).

The peer review on the renewal of approval of imazamox in accordance with Regulation (EC) No 1107/2009 is finalised (EFSA, 2016). The lower toxicological reference values for imazamox were confirmed by the Standing Committee on Plants, Animals, Food and Feed (European Commission, 2017b), differing from the values referred to in the MRL review.

The approval of imazamox as a candidate for substitution was implemented by Commission Implementing Regulation (EU) No 2017/1531[4]. For metabolite CL 354825, a data gap related to genotoxicity was identified by the peer review, which has now been addressed in the framework of this assessment (see section 1).

EFSA based its assessment on the updated evaluation report submitted by the RMS (France, 2018a), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2013), the Evaluation report of the JMPR (FAO, 2014), the Scientific Report on the support for preparing EU position for the 2015 CCPR (EFSA, 2015) and the conclusions on the peer review of the pesticide risk assessment of the active substance imazamox (EFSA, 2016).

For this application, the data requirements established in Regulation (EU) No 544/2011[5] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 1146/2014 are applicable. 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].

A detailed description of the GAP for the uses of imazamox on rice, relevant for the current confirmatory data evaluation, is reported in Appendix A.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The updated evaluation report submitted by the RMS (France, 2018a) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. Mammalian toxicology

Following the peer review, the RMS provided an assessment of additional toxicological studies on plant metabolites CL 263284, its glucose conjugate CL 189215 and on the soil and groundwater metabolite CL 354825 (France, 2018b), which were not available during the peer review and in the absence of which the enforcement and risk assessment residue definitions could not be finalised. The toxicological profile of the metabolites was discussed in the peer review expert meeting 186 held on 21 and 22 November 2018 (EFSA, 2018).

The metabolites presented a similar acute toxicity profile as the parent imazamox with an acute oral LD_{50} above 5,000 mg/kg body weight (bw) in rat for all compounds. Gene mutation tests gave consistently negative results while positive results were obtained for chromosome aberration *in vitro*, with and without liver metabolic activation system (S9) for metabolite CL 354825 and in the presence of S9 for the metabolite CL 263284. Follow-up *in vivo* micronucleus tests were negative with appropriate evidence of bone marrow exposure for each metabolite and it was concluded that the metabolites are unlikely to be genotoxic *in vivo*.

Twenty-eight day dietary toxicity studies were provided for the metabolites allowing to compare their toxicity profile with the parent imazamox. **CL 263284** presented a no observed adverse effect level (NOAEL) of 333 mg/kg bw per day in the 28-day study based on reduction in body weight gain in males. Although some experts would have considered the metabolite more potent than the parent quantitatively (this effect was not observed in the short-term studies with imazamox), a maternal NOAEL of 500 mg/kg bw per day was established for imazamox in the developmental toxicity study in

[4] Commission Implementing Regulation (EU) 2017/1531 of 7 September 2017 renewing the approval of the active substance imazamox, as a candidate for substitution, 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 232, 8.9.2017, p. 6–10.

[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.

rats based on the same body weight effects. It was concluded that the toxicity profile of the metabolite is similar to imazamox. In agreement with the RMS proposal, the toxicological reference values of the parent are applicable to the metabolite CL 263284 – and its glucose conjugate **CL 189215** by read-across.

Regarding the metabolite **CL 354825**, based on a NOAEL of 88.4 mg/kg bw per day in the 28-day toxicity study in rats for body weight and kidney effects, it was concluded that the metabolite presents a distinct toxicological profile to the parent imazamox. The acceptable daily intake (ADI) and acute reference dose (ARfD) were established at 0.09 mg/kg bw per day, based on the NOAEL from the 28-day study with the metabolite and applying an uncertainty factor of 1,000 to account for the limited data package. It could not be excluded that the metabolites share the developmental toxicity properties of imazamox that was proposed to be classified as Repr 2 H361d 'Suspected of damaging the unborn child' by the peer review[7] (EFSA, 2016).

2. Residues

2.1. Nature of residues and methods of analysis in plants

2.1.1. Nature of residues in primary crops

The data gap number 3[8] was sufficiently addressed in the framework of the renewal of the approval of imazamox (EFSA, 2016). New plant metabolism studies with imazamox radiolabelled at the imidazolinone ring were performed with oilseed rape, rice and wheat.

The results of all available studies indicate that at harvest in mature plants and seeds, imazamox was present in low proportions (< 10% total radioactive residue (TRR)), except in wheat grain. Two to three weeks after application, the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) were identified as the most abundant components. The *d*-acid metabolite (CL 312622) was present at high proportions in alfalfa forage and hay, but since alfalfa is only used for animal feed, the peer review did not include this metabolite in the residue definitions, taking also into account the fact that animal metabolism studies showed that this metabolite is to a large extent excreted with no residues expected in animal matrices.

The metabolism of imazamox in primary crops proceeds mainly by O-demethylation of the methoxymethyl group to form the hydroxymethyl metabolite (CL 263284) which undergoes further metabolism via oxidation and glucose conjugation to form the diacid and glucose conjugate metabolites respectively. A shift of the enantiomeric ratio was not observed for imazamox and its hydroxymethyl metabolite in wheat forage, straw, grain and in rice straw (EFSA, 2016).

The peer review concluded that imazamox, its hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215) are relevant plant metabolites.

2.1.2. Nature of residues in rotational crops

The data gap number 3[9] was sufficiently addressed in the framework of the renewal of the approval of imazamox (EFSA, 2016). New rotational crop metabolism studies with $^{14}C/^{15}N$-imidazoline-imazamox and ^{14}C-pyridine imazamox were submitted.

In rotational crops – spinach, radish and wheat – grown in the soil treated at a rate of 75 g/ha, the TRRs were low, except in wheat hay, straw and grains. Only parent imazamox and its hydroxymethyl metabolite were identified and thus the peer review concluded that metabolism in rotational crops proceeds in a similar pathway as in primary crops (EFSA, 2016).

2.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

[7] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1–1355.

[8] Data gap number 3 refers to 'representative plant metabolism studies with imazamox labelled at the imidazole ring'.

[9] Data gap number 3 refers to ''representative plant metabolism studies with imazamox labelled at the imidazole ring'.

2.1.4. Methods of analysis in plants

The data gap number 1[10] has been sufficiently addressed in the framework of the renewal of the approval of imazamox (EFSA, 2016).

A sufficiently validated analytical method (liquid chromatography with tandem mass spectrometry (LC–MS/MS)) is available for the determination of imazamox and its metabolites CL 312622, CL 263284 and CL 189215 in high protein (dry peas), high water (green beans, rice forage), high acid (grapes), high oil (sunflower seeds) and high starch (rice grain) commodities at the validated limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2016).

2.1.5. Stability of residues in plants

The storage stability of imazamox has been demonstrated for a maximum of 44 and 48 months (at −10°C) in high starch and high oil content matrices (EFSA, 2016), relevant for the crops under consideration in this assessment.

According to the conclusions of the peer review, the storage stability of imazamox, CL 189215 and CL 263284 has been investigated in high water content matrices, high starch (dry) and high oil content matrices except for that of metabolite CL 189215 in high starch content (dry) matrices (EFSA, 2016).

For details, see Appendix B.1.1.2.

2.1.6. Proposed residue definitions

In the framework of the MRL review, EFSA derived the following tentative residue definitions:

- Residue definition for enforcement:
  - imazamox (limited to cereals/grass and oilseeds/pulses crop groups).
- Residue definition for risk assessment:
  - imazamox (limited to cereals/grass and oilseeds/pulses crop groups)
  - imazamox and its hydroxymethyl metabolite free and conjugated, expressed as imazamox (fodder commodities, e.g. maize and alfalfa forage).

Taking into account the new primary and rotational crop metabolism studies submitted and assessed during the process of renewal of the approval for imazamox, the EU pesticides peer review proposed new provisional[11] plant residue definitions:

- Residue definition for enforcement: sum of imazamox and its hydroxymethyl metabolite CL 263284 expressed as imazamox (limited to cereals/grass and oilseeds/pulses crop groups)
- Residue definition for risk assessment: sum of imazamox and the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215), expressed as imazamox (for food and feed commodities).

The proposed residue definitions are applicable to primary crops, rotational crops and processed commodities.

The new enforcement residue definition differs from the residue definition considered in the framework of the MRL review and implemented in the Regulation (EC) No 396/2005. It is noted that in 2014 JMPR derived the following residue definitions: imazamox for enforcement purposes and imazamox and its metabolite CL 263284 for risk assessment (FAO, 2014).

Based on the results of metabolism studies, EFSA concludes that in some crop matrices (alfalfa forage and hay, rice grain and straw, maize grain and forage, rape seed and straw, foliage of legumes) parent imazamox is not a sufficiently reliable marker compound and therefore proposes to modify the existing enforcement residue definition according to the conclusions of the peer review. A modification of the residue definitions triggers a re-assessment of the existing MRLs which goes beyond the scope of the current assessment. A further discussion with risk managers is required on the prioritisation of the re-assessment of the existing MRLs to align them with the new residue definition.

[10] Data gap number 1 refers to 'a validated method of analysis for the determination of imazamox residues in high oil content crops and a confirmatory method for the determination of imazamox residues in high oil content, high water content, acidic and dry crops'.

[11] The residue definitions were considered as provisional, since the toxicological properties of metabolites CL 263284 and CL 189215 were not sufficiently addressed. Considering that the required information has been provided in the meantime, the residue definitions are considered as confirmed (see Section 1).

2.2. Magnitude of residues in plants

Rice grain:

In order to address the data gap number 4,[12] the applicant provided six independent residue trials on **rice** approximating the critical southern Europe (SEU) GAP (the trials were slightly overdosed, but within the acceptable deviation). Residue trials were performed in Italy and Spain in 2011 and 2012. In all trials, the formulation contained an adjuvant. Three trials were designed as bridging trials – with and without adjuvant, and indicated slightly higher residues with an adjuvant present. For calculating the MRL proposal, EFSA selected the highest value of the side-by-side trials with and without adjuvant. The preharvest interval (PHI) interval in all trials ranged from 77 to 90 days. The samples were analysed for parent imazamox and its metabolites CL 263284 and CL 189215. One additional trial was submitted under the MRL review. Also, this trial was analysed for parent imazamox and its metabolite CL 263284 (France, 2018a). Thus, overall, seven residue trials are available for rice grain.

In addition to the residue trials supporting the critical GAP, the applicant submitted six residue trials performed according to alternative GAP (2 × 35 g/ha). The samples were analysed for imazamox, metabolite CL 263284 and metabolite CL 189215. In none of the samples, parent imazamox was found, whereas the total residues ranged from the LOQ (< 0.02 mg/kg) to 0.04 mg/kg, indicating that split application of imazamox results in a less critical residue situation in the crop. However, the number of trials is not in compliance with the data requirements as two additional trials would be required.

The residue trial samples prior to analysis were stored for a maximum of 354 days, thus not exceeding the demonstrated storage stability intervals for imazamox and metabolite CL 263284. Data on the storage stability of metabolite CL 189215 in high starch content matrices has not been reported. The analytical method used to analyse trial samples is considered sufficiently validated and fit for purpose (France, 2018a).

EFSA concludes that the number of residue trials is not fully compliant with the data requirement since for rice at least eight residue trials would be required (European Commission, 2017a). Based on the available residue data from seven trials, an MRL of 0.05 mg/kg for imazamox in rice grain would be sufficient.

The data give an indication that for the new enforcement residue definition not only a higher MRL of 0.15 mg/kg would be required, but also in this case one additional residue trial still needs to be submitted. To complement the data set for the risk assessment reflecting the new residue definition derived in the peer review, two trials on rice analysed for metabolites CL 263284 and CL 189215 as well as the data demonstrating freezer storage stability for metabolite CL 189215 would need to be provided.

Soybeans and maize:

For soybean and maize, the plant metabolism studies with imazamox labelled at the imidazolinone ring were requested by the MRL review. These data were provided in the framework of the renewal of the approval of imazamox (see Section 2.1.1) and studies indicated that in certain crops imazamox is not a sufficient marker compound and metabolites CL 263284 and CL 189215 can be present at higher levels than the parent compound.

For **soybean**, new residue data were not requested. The tentative MRL at the LOQ of 0.05 mg/kg was established following the MRL review, based on the residue data set on sunflowers (two northern Europe (NEU) trials and three SEU) with residues of imazamox below the LOQ of 0.05 mg/kg (EFSA, 2013). In the framework of the EU pesticides peer review, specific residue trials with soybeans were provided for a similar GAP; the samples were analysed for parent imazamox and its metabolites CL 263284 and CL 189215. These trials suggest an MRL at the (combined) LOQ of 0.02 mg/kg for the new enforcement residue definition (EFSA, 2016). For the existing enforcement residue definition, an MRL at the LOQ of 0.01 mg/kg would be appropriate. The residue data on metabolites were provided only for four NEU trials; additional four trials would be required to derive a final risk assessment value (supervised trials median residue (STMR)) for the new residue definition.

For **maize**, new residue data were not requested. EFSA noted that according to the new metabolism studies, metabolites CL 263284 and CL 189215 are expected in maize grain and forage at

[12] Data gap number 4 refers to '7 additional residues trials supporting the southern outdoor GAP on rice'.

higher levels than the parent imazamox (France, 2015), allowing to derive an indicative conversion factors of 8 and 5, respectively, for the risk assessment.

Overall, EFSA is of the opinion that the existing MRLs for soybean and maize would need to be revised, taking into consideration the new enforcement residue definition derived in the framework of the peer review and the new analytical method which allows to quantify residues at or above the LOQ of 0.01 mg/kg.

In the framework of the current assessment, EFSA is not in a position to perform a complete MRL review, since the complete residue data package according to the revised risk assessment residue definition for all plant commodities on which the use of imazamox is authorised, is not available.

2.2.1. Magnitude of residues in rotational crops

The peer review on the renewal of the approval of imazamox concluded that rotational crop field studies are not required as no residues are expected in crops according to the confined rotational crop studies (EFSA, 2016).

Although not identified in the confined rotational crop studies, an imazamox metabolite CL 354825 exhibits high persistence in soil with DT_{90} value of 1,000 days (EFSA, 2016). Considering the high persistence of metabolite CL 354825 in soil and its toxicological properties (see Section 1), EFSA recommends to take appropriate risk management measures to avoid occurrence of this metabolite in rotational crops.

3. Residues in livestock

3.1. Nature of residues

The peer review on the renewal of the approval confirmed that the enforcement and risk assessment residue definition in animal commodities is parent imazamox (EFSA, 2016).

3.2. Methods of analysis in livestock

The data gap number 2[13] has been sufficiently addressed in the framework of the renewal of the approval of imazamox (EFSA, 2016).

A sufficiently validated analytical method (LC–MS/MS) is available for the determination of imazamox in liver, kidney, muscle, milk, fat and egg at the validated LOQ of 0.01 mg/kg (EFSA, 2016). The method also allows quantifying metabolite CL 263284 at an LOQ of 0.01 mg/kg.

3.3. Magnitude of residues in livestock

In the framework of the MRL review, the dietary burden was calculated according to the EU guidance document applicable at that time (European Commission, 1996). In accordance with the agreed procedure (SANTE/10235/2016), the same version of the animal dietary burden calculator used in the initial Article 12 review should be used in the framework of the assessment of confirmatory data. According to the EU guidance document, rice and its by-products (straw, rice bran/pollard) were not considered as livestock feed items. For the remaining crops on which the existing imazamox MRLs are set above the LOQ and which can be used as livestock feed items, new residue data were not provided in the framework of the current assessment. Thus, the dietary burden calculated by the MRL review was not updated.

Once the residue data on all feed crops and their by-products is available according to the new risk assessment residue definition, the livestock exposure to imazamox residues shall be recalculated according to the currently used OECD methodology (OECD, 2013).

4. Consumer risk assessment

The assessment of confirmatory data triggers the modification of the previous risk assessment performed in the framework of the MRL review, since new residue data in rice were provided by the RMS.

[13] Data gap number 2 refers to 'a validated method of analysis for the determination of imazamox residues in commodities of animal origin (supported by independent laboratory validation data and a confirmatory method)'.

Furthermore, based on the information provided for the data gap number 3, a new risk assessment residue definition was suggested by EFSA which includes imazamox metabolites CL 263284 and CL 189215. It should also be highlighted that in the framework of the peer review, a lower ADI was derived and the setting of the reference value for the acute intake (ARfD) was considered necessary (EFSA, 2016; European Commission, 2017b).

EFSA calculated two consumer exposure scenarios: scenario 1 for the risk assessment residue definition ('imazamox') and scenario 2 for the new residue definition ('sum of imazamox and the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215), expressed as imazamox'). In both exposure scenarios, new toxicological reference values were applied.

Scenario 1

EFSA updated the consumer exposure calculation which was performed by the MRL review (residue definition 'imazamox'), using the median residue value (STMR) as derived for rice from the residue trials submitted in the framework of the current assessment. For the remaining commodities, the STMR and highest residue (HR) values corresponding to the existing EU MRLs set in Regulation (EU) No 2016/567 were used as input values as derived either in the framework of the MRL review, peer review or by the JMPR (FAO, 2014). Those crops on which no authorised uses of imazamox were reported in the MRL review were not considered in the calculation.

Scenario 2

EFSA notes that the calculated exposure in scenario 2 is indicative, pending the submission of a complete residue data package according to the new risk assessment residue definition, proposed as 'the sum of imazamox and the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215), expressed as imazamox'. For rice, residue data on metabolite CL 263284 and CL 189215 were submitted in the framework of the current assessment; the database however is not fully compliant with the data requirement (see Section 2.2). For those crops where recently CXLs have been implemented/confirmed in EU legislation (beans with pods, peas without pods, dry beans, lentils, peas, sunflower seed and rape seed), the residue data on imazamox and CL 263284 could be retrieved from the JMPR evaluation 2014. For soybean, residue data covering parent compound and metabolite CL 263284 were reported in the framework of the peer review, supporting the GAPs as assessed by the MRL review. For the mentioned crops, the residue information on metabolite CL 189215 is either limited, not validated or not available. For maize, in the absence of residue data, a conversion factor of 8, as derived from metabolism studies, was applied. Those crops on which no authorised uses of imazamox were reported in the MRL review were not considered in the calculation.

The summary of the input values is provided in Appendix D.

No long-term consumer intake concerns were identified for the authorised uses of imazamox, as the estimated maximum long-term dietary intake accounted for 0.01% of the ADI (NL child diet) in scenario 1 and for 0.04% of the ADI (WHO Cluster diet B) in scenario 2.

The short-term exposure did not exceed the ARfD for any of the crops on which imazamox is authorised, with maximum individual acute exposure being below 1% of ARfD in both exposure scenarios.

5. Conclusion and Recommendations

Data gap number 1 (validated analytical method of analysis for the determination of imazamox residues in high oil content crops and a confirmatory method for the determination of imazamox residues in high oil content, high water content, acid and dry crops) and data gap number 3 (representative plant metabolism studies (in primary and rotational crops) with imazamox labelled at the imidazolinone ring) have been fully addressed in the framework of the renewal of the approval for imazamox. Based on the new metabolism studies, a modification of the plant residue definitions was proposed. Thus, this would trigger a review of the existing MRLs which goes beyond the scope of the current assessment.

To address the data gap number 4 identified in the framework of the MRL review (residue trials supporting the southern outdoor GAP on rice), the applicant submitted new residue trials. However, the number of trials is not fully compliant with the data requirement (seven instead of eight trials are available for the critical GAP; for the alternative GAP in total six residue trials are available), and therefore the data gap is only partially addressed.

The footnote related to data gap number 2 (analytical method of analysis for the determination of imazamox residues in commodities of animal origin (including independent laboratory validation data

and a confirmatory method)) was deleted when CXLs have been taken over in the EU legislation. It is noted that the analytical method for animal products were provided in the framework of the peer review and was considered acceptable.

The data gaps for maize and soybean have been addressed in the framework of the peer review.

EFSA updated the previously calculated dietary consumer risk assessment, including the revised risk assessment values for rice and other relevant information, such as revised toxicological reference values. Furthermore, EFSA calculated the consumer exposure for the new residue definition, noting that this calculation is indicative, pending the submission of a complete residue data package according to the new risk assessment residue definition for all uses on which imazamox is authorised.

For none of the risk assessment scenarios, the estimated long-term and short-term exposure exceeded the toxicological reference values.

Overall, EFSA is of the opinion that existing EU MRLs for imazamox should be reviewed for all plant commodities on which the use of imazamox is authorised, considering the new residue definitions derived in the framework of the peer review. A further discussion with risk managers is required on the prioritisation of the re-assessment of the existing MRLs to align them with the new residue definition.

The overview of the assessment of confirmatory data and the recommended MRL modifications 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
CA	chromosome aberration
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
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
GS	growth stage
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
LC– MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
NEU	northern Europe
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RD	residue definition
RMS	rapporteur Member State
S9	rat liver metabolic activation system
SEU	southern Europe
SL	soluble concentrate
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
TK	thymidine kinase
TRR	total radioactive residue
UF	uncertainty factor
WHO	World Health Organization

Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

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 (min)	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Rice	SEU (IT)	F	Weeds	SL	40 g/L	Foliar	13–22	1				70	g/ha		Critical SEU GAP. (EFSA, 2013)
	SEU (IT, EL, ES)	F	Weeds	SL	40 g/L	Foliar	13–24	2				35	g/ha		Alternative GAP reported for an MRL review (EFSA, 2013)

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: soluble concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide 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	–	–	–	
	Root	–	–	–	
	Leafy	–	–	–	
	Cereals/ grass	Maize (imidazoline-tolerant variety)	Soil, pre-emergence, 141 g/ha	14, 30, 62, 112	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
			Foliar, BBCH 14–18, 130 g/ha	0, 14, 62, 100	
		Wheat (imidazoline-tolerant variety)	Foliar, post-emergence, 140 g/ha	28, 45, 70	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
			Foliar, BBCH 13–24, 75.7 g/ha + adjuvant	8, 62	Radiolabelled active substance in imidazolinone ring (EFSA, 2016; France, 2018a)
		Rice (imidazoline-tolerant variety)	Foliar, BBCH 13–25, 75.7 g/ha + adjuvant	42, 182	Radiolabelled active substance in imidazolinone ring (EFSA, 2016; France, 2018a)
		Alfalfa (imidazoline-tolerant variety)	Foliar, post emergence, 134.5 g/ha	0–157	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
	Pulses/ oilseeds	Peas	Foliar BBCH 33–35, 40 g/ha	20, 61, 84	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
		Rape seed (imidazoline-tolerant variety)	Foliar, BBCH 13–14, 20 g/ha	0, 84	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
			Foliar, BBCH 13-14, 51 or 89 g/ha	0, 22, 78	
			Foliar, BBCH 10–18, 75 g/ha + adjuvant	22, 90	Radiolabelled active substance in imidazolinone ring (EFSA, 2016; France, 2018a)
		Soybean	Soil, pre-planting, 146 g/ha	25, 58, 91, 151	Radiolabelled active substance in pyridine moiety (EFSA, 2016)
			Foliar, post-emergence, 76 or 150 g/ha	0, 30, 123	

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radish[1]	1) Post-emergence (70 g/ha) on soybean plant. 2) Bare soil, 75 g/ha.	268	1) Imazamox radiolabelled on pyridine ring 2) Imazamox radiolabelled on pyridine or imidazolinone ring (EFSA, 2016)
		Radish[2]		30, 120, 365	
	Leafy crops	Lettuce[1]		268, 420	
		Lettuce[2]		30, 120, 365	
	Cereal (small grain)	Wheat/corn[1]		100/268	
		Wheat[2]		30, 120, 365	
	Other	–	–	–	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		Imazamox is stable under conditions representing pasteurisation, boiling and sterilisation. Due to similarity of structure between imazamox and CL 263284 it can be assumed that metabolite CL 263284 will be stable under standard hydrolysis conditions (EFSA, 2016)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		
	Sterilisation (20 min, 120°C, pH 6)		Yes		
	Other processing conditions		–		

Can a general residue definition be proposed for primary crops?	No	Residue definition limited to the pulses and oilseeds and cereals/grass crop groups (EFSA, 2016)
Rotational crop and primary crop metabolism similar?	Yes	In most of succeeding crops, TRR was too low to allow any metabolite identification. Imazamox and metabolite CL 263284 were only detected in very low amount (up to 0.007 mg/kg) in wheat commodity following bare soil application. As no other compound than the ones observed in primary crops is observed in rotational crops, it is assumed that metabolism in rotational crop is similar to metabolism in primary crop (EFSA, 2016)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	Residue pattern is expected to be qualitatively similar. The residue definitions proposed for plants are also applicable to processed commodities (EFSA, 2016)
Plant residue definition for monitoring (RD-Mo)	Article 12 MRL review (EFSA, 2013): – Imazamox (tentative pending metabolism studies with imazamox labelled in imidazole group)	

	EU pesticides peer review (EFSA, 2016): – Sum of imazamox and CL 263284, expressed as imazamox Residue definition limited to the pulses and oilseeds and cereals/grass crop groups (EFSA, 2016)
Plant residue definition for risk assessment (RD-RA)	Article 12 MRL review (EFSA, 2013): – Imazamox (tentative pending metabolism studies with imazamox labelled in imidazole group) EU pesticides peer review (EFSA, 2016): – Sum of imazamox, CL 263284, and CL 189215, expressed as imazamox Residue definition limited to the pulses and oilseeds and cereals/grass crop groups (EFSA, 2016) Conversion factors for enforcement and risk assessment residue definition derived by the peer review: 1.9 for sunflower seeds (derived from residue trials) 2 for alfalfa (derived from metabolism study) (EFSA, 2016)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	LC–MS/MS (method L0188/01): high water content (green beans), high protein content (dry peas), high acid content (grapes), high oil content (sunflower seeds) and high starch content (rice), rice green plant and rice straw: LOQ 0.01 mg/kg (EFSA, 2016)

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; MRL: maximum residue level; PBI: plant-back interval; LC–MS/MS: liquid 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	Wheat forage	−10	48	Months	Imazamox, CL 263284	EFSA (2016)
		Maize plant	−18	24	Months	Imazamox, CL 263284	EFSA (2016)
		Soybean forage	−15	44	Months	Imazamox	EFSA (2016)
		Alfalfa forage	−10 −35	18	Months	Imazamox, CL 263284, CL 189215, CL 312622	EFSA (2016)
	High oil content	Soybean seed	−10	24	Months	Imazamox	EFSA (2016)
			−15	44	Months	Imazamox, CL 263284	EFSA (2016)
			−20	10	Months	CL 263284, CL 189215	EFSA (2016)
		Peanut	−5 −25	24	Months	CL 263284, CL 189215	EFSA (2016)
	High protein content	–	–	–	–	–	–
	High starch content	Wheat grain	−10	48	Months	Imazamox, CL 263284	EFSA (2016)
		Maize grain	−18	24	Months	Imazamox, CL 263284	EFSA (2016)
	High acid content	–	–	–	–	–	–
	Processed products	Soybean, oil defatted meal	−20	3	Months	CL 263284, CL 189215	EFSA (2016)
	Others	Wheat straw, hay	−10	48	Months	Imazamox, CL 263284	EFSA (2016)
		Alfalfa hay		18	Months	Imazamox, CL 263284, CL 189215, CL 312622	EFSA (2016)

B.1.1.3. Stability of residues in plants

Not relevant for the current application.

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
Residue definition for enforcement and risk assessment (MRL review, EFSA, 2013): Imazamox (sum of imazamox and its salts, expressed as imazamox)							
Rice (grain)	SEU (critical GAP: 1 × 70 g/ha)	4 × < 0.01; 0.01; 0.02; < 0.05	Residue trials on rice approximating the GAP (1×75 g/kg); 1 additional trial would be required to complement the data package	**0.05**	0.05	0.01	n/a
	SEU (alternative GAP: 2 × 35 g/ha)	6 × < 0.01	For the alternative GAP, 2 additional trials would be required to complement the data package	**0.01***	0.01	0.01	n/a
Rice straw	SEU (critical GAP: 1 × 70 g/ha)	6 × < 0.01		(0.01*)	0.01	0.01	n/a
	SEU (alternative GAP: 2 × 35 g/ha)	6 × < 0.01		(0.01*)	0.01	0.01	n/a
Residue definition for enforcement and risk assessment (feed commodities) (MRL review, EFSA, 2013): imazamox and CL 263284, free and conjugated, expressed as imazamox							
Rice (straw)	SEU (critical GAP: 1 × 70 g/ha)	3 × < 0.02; 0.03; 0.04; 0.07	Residue trials on rice compliant with the GAP	0.15	0.07	0.03	n/a
	SEU (alternative GAP: 2 × 35 g/ha)	3 x < 0.02; 0.02; 2 × 0.03		0.05	0.03	0.02	n/a
Residue definition for enforcement (EU pesticides peer review, EFSA, 2016): sum of imazamox and CL 263284, expressed as imazamox **Residue definition for risk assessment (EU pesticides peer review, EFSA, 2016):** sum of imazamox, CL 263284, and CL 189215, expressed as imazamox							
Rice (grain)	SEU (critical GAP: 1 × 70 g/ha)	Mo: 3 × < 0.02; < 0.05; 0.05; 0.06; 0.07 RA: 3 × < 0.03; 0.06; 0.07; 0.09	Residue trials on rice approximating the GAP; 1 additional residue trial required	0.15	Mo: 0.07 RA: 0.09[d]	Mo: 0.05 RA: 0.05[d]	1.4[d]
	SEU(alternative GAP: 2 × 35 g/ha)	Mo: 3 × < 0.02; 0.03; 2 × 0.04 RA: 3 × < 0.03; 0.04; 2 × 0.05	For the alternative GAP, 2 additional trials would be required to complement the data package	0.07	Mo: 0.04 RA: 0.05[d]	Mo: 0.03 RA: 0.04[d]	1.4[d]

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
Rice (straw)	SEU (critical GAP: 1 × 70 g/ha)	Mo: 3 × < 0.02; 0.03; 0.04; 0.07 RA: 3 × < 0.03; 0.04; 0.05; 0.09	Residue trials on rice approximating the GAP	(0.15)	Mo: 0.07 RA: 0.09[d]	Mo: 0.03 RA: 0.04[d]	1.4[d]
	SEU (alternative GAP: 2 × 35 g/ha)	Mo: 3 × < 0.02; 0.02; 2 × 0.03 RA: 3 × < 0.03; 0.03; 2 × 0.04		(0.05)	Mo: 0.03 RA: 0.04[d]	Mo: 0.02 RA: 0.03[d]	1.5[d]

MRL: maximum residue level; GAP: Good Agricultural Practice; CF: Conversion factor from monitoring to risk assessment residue definition; n/a: not applicable.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Tentative, pending the investigation of freezer storage stability of metabolite CL 189215.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	In most of succeeding crop, and whatever the plant–back interval, TRR was too low to allow any metabolite identification. Imazamox and metabolite CL 263284 were the only identified compounds and they were only detected in very low amount (up to 0.007 mg/kg) in wheat commodity following bare soil application (EFSA, 2016)
Residues in rotational and succeeding crops expected based on field rotational crop study?	No	Not required as no residues are expected in following crops according to confined rotational crop studies

TRR: total radioactive residue.

B.2. Residues in livestock

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

Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Imazamox
Animal residue definition for risk assessment (RD-RA)	Imazamox
Conversion factor (monitoring to risk assessment)	None
Fat soluble residues (Yes/No)	No
Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)	LC–MS/MS (method D0303) LOQ 0.01 mg/kg for imazamox and its metabolite CL 263284 in liver, kidney, muscle, milk, fat and egg (EFSA, 2016)

LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.3. Consumer risk assessment

ARfD	3 mg/kg bw (European Commission, 2017b)
Highest IESTI, according to EFSA PRIMo	**Scenario 1** Milk: 0.04% of ARfD Beans with pods: 0.02% of ARfD Other commodities of plant and animal origin: ≤ 0.01% of ARfD **Scenario 2 (indicative)** Maize: 0.09% of ARfD Milk: 0.04% of ARfD Other commodities of plant and animal origin: ≤ 0.03% of ARfD
Assumptions made for the calculations	In the MRL review, acute exposure assessment was not undertaken because the ARfD was not set for imazamox at that time. For the calculation, EFSA considered only those commodities for which the authorised use was reported under the MRL review

ADI	3 mg/kg bw per day (European Commission, 2017b)
Highest IEDI, according to EFSA PRIMo	**Scenario 1**: 0.01% ADI (NL child diet) **Scenario 2 (indicative)**: 0.04% ADI (WHO Cluster diet
	B, IE Adult diet)
Assumptions made for the calculations	For the calculation, EFSA considered only those commodities for which the authorized use was reported under the MRL review

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

B.4. Mammalian toxicology

Other toxicological studies

Studies performed on metabolites or impurities

Metabolite CL 263284 and its glucose conjugate (CL 189215)	Minor rat metabolite (2% in urine) Rat, acute oral LD_{50} > 5,000 mg/kg bw Ames tests ± S9: negative *In vitro* micronucleus tests: positive +S9 and negative –S9 *In vivo* micronucleus tests: negative (bioavailability confirmed) Unlikely to be genotoxic *in vivo* 28-day, rat NOAEL: 333 mg/kg bw per day for males based on bw effects (decreased body weight gain) The toxicological reference values of the parent (ADI and ARfD) are applicable to the metabolite It cannot be excluded that the metabolites share the developmental toxicity properties of imazamox (proposed to be classified as Repr 2 H361d 'Suspected of damaging the unborn child')[14]

[14] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

Metabolite CL 354825	Rat, acute oral LD_{50}: 2,313 mg/kg bw (males) and 2,121 mg/kg bw (females) Ames test ± S9: negative *In vitro* CA assay: clastogenicity ± S9: positive aneugenicity ± S9: negative *In vitro* mouse lymphoma TK gene mutation assay ± S9: negative *In vivo* micronucleus test: negative (bioavailability confirmed) Unlikely to be genotoxic *in vivo* 28-day, rat NOAEL: 88.4 mg/kg bw per day based on body weight and kidneys effects ADI: 0.09 mg/kg bw per day, based on the 28-day study in rat conducted with the metabolite and applying an UF of 1,000 due to the limited database The ARfD is 0.09 mg/kg bw based on the same 28-day study in rat and considering the structure similarity with imazamox It cannot be excluded that the metabolite share the developmental toxicity properties of imazamox (proposed to be classified as Repr 2 H361d 'Suspected of damaging the unborn child')

	Value	Study	Safety factor
ADI (CL 354825)	0.09 mg/kg bw per day	28-day, rat	1,000
ARfD (CL 354825)	0.09 mg/kg bw	28-day, rat	1,000

LD50: lethal dose, median; bw: body weight; NOAEL: no observed adverse effect level; ADI: acceptable daily intake; ARfD: acute reference dose; CA: chromosome aberration; UF: uncertainty factor; TK: thymidine kinase

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
Existing enforcement residue definition: Imazamox (sum of imazamox and its salts, expressed as imazamox) General **recommendation:** Based on the metabolism studies provided as confirmatory data, revised residue definitions for enforcement (i.e. sum of imazamox and its hydroxymethyl metabolite CL 263484 expressed as imazamox) and risk assessment (sum of imazamox and the hydroxymethyl metabolite (CL 263284) and its glucose conjugate (CL 189215), expressed as imazamox) were derived. **Thus, EFSA** recommends a review of the existing MRLs, including a comprehensive risk assessment based on the revised residue definition. This review could not be performed under the current assessment, since currently only very limited information is available on the expected residue concentrations related to the new residue definitions. Considering that the analytical methods provided as confirmatory data demonstrated that a lower LOQ of 0.01 mg/kg is achievable in routine MRL enforcement for matrices with high water content, high protein content, high acid content, high oil content and high starch content, the lowering of the existing LOQ MRLs set for commodities where no uses were reported in the framework of the MRL review could be considered.				

Code[(a)]	Commodity	Existing MRL[(b)]	Proposed MRL	Conclusion/recommendation
0260030	Peas (with pods)	0.05* (ft 1)	(0.01*) risk management decision	In the framework of the MRL review, no authorised use of imazamox on peas (with pods) was reported. Thus, the footnote requesting confirmatory data for peas with pods was erroneously implemented in Regulation (EU) No 2016/567. The lowering of the MRL set at the LOQ of 0.05 mg/kg to a lower LOQ of 0.01 mg/kg which is achievable with routine analytical methods could be considered. The footnote should be deleted
0401070	Soya bean	0.05* (ft 2)	(0.01*) risk management decision	The confirmatory data requirements have been sufficiently addressed The lowering of the MRL to a lower LOQ of 0.01 mg/kg which is achievable with routine analytical methods could be considered The previous consumer risk assessment was updated, using lower ADI and a new ARfD. No consumer intake concerns were identified
0500030	Maize/corn	0.05* (ft 1)		
0500060	Rice	0.05* (ft 3)	Risk management decision	The requested metabolism studies were provided. Additional residue trials have been submitted, which suggest a MRL of 0.05 mg/kg. However, one additional SEU trial required is still missing The previous consumer risk assessment was updated, using lower ADI and a new ARfD. No consumer intake concerns were identified A risk management decision to be taken whether it is appropriate to lower the MRL to the LOQ of 0.01 mg/kg due to the lack of supporting data

MRL: maximum residue level; LOQ: limit of quantification; ADI: acceptable daily intake; ARfD: acute reference dose; SEU: southern Europe.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
ft 1: EFSA identified some information on plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 3).
ft 2: EFSA identified some information on analytical methods and plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 1 and 3).
ft 3: EFSA identified some information on residue trials and plant metabolism with imazamox labelled at the imidazolinone ring as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 3 and 4).

Appendix C – Pesticide Residue Intake Model (PRIMo)

Imazamox			
Status of the active substance:	**Approved**	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**3**	ARfD (mg/kg bw):	**3**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2017**	Year of evaluation:	**2017**

Update following the submission of conifmatory data.

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

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)
0.01	NL child	0.01	Milk and milk products: Cattle	0.00	Beans (with pods)	0.00	Peas (without pods)	
0.01	FR infant	0.01	Milk and milk products: Cattle	0.00	Beans (with pods)	0.00	Peas (without pods)	
0.01	WHO Cluster diet B	0.00	Maize	0.00	Sunflower seed	0.00	Soya bean	
0.01	ES child	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Bovine: Meat	
0.01	IE adult	0.00	Maize	0.00	Milk and milk products: Cattle	0.00	Peas	
0.01	WHO cluster diet E	0.00	Milk and milk products: Cattle	0.00	Rape seed	0.00	Soya bean	
0.01	DE child	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Peas (without pods)	
0.00	WHO cluster diet D	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Sunflower seed	
0.00	SE general population 90th percentile	0.00	Milk and milk products: Cattle	0.00	Beans (with pods)	0.00	Beans (with pods)	
0.00	WHO Cluster diet F	0.00	Milk and milk products: Cattle	0.00	Soya bean	0.00	Rape seed	
0.00	WHO regional European diet	0.00	Milk and milk products: Cattle	0.00	Swine: Meat	0.00	Bovine: Meat	
0.00	NL general	0.00	Milk and milk products: Cattle	0.00	Beans (with pods)	0.00	Peas (without pods)	
0.00	ES adult	0.00	Milk and milk products: Cattle	0.00	Beans (with pods)	0.00	Bovine: Meat	
0.00	FR toddler	0.00	Beans (with pods)	0.00	Peas (without pods)	0.00	Bovine: Meat	
0.00	UK Infant	0.00	Maize	0.00	Peas (without pods)	0.00	Rice	
0.00	PT General population	0.00	Maize	0.00	Soya bean	0.00	Sunflower seed	
0.00	FR all population	0.00	Milk and milk products: Cattle	0.00	Sunflower seed	0.00	Beans (with pods)	
0.00	LT adult	0.00	Milk and milk products: Cattle	0.00	Swine: Meat	0.00	Bovine: Meat	
0.00	UK Toddler	0.00	Peas (without pods)	0.00	Beans	0.00	Rice	
0.00	UK vegetarian	0.00	Peas (without pods)	0.00	Rice	0.00	Beans	
0.00	IT kids/toddler	0.00	Peas (without pods)	0.00	Beans (with pods)	0.00	Rice	
0.00	IT adult	0.00	Beans (with pods)	0.00	Peas (without pods)	0.00	Rice	
0.00	UK Adult	0.00	Peas (without pods)	0.00	Rice	0.00	Beans (with pods)	
0.00	DK adult	0.00	Bovine: Meat	0.00	Peas (without pods)	0.00	Rice	
0.00	FI adult	0.00	Beans (with pods)	0.00	Maize	0.00	Rice	
0.00	DK child	0.00	Bovine: Liver	0.00	Rice	0.00	Beans (with pods)	
0.00	PL general population	0.00	Peas	0.00	Sunflower seed	0.00	Beans	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Imazamox 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)
0.04	Milk and milk products:	0.01/-	0.0	Milk and milk	0.01/-	0.0	Beans (with pods)	0.05/-	0.0	Beans (with pods)	0.05/-
0.02	Beans (with pods)	0.05/-	0.0	Beans (with pods)	0.05/-	0.0	Peas (without pods)	0.05/-	0.0	Peas (without pods)	0.05/-
0.01	Peas (without pods)	0.05/-	0.0	Peas (without	0.05/-	0.0	Milk and milk	0.01/-	0.0	Milk and milk products: Cattle	0.01/-
0.01	Maize	0.05/-	0.0	Maize	0.05/-	0.0	Peas	0.05/-	0.0	Peas	0.05/-
0.01	Lentils	0.05/-	0.0	Lentils	0.05/-	0.0	Lentils	0.05/-	0.0	Lentils	0.05/-
0.01	Milk and milk products:	0.01/-	0.0	Milk and milk	0.01/-	0.0	Maize	0.05/-	0.0	Maize	0.05/-
0.01	Peas	0.05/-	0.0	Peas	0.05/-	0.0	Rice	0.01/-	0.0	Rice	0.01/-
0.01	Beans	0.01/-	0.0	Beans	0.01/-	0.0	Milk and milk products: Goat	0.01/-	0.0	Milk and milk products: Goat	0.01/-
0.01	Sunflower seed	0.05/-	0.0	Sunflower seed	0.05/-	0.0	Beans	0.01/-	0.0	Beans	0.01/-
0.00	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-
0.00	Rice	0.01/-	0.0	Rice	0.01/-	0.0	Sunflower seed	0.05/-	0.0	Sunflower seed	0.05/-
0.00	Soya bean	0.05/-	0.0	Soya bean	0.05/-	0.0	Swine: Meat	0.01/-	0.0	Swine: Meat	0.01/-
0.00	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-
0.00	Swine: Meat	0.01/-	0.0	Swine: Meat	0.01/-	0.0	Soya bean	0.05/-	0.0	Soya bean	0.05/-
0.00	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-
0.00	Rape seed	0.05/-	0.0	Rape seed	0.05/-	0.0	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-
0.00	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-	0.0	Milk and milk products: Sheep	0.01/-	0.0	Milk and milk products: Sheep	0.01/-
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)	
0.0	Maize flour	0.05/-		0.0	Maize flour	0.05/-	

*) 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 Imazamox, 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.

Imazamox, CL 263284 and CL 189215, expressed as imazamox			
Status of the active substance:	Approved	Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	3	ARfD (mg/kg bw):	3
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2017	Year of evaluation:	2017

Update following the submission of conifmatory data

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

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)
0.04	WHO Cluster diet B	0.03	Maize	0.00	Sunflower seed	0.00	Milk and milk products: Cattle	
0.04	IE adult	0.03	Maize	0.00	Sunflower seed	0.00	Milk and milk products: Cattle	
0.02	UK Infant	0.01	Maize	0.00	Peas (without pods)	0.00	Rice	
0.02	NL child	0.01	Milk and milk products: Cattle	0.00	Maize	0.00	Peas (without pods)	
0.02	WHO cluster diet E	0.01	Maize	0.00	Sunflower seed	0.00	Rape seed	
0.01	WHO cluster diet D	0.01	Maize	0.00	Sunflower seed	0.00	Milk and milk products: Cattle	
0.01	ES child	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Rice	
0.01	PT General population	0.01	Maize	0.00	Sunflower seed	0.00	Rice	
0.01	FR infant	0.01	Milk and milk products: Cattle	0.00	Peas (without pods)	0.00	Beans (with pods)	
0.01	DE child	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Sunflower seed	
0.01	WHO regional European diet	0.00	Maize	0.00	Milk and milk products: Cattle	0.00	Sunflower seed	
0.01	WHO Cluster diet F	0.00	Maize	0.00	Milk and milk products: Cattle	0.00	Rape seed	
0.01	ES adult	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Sunflower seed	
0.01	SE general population 90th percentile	0.00	Milk and milk products: Cattle	0.00	Rice	0.00	Peas (without pods)	
0.00	NL general	0.00	Milk and milk products: Cattle	0.00	Maize	0.00	Peas (without pods)	
0.00	FR toddler	0.00	Peas (without pods)	0.00	Sunflower seed	0.00	Beans (with pods)	
0.00	FR all population	0.00	Sunflower seed	0.00	Milk and milk products: Cattle	0.00	Rice	
0.00	UK Toddler	0.00	Peas (without pods)	0.00	Rice	0.00	Beans	
0.00	LT adult	0.00	Milk and milk products: Cattle	0.00	Rice	0.00	Swine: Meat	
0.00	UK vegetarian	0.00	Rice	0.00	Peas (without pods)	0.00	Beans	
0.00	IT kids/toddler	0.00	Maize	0.00	Peas (without pods)	0.00	Rice	
0.00	UK Adult	0.00	Rice	0.00	Peas (without pods)	0.00	Beans	
0.00	IT adult	0.00	Rice	0.00	Maize	0.00	Peas (without pods)	
0.00	DK adult	0.00	Peas (without pods)	0.00	Bovine: Meat	0.00	Rice	
0.00	FI adult	0.00	Maize	0.00	Rice	0.00	Beans (with pods)	
0.00	DK child	0.00	Rice	0.00	Bovine: Liver	0.00	Beans (with pods)	
0.00	PL general population	0.00	Peas	0.00	Sunflower seed	0.00	Beans	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Imazamox, CL 263284 and CL 189215, expressed as imazamox 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)
0.09	Maize	0.4/-	0.1	Maize	0.4/-	0.0	Maize	0.4/-	0.0	Maize	0.4/-
0.04	Milk and milk products:	0.01/-	0.0	Milk and milk	0.01/-	0.0	Peas (without pods)	0.1/-	0.0	Peas (without pods)	0.1/-
0.03	Peas (without pods)	0.1/-	0.0	Peas (without	0.1/-	0.0	Rice	0.05/-	0.0	Rice	0.05/-
0.02	Rice	0.05/-	0.0	Rice	0.05/-	0.0	Peas	0.1/-	0.0	Peas	0.1/-
0.02	Lentils	0.1/-	0.0	Lentils	0.1/-	0.0	Lentils	0.1/-	0.0	Lentils	0.1/-
0.02	Sunflower seed	0.19/-	0.0	Sunflower seed	0.19/-	0.0	Sunflower seed	0.19/-	0.0	Sunflower seed	0.19/-
0.01	Peas	0.1/-	0.0	Peas	0.1/-	0.0	Milk and milk	0.01/-	0.0	Milk and milk products: Cattle	0.01/-
0.01	Beans	0.02/-	0.0	Beans	0.02/-	0.0	Beans	0.02/-	0.0	Beans	0.02/-
0.01	Milk and milk products: Goat	0.01/-	0.0	Milk and milk products: Goat	0.01/-	0.0	Beans (with pods)	0.02/-	0.0	Beans (with pods)	0.02/-
0.01	Beans (with pods)	0.02/-	0.0	Beans (with pods)	0.02/-	0.0	Milk and milk products: Goat	0.01/-	0.0	Milk and milk products: Goat	0.01/-
0.00	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-	0.0	Bovine: Meat	0.01/-
0.00	Rape seed	0.1/-	0.0	Rape seed	0.1/-	0.0	Swine: Meat	0.01/-	0.0	Swine: Meat	0.01/-
0.00	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-	0.0	Sheep: Meat	0.01/-
0.00	Swine: Meat	0.01/-	0.0	Swine: Meat	0.01/-	0.0	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-
0.00	Bovine: Liver	0.01/-	0.0	Bovine: Liver	0.01/-	0.0	Soya bean	0.03/-	0.0	Soya bean	0.03/-
0.00	Soya bean	0.03/-	0.0	Soya bean	0.03/-	0.0	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-
0.00	Bovine: Kidney	0.01/-	0.0	Bovine: Kidney	0.01/-	0.0	Milk and milk products: Sheep	0.01/-	0.0	Milk and milk products: Sheep	0.01/-
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)			
0.0	Maize flour	0.05/-				0.0	Maize flour	0.05/-			

*) 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 Imazamox, CL 263284 and CL 189215, expressed as imazamox 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.

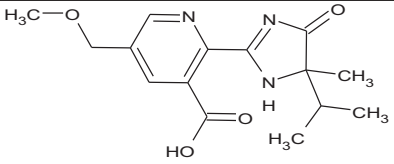
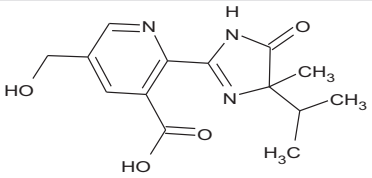
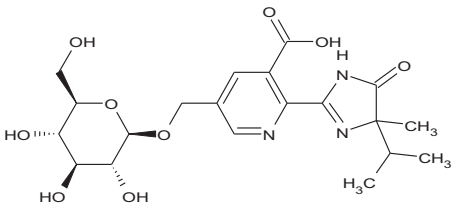
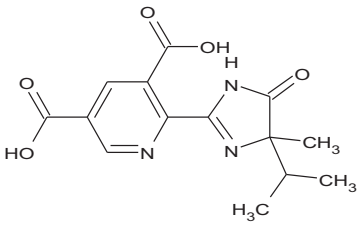
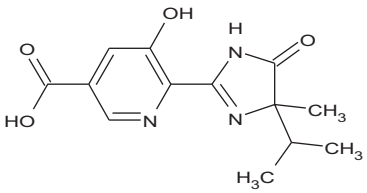
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Existing risk assessment residue definition: imazamox				
Beans (with pods)	0.05	STMR (FAO, 2014)	0.05	HR (FAO, 2014)
Peas (without pod)	0.05	STMR (FAO, 2014)	0.05	HR (FAO, 2014)
Beans	0.01	STMR (FAO, 2014)	0.01	STMR (FAO, 2014)
Lentils	0.05	STMR (FAO, 2014)	0.05	STMR (FAO, 2014)
Peas	0.05	STMR (FAO, 2014)	0.05	STMR (FAO, 2014)
Sunflower seed	0.05	STMR (FAO, 2014)	0.05	STMR (FAO, 2014)
Rapeseed	0.05	STMR (FAO, 2014)	0.05	STMR (FAO, 2014)
Soybean	0.05	STMR (EFSA, 2013)	0.05	STMR (EFSA, 2013)
Maize	0.05	STMR (EFSA, 2013)	0.05	STMR (EFSA, 2013)
Rice	0.01	STMR (France, 2018a)	0.01	STMR (France, 2018a)
Meat, fat, liver, kidney of swine, bovine, sheep and goat; milk of cattle, sheep and goat	0.01*	EU MRL (Regulation (EU) 2016/567)	0.01	EU MRL (Regulation (EU) 2016/567)
Risk assessment residue definition: 1) sum of imazamox, CL 263284 and CL 189215, expressed as imazamox (EFSA, 2016)				
Beans (with pods)	0.02[(a)]	STMR[(a)] (FAO, 2014)	0.02[(a)]	HR[(a)] (FAO, 2014)
Peas (without pod)	0.10[(a)]	STMR[(a)] (FAO, 2014)	0.10[(a)]	HR[(a)] (FAO, 2014)
Beans	0.02[(a)]	STMR[(a)] (FAO, 2014)	0.02[(a)]	STMR[(a)] (FAO, 2014)
Lentils	0.10[(a)]	STMR[(a)] (FAO, 2014)	0.10[(a)]	STMR[(a)] (FAO, 2014)
Peas	0.10[(a)]	STMR[(a)] (FAO, 2014)	0.10[(a)]	STMR[(a)] (FAO, 2014)
Sunflower seed	0.19[(a)]	STMR[(a)] (FAO, 2014)	0.19[(a)]	STMR[(a)] (FAO, 2014)
Rape seed	0.10[(a)]	STMR[(a)] (FAO, 2014)	0.10[(a)]	STMR[(a)] (FAO, 2014)
Soya bean	0.03	STMR[(b)] (EFSA, 2016)	0.03	STMR[(b)] (EFSA, 2016)
Maize grain	0.40	STMR (EFSA, 2013)* CF (8)	0.40	STMR (EFSA, 2013)* CF (8)
Rice grain	0.05	STMR[(c)] (France, 2018a)	0.05	STMR[(c)] (France, 2018a)
2) imazamox (EFSA, 2016)				
Meat, fat, liver, kidney of swine, bovine, sheep and goat; milk of cattle, sheep and goat	0.01	EU MRL (Regulation (EU) 2016/567)	0.01	EU MRL (Regulation (EU) 2016/567)

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
(a): Value refers to the sum of imazamox and metabolite CL 263284.
(b): Residue data on CL 189215 derived from four trials only.
(c): The validity of residue data on CL 189215 cannot be confirmed due to the lack of study investigating freezer storage stability.

Appendix E – Used compound codes

Code/ trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Imazamox	2-[(*RS*)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid O=C1N=C(NC1(C)C(C)C)c1ncc(COC)cc1C(=O)O NUPJIGQFXCQJBK-UHFFFAOYSA-N	
CL 263284	5-(hydroxymethyl)-2-[(4*RS*)-4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1*H*-imidazol-2-yl]nicotinic acid CC1(N=C(NC1=O)c1ncc(CO)cc1C(=O)O)C(C)C XQOJIMLCWGIOCP-UHFFFAOYSA-N	
CL 189215	5-[(β-D-glucopyranosyloxy)methyl]-2-[(4*RS*)-4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1*H*-imidazol-2-yl]nicotinic acid CC(C)C1(C)N=C(NC1=O)c1ncc(CO[C@@H]2O[C@H](CO)[C@@H](O)[C@H](O)[C@H]2O)cc1C(=O)O YYCWLOSSRKXBSC-DLIFEIRTSA-N	
CL 312622	2-[(4*RS*)-4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1*H*-imidazol-2-yl]pyridine-3,5-dicarboxylic acid CC1(N=C(NC1=O)c1ncc(cc1C(=O)O)C(=O)O)C(C)C ZRPVTLGVORAGCY-UHFFFAOYSA-N	
CL 354825	5-hydroxy-6-[(4*RS*)-4-isopropyl-4-methyl-5-oxo-4,5-dihydro-1*H*-imidazol-2-yl]nicotinic acid CC1(N=C(NC1=O)c1ncc(cc1O)C(=O)O)C(C)C HSZSMTXJHICIFJ-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 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).