REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for imazamox according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance imazamox. In order to assess the occurrence of imazamox residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

KEY WORDS

imazamox, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, imidazolinone, herbicide

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SUMMARY

Imazamox was included in Annex I to Directive 91/414/EEC on 01 July 2003, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked France, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 11 June 2009 and, after having considered several comments made by EFSA, the RMS provided on 19 October 2012 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 24 January 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 29 March 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of imazamox was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 9.0 mg/kg bw per d. An ARfD was not deemed necessary.

Metabolism of imazamox was investigated for soil application, pre-emergence treatment (via incorporation to soil) and by foliar application post emergence on cereals (maize) and on pulses and oilseeds (soya bean, pea and oilseed rape), using 6-pyridine-^{14}C labelled-imazamox. The fate of the imidazolinone moiety was not addressed in the submitted plant metabolism studies and needs to be further addressed. Nevertheless, in the absence of significant residues of parent imazamox and any degradation products (using the pyridine label), it is considered that the residue for enforcement and risk assessment in pulses and oilseeds and cereal grain is tentatively defined as parent imazamox only, which is sufficient to cover the authorised uses. Analytical methods for enforcement of the proposed residue definition in high water content, acidic and dry commodities are available but a confirmatory method and a validated analytical method for enforcement of residue in high oil content commodities are still required. With regard to the authorisation of further uses confirmation that the hydroxymethyl metabolite does not occur in practice will be required. In fodder the levels of the hydroxymethyl metabolite and the glucoside metabolite, were greater than that for the parent imazamox. The residue for risk assessment in fodder commodities is therefore tentatively proposed as the sum of imazamox and its hydroxymethyl metabolite free and conjugated expressed as imazamox. This residue definition is also proposed for enforcement purposes in view of the future need to set MRLs in feed items and a validated analytical method for enforcement of the proposed future residue definition in forage crops may still be required by risk managers in the future.

Regarding the magnitude of residues in crops, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for rice where the available data were insufficient to derive tentative MRLs. MRL proposals are in any case considered on a tentative basis only due to the lack of a metabolism study with labelling of the imidazolinone ring and due to the analytical method deficiencies for enforcement in oilseeds (see above).

As residues of imazamox exceeding 0.1 mg/kg are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Occurrence of imazamox residues in rotational crops was investigated. It is concluded that significant residues in rotational crops are not expected, provided that imazamox is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant exposures to imazamox are expected for dairy and meat ruminants and pigs. A metabolism study for goat confirms an expectation that residue levels in livestock commodities (excluding poultry) are expected to remain below the enforcement LOQ of 0.01 mg/kg and a residue definition of parent imazamox only is proposed for dairy and meat ruminants and pigs. However validated analytical methods for enforcement of the proposed residue definition in food of animal origin are not available. In the absence of an analytical method of analysis for enforcement of imazamox in food of animal origin with a validated LOQ it is considered that the MRL be established at the default value of 0.01 mg/kg. MRLs for poultry products are not required because they are not expected to be exposed to significant levels of imazamox residues.

Chronic consumer exposure resulting from the uses authorised in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 0.005 % of the ADI (Dutch children). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, tentative MRLs need to be confirmed by the following data:

- 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 (will be considered as part of the active substance renewal program scheduled for 2014);
- 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);
- representative plant metabolism studies with imazamox labelled at the imidazolinone ring (will be considered as part of the active substance renewal program scheduled for 2014);
- 7 additional residues trials supporting the southern outdoor GAP on rice;

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

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

- information on the storage conditions for all residues trials samples reported in the framework of this review.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: imazamox				
260010	Beans (fresh, with pod)	0.05*	0.05*	Further consideration needed [(a)]
260040	Peas (fresh, without pod)	0.05*	0.05*	Further consideration needed [(a)]
300010	Beans (dry)	0.05*	0.05*	Further consideration needed [(a)]
300020	Lentils (dry)	0.05*	0.05*	Further consideration needed [(a)]
300030	Peas (dry)	0.05*	0.05*	Further consideration needed [(a)]
401050	Sunflower seed	0.05*	0.05	Further consideration needed [(a)]
401060	Rapeseed	0.05*	0.05	Further consideration needed [(a)]
401070	Soya bean	0.05*	0.05	Further consideration needed [(a)]
500030	Maize	0.05*	0.05*	Further consideration needed [(a)]
500060	Rice	0.05*	0.05*	Further consideration needed [(b)]
1011010	Swine meat	-	0.01	Further consideration needed [(a)]
1011020	Swine fat (free of lean meat)	-	0.01	Further consideration needed [(a)]
1011030	Swine liver	-	0.01	Further consideration needed [(a)]
1011040	Swine kidney	-	0.01	Further consideration needed [(a)]
1012010	Bovine meat	-	0.01	Further consideration needed [(a)]
1012020	Bovine fat	-	0.01	Further consideration needed [(a)]
1012030	Bovine liver	-	0.01	Further consideration needed [(a)]
1012040	Bovine kidney	-	0.01	Further consideration needed [(a)]
1013010	Sheep meat	-	0.01	Further consideration needed [(a)]
1013020	Sheep fat	-	0.01	Further consideration needed [(a)]
1013030	Sheep liver	-	0.01	Further consideration needed [(a)]
1013040	Sheep kidney	-	0.01	Further consideration needed [(a)]
1014010	Goat meat	-	0.01	Further consideration needed [(a)]
1014020	Goat fat	-	0.01	Further consideration needed [(a)]
1014030	Goat liver	-	0.01	Further consideration needed [(a)]
1014040	Goat kidney	-	0.01	Further consideration needed [(a)]
1020010	Cattle milk	-	0.01	Further consideration needed [(a)]
1020020	Sheep milk	-	0.01	Further consideration needed [(a)]
1020030	Goat milk	-	0.01	Further consideration needed [(a)]
-	Other products of plant and animal origin	See App C	-	Further consideration needed [(c)]

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix D).

(b): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix D).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As imazamox was included in Annex I to the above mentioned directive on 01 July 2003, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-563 was included in the EFSA Register of Questions.

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

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

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

France, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for imazamox. The requested information was submitted to EFSA on 11 June 2009 and subsequently checked for completeness. On 19 October 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 24 January 2013 and submitted to Member States (MS) for commenting. All MS comments received by 29 March 2013 were considered by EFSA in the finalisation of the reasoned opinion.

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

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

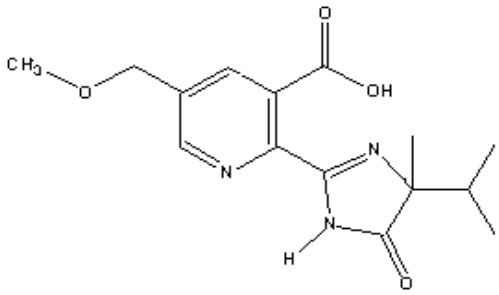
TERMS OF REFERENCE

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Imazamox is the ISO common name for 2-[(RS)-4-isopropyl-4-methyl-5-oxo-2-imidazolin-2-yl]-5-methoxymethylnicotinic acid (IUPAC).



Imazamox belongs to the group of imidazolinone compounds which are used as herbicides. It is used to target weeds as a contact herbicide applied as a spray both pre- and post-emergence. It acts by inhibiting the enzyme acetohydroxyacid synthase (AHAS), which is involved in the synthesis of branched-chain aliphatic amino acids. This inhibition disrupts protein synthesis and subsequently interferes with DNA synthesis and cell growth

Imazamox was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was outdoor pre-emergence and early post-emergence use on peas (without pod), peas (dry), beans (dry) and imidazolinone tolerant varieties of both maize and rape seed with a maximum application rate of 0.075 kg as/ha. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/23/EC[6], which entered into force on 01 July 2003. According to Regulation (EU) No 540/2011[7], imazamox is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as a herbicide only. As EFSA was not yet involved in the peer review of imazamox, an EFSA Conclusion on this active substance is not available.

The EU MRLs for imazamox are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for imazamox are summarised in Appendix C to this document. CXLs for imazamox are not available.

[6] Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances. OJ L 81, 28.3.2003, p. 39-42.

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

[8] 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 309, 24.11.2009, p. 1–50.

For the purpose of this MRL review, the critical uses of imazamox currently authorised within the EU have been collected by the RMS and reported in the PROFile. Additional GAPs reported during the consultation of Member States were also considered (see Appendix A). According to the reported edible crop GAPs imazamox is applied as a single outdoor pre- or early post-emergence spray treatment on several legume vegetables and pulses, sunflower, soya bean, rice, alfalfa and imidazolinone tolerant varieties of both maize and rape seed with a maximum application rate of 0.075 kg as/ha. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (France, 1999, 2001), the Review Report on imazamox (EC, 2002) as well as the evaluation report submitted during the consultation of Member States (France, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011 and OECD, 2011).

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-UV was evaluated for the determination of imazamox in high water and dry plant matrices and an analytical method using GC-NPD was evaluated for the determination of imazamox in high oil plant matrices (France 1999). Insufficient validation data were presented for both these methods as insufficient recovery determinations were made.

A multi residue method was considered at a later stage during the peer review under Directive 91/414/EEC. This analytical method using HPLC-UV and its ILV were evaluated and validated for the determination of imazamox in plant matrices with an LOQ of 0.05 mg/kg in high water (fresh pea), acidic (oranges and grapes) and dry (maize grain) and an LOQ of 0.01 mg/kg in dry commodities (wheat grain) (EC, 2002a). An evaluation report detailing the methodology and acceptable validation data for this method have been presented, ILV data were also presented for grape, maize grain and wheat grain (France 2013). However, a confirmatory method for analysis of high water, acidic and dry commodities is not available and is therefore still required.

In addition, the multi-residue QuEChERS method in combination with HPLC-MS/MS and GC/MS, described in the European Standards EN 15662:2008 (CEN, 2008), is available for the determination of parent imazamox in high water, dry and high acid commodities, but validation data for this method are limited and the method is therefore not considered acceptable.

Hence there are indications that imazamox can be enforced in food of plant origin with an overall LOQ of 0.05 mg/kg in high water content, acidic and dry commodities but a confirmatory method is still required. An analytical method for enforcement in commodities with high oil content is also not available but it is noted that a method of analysis for high oil commodities will be presented as part of the active substance renewal program scheduled for 2014.

[9] 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, 11.06.2011, p. 127-175.

1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method of analysis was not proposed for food of animal origin as it was not considered that residues would occur in food of animal origin under approved conditions of use (France, 1999).

It is now considered that there is significant intake of residues by livestock. Based upon the metabolism data, a residue definition of parent imazamox only is proposed and MRLs for commodities of animal origin are indicated at the default LOQ. An analytical method for enforcement of residues in food of animal origin, supported by independent laboratory validation data and a confirmatory method is required.

2. Mammalian toxicology

The toxicological assessment of imazamox was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (EC, 2002b). These toxicological reference values are summarised in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
imazamox					
ADI	EC	2002	9.0 mg/kg bw per d	Rabbit developmental NOAEL, supported by the 2-year rat study	100
ARfD	EC	2002	Not necessary.		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of imazamox was investigated for soil application, pre-emergence treatment (via incorporation to soil) and by foliar application post emergence on cereals (maize) and on pulses and oilseeds (soya bean, pea and oilseed rape), using 6-pyridine-^{14}C labelled-imazamox (France, 1999). The characteristics of these studies are summarised in Table 3-1. It is noted that the fate of the imidazolinone moiety was not addressed in the submitted plant metabolism studies; it is further noted that metabolism studies in wheat, oilseed rape and rotational crops have been conducted to include labelling of the imidazolinone moiety and these data will be available as part of the active substance renewal program for imazamox scheduled for 2014.

In all crops the residue levels at harvest of imazamox and its metabolites are low with TRR levels at <0.02 mg/kg ^{14}C-imazamox equivalents in the edible crop parts and <0.05 mg/kg ^{14}C-imazamox equivalents in the fodder. In the pea samples 84 DAT it was indicated that 8% (<0.01 mg/kg) of the TRR was determined as parent compound, with 6% (<0.01 mg/kg) being the hydroxymethyl metabolite[10] (CL 263,284) and 8% (<0.01 mg/kg) being determined as the glucoside metabolite[11] (CL

[10] Hydroxymethyl metabolite: 5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3-carboxylic acid

[11] Glucoside metabolite: 2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)-5-[[3,4,5-trihydroxy-6-(hydroxyl methyl) tetrahydropyran-2-yl]oxymethyl]pyridine-3-carboxylic acid

189,215). In maize samples 30 DAT 0.01 mg/kg (37%) was determined as parent compound with 0.005 mg/kg (18.5%) being determined as the hydroxymethyl metabolite. In maize forage samples 62 DAT, 41% of TRR (0.032 mg/kg) was determined as the hydroxymethyl metabolite and 3.8% of TRR (0.001 mg/kg) was determined as parent imazamox. In soya bean seed residues were considered too low for identification. In soya bean forage samples 30 DAT, 23.7% TRR (0.02 mg/kg) was determined as the glucoside metabolite, 11.6% of TRR (0.01 mg/kg) was determined as the hydroxymethyl metabolite, 5.5% TRR (0.01 mg/kg) was determined as the di-acid metabolite[12] (CL 312,622) and 1.5% TRR (<0.01 mg/kg) was determined as parent imazamox, with similar proportions also being determined in the 28 DAT pre-planting treatment. In rape seed, residues were considered too low for identification.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Pulses and oilseeds	Soya bean	6-^{14}C-pyridine	F, soil application pre planting	0.146	1	151	-
			F, post planting	0.076	1	123	-
			F, post planting	0.15	1	123	-
	Pea	6-^{14}C-pyridine	F, post planting	0.04	1	84	-
	Rapeseed	6-^{14}C-pyridine	F, post planting	0.02	1	82	-
Cereals	Maize[(b)]	6-^{14}C-pyridine	F, pre emergence	0.141	1	112	-
		6-^{14}C-pyridine	F, post emergence	0.130	1	100	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): IMI-CORN™ plants (Zea mays L., Pioneer hybrid 3751 IR)

In the crop categories investigated (pulses and oilseeds and cereals) a similar metabolic pathway is seen. Metabolism begins at the methoxy methyl position to form the hydroxymethyl metabolite. This metabolite is subsequently either oxidised to form the di-acid metabolite or conjugated to form the glucoside metabolite. Minor amounts of hydroxy-acid metabolite[13] (CL 354,825) may also be produced.

In the absence of significant residues of parent imazamox and any degradation products from the 6-pyridine-^{14}C labelled-imazamox studies, the residue for enforcement and risk assessment in pulses and oilseeds and cereal grain is tentatively proposed as parent imazamox only. This will need to be confirmed by metabolism data with labelling of the imidazolinone ring, which will be available as part of the active substance renewal program scheduled for 2014. EFSA is also of the opinion that as only two crop categories have been considered there is insufficient data to propose a general residue definition for all commodities of plant origin. This residue definition is limited to the evaluated uses, i.e. pre-emergence and early post-emergence application to pulses/oilseeds and cereals at the requested

[12] Di-acid metabolite: 2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3,5-dicarboxylic acid
[13] Hydroxy acid metabolite: 5-hydroxy-6-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3-carboxylic acid

application rates. In order to extend the proposed residue definition to applications at higher rates or later timings residue trials, also demonstrating that residues of the hydroxymethyl metabolite will not occur in practice, are required.

It is recognised that in fodder the levels of the hydroxymethyl metabolite and the glucoside metabolite, are greater than that for the parent imazamox. The residue for risk assessment in fodder commodities is therefore tentatively proposed as the sum of imazamox and its hydroxymethyl metabolite free and conjugated expressed as imazamox. This residue definition is also proposed for enforcement purposes in view of the future need to set MRLs in feed items; a validated analytical method for enforcement of this complex residue definition in forage crops might therefore still be required by risk managers in the future.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance imazamox is authorised in northern and southern Europe for both pre-emergence soil treatment and foliar spray treatment in a range of pulses and oilseed crops, maize, rice and alfalfa, only under outdoor conditions (see Appendix A). To assess the magnitude of imazamox residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (France, 1999) and additional data submitted during the consultation of Member States (France, 2013). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). As detailed below a sufficient number of trials complying with the GAP was reported by the RMS for most crops under assessment, except in the case of rice:

- Beans (fresh with pods), peas (fresh without pods), oilseed crops (sunflower, oilseed rape and soya bean) and maize: The number of residue trials supporting the northern and southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were all below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Rice: insufficient residue trials are available to support the southern use. Considering that it is a major crop in southern Europe, 7 additional residue trials complying with the southern outdoor GAP are required. Consequently, neither MRLs nor risk assessment values can be derived.

The potential degradation of residues during storage of the residue trials samples was assessed in the framework of the peer review under Directive 91/414/EEC, storage stability of imazamox was demonstrated for a period of 24 months at -10 °C in soya bean seed and a freezer stability study on maize grain, ears and immature whole plant was ongoing but results were not detailed. An evaluation report demonstrating freezer stability of imazamox for a period of 18 months at -10 °C in wheat forage, straw and grain and also alfalfa seed, forage and hay has been presented (France, 2013). Data presented for wheat hay indicate 6 months freezer stability only but this is thought to be due to extraction difficulties. These data are considered sufficient to cover storage stability in high water content, high oil content and dry commodities. The storage conditions for all available residue trials were not reported by the RMS, this information would be desirable in order to confirm the validity of the residue trials reported.

Table 3-2: Overview of the available residue trials data

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments[e]
			Enforcement	Risk assessment					
Residue definition for enforcement and risk assessment (tentative): imazamox									
Beans (fresh with pods)	SEU	Outdoor	3 x <0.05	3 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials conducted at PHI 88 – 110 days
	NEU	Outdoor	5 x <0.01	5 x <0.01	0.01	0.01	0.05* (tentative)	1	Trials on pea (fresh with pod) extrapolated to bean (fresh with pod), compliant with GAP.
Peas (fresh without pods)	NEU	Outdoor	4 x <0.05	4 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials compliant with GAP
	SEU	Outdoor	6 x <0.05	6 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials compliant with GAP
Beans (dry) Peas (dry) Lentils (dry)	NEU	Outdoor	8 x <0.05	8 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials on dry peas extrapolated to dry beans and lentils compliant with GAP, PHI 106 – 129d
Sunflower seed Soya bean	NEU	Outdoor	2 x <0.05	2 x <0.05	0.05	0.05	0.05 (tentative)	1	Trials on sunflower compliant with GAP
	SEU	Outdoor	3 x <0.05	3 x <0.05	0.05	0.05	0.05 (tentative)	1	Combined data set on sunflower (2) and soya bean (1) compliant with GAP.
Rapeseed	NEU	Outdoor	6 x <0.05	6 x <0.05	0.05	0.05	0.05 (tentative)	1	Trials compliant with GAP
	SEU	Outdoor	5 x <0.05	5 x <0.05	0.05	0.05	0.05 (tentative)	1	Trials compliant with GAP

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments[(e)]
			Enforcement	Risk assessment					
Maize	NEU	Outdoor	6 x <0.05	6 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials compliant with GAP at a PHI value 147 – 158 d.
	SEU	Outdoor	4 x <0.05	4 x <0.05	0.05	0.05	0.05* (tentative)	1	Trials compliant with GAP
Rice	SEU	Outdoor	<0.05	<0.05	-	-	-	-	Trial compliant with GAP
Residue definition for enforcement and risk assessment (tentative): sum of parent imazamox and the hydroxymethyl metabolite free and conjugated, expressed as imazamox									
Alfalfa forage	NEU	Outdoor	2 x <0.2, 0.28, 0.41	2 x <0.2, 0.28, 0.31	0.24	0.31	**0.6 (tentative)**	1	Trials compliant with GAP
	SEU	Outdoor	4 x <0.2	4 x <0.2	0.2	0.2	0.2 (tentative)	1	Trials compliant with GAP
Maize forage	NEU	Outdoor	6 x <0.1	6 x <0.1	0.1	0.1	0.1 (tentative)	1	Trials compliant with GAP
	SEU	Outdoor	6 x <0.1	6 x <0.1	0.1	0.1	0.1 (tentative)	1	Trials compliant with GAP

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Rber, Rmax and OECD MRL values not given as all residue levels at LOQ, MRL proposals at 0.05 mg/kg
(*): Indicates that the MRL is set at the limit of analytical quantification.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for rice where the available data were insufficient to derive tentative MRLs (see also Table 3-2). MRL proposals are in any case considered on a tentative basis only due to the lack of a metabolism study with labelling of the imidazolinone ring (see Section 3.1.1.1) and due to the analytical method deficiencies for enforcement (see also section 1.1). Tentative MRLs were also derived for maize forage and alfalfa in view of the future need to set MRLs in feed items.

3.1.1.3. Effect of industrial processing and/or household preparation

As residues of imazamox exceeding 0.1 mg/kg are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI (see also section 4), there is no need to investigate the effect of industrial and/or household processing.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values determined from field based soil dissipation studies ranged between 15 to 138 days with values above the trigger of 100 days being determined in 2 scenarios (France, 1999). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is required.

3.1.2.2. Nature and magnitude of residues

The metabolism of imazamox in rotational crops wheat, maize, radish and lettuce has been evaluated (France, 1999). Two field rotational crop studies investigating the nature of residues following different plant-back intervals are available. Rotational crops were grown following soya beans which received a 70 g a.s./ha application of imazamox. The characteristics of these studies are summarised in Table 3-3.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	lettuce	6-^{14}C-pyridine	Foliar, F	0.07	268	335	Application was carried out on soya bean as a primary crop
Root and tuber vegetables	radish	6-^{14}C-pyridine	Foliar, F	0.07	268	311	
Cereals	wheat	6-^{14}C-pyridine	Foliar, F	0.07	100	331	
	maize	6-^{14}C-pyridine	Foliar, F	0.07	268	420	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

At harvest, imazamox residues were below the LOQ (0.01 mg/kg) in all mature plant parts (France, 1999). No further analysis of metabolites was possible at these levels. It is noted that shorter plant back intervals have not been considered, however for pulses and oilseed this can be considered as addressed by the soya bean primary metabolism study (section 3.1.1.1) in which plants were transplanted into soil 1 hour after treatment at 146 g as/ha. TRR levels were determined at 0.02 mg/kg

imazamox equivalents 28 DAT, which declined to 0.01 mg/kg imazamox equivalents at both 58 DAT and 91 DAT.

The available data indicates low residue levels in the rotational crops of wheat, lettuce, radish and maize; this is supported by the data available in the soya bean primary metabolism study which indicated low residue levels in the soil immediately following soil treatment at an overdosed rate (see Section 3.1.1.1). It is considered by EFSA that these data studies are sufficient to demonstrate the absence of residues in rotational crops, provided that imazamox is applied in compliance with the GAPs reported in Appendix A. A specific residue definition for rotational crops is not deemed necessary due to the very low residue levels expected.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Imazamox is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996).The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-4. For alfalfa hay, rape seed, sunflower and soybean meal, default processing factors of 4, 2, 2 and 1.3, respectively, have been included in the calculation in order to consider the potential concentration of residues in these commodities.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of parent imazamox and the hydroxymethyl metabolite free and conjugated, expressed as imazamox				
Afalfa fresh and silage	0.24	Median residue	0.31	Highest Residue
Maize silage	0.1	Median residue	0.1	Highest residue
Alfalfa hay	0.96	Median residue x 4	1.24	Highest residue x 4
Risk assessment residue definition: imazamox				
Maize grain	0.05	Median residue	0.05	Median residue
Peas (dry)	0.05	Median residue	0.05	Median residue
Beans (dry)	0.05	Median residue	0.05	Median residue
Rapeseed meal	0.1	Median residue x 2	0.1	Median residue x 2
Sunflower seed meal	0.1	Median residue x 2	0.1	Median residue x 2
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.065	Median residue x 1.3	0.065	Median residue x 1.3

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for dairy and meat ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore only required in these groups of livestock.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of parent imazamox and the hydroxymethyl metabolite free and conjugated, expressed as imazamox					
Dairy ruminants	0.044	0.056	Alfalfa silage	1.57	Y
Meat ruminants	0.051	0.066	Alfalfa silage	1.54	Y
Poultry	0.004	0.004	Maize grain	0.06	N
Pigs	0.010	0.012	Alfalfa (fresh)	0.29	Y

3.2.2. Nature of residues

The nature of imazamox residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (France, 1999). Reported metabolism studies include one study in lactating goats and one study in laying hens using 6-^{14}C-pyridine-labelled imazamox. The characteristics of these studies are summarised in Table 3-6.

Table 3-6: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	6-^{14}C-pyridine	2	0.065, 0.4 (one animal at each dose rate)	7	Milk	Twice daily
						Urine and faeces	daily
						Tissues	At sacrifice
Laying poultry	Hens	6-^{14}C-pyridine	16	0.35, 2.0 (eight animals at each dose rate)	7	Eggs	Twice daily
						Excreta	daily
						Tissues	At sacrifice

Lactating goats were administered a single daily dose for seven consecutive days of radiolabelled imazamox. Goats were dosed with 0.065 or 0.4 mg/kg bw per d of imazamox, corresponding to approximately 1 or 6 times the exposure of meat ruminant respectively. The majority of the radioactivity was observed in the urine 91.2 % and 64.8 %, respectively in the low and high dose animals, with a further 15 % and 24 % being present in the faeces of the low and high dose animals respectively. Analysis of urine collected from the high dose goat indicated that 91 % of the radioactivity present corresponded to unchanged parent imazamox. The transfer of residues to milk and tissues is insignificant with ≤0.01 mg/kg imazamox equivalents being present in all tissues except kidney. In kidney a TRR of ≤0.06 mg/kg imazamox equivalents was determined in the high dose animal, of this 89 % (0.05 mg/kg) corresponded to unchanged parent imazamox.

Laying hens were administered a single daily dose for seven consecutive days of radiolabelled imazamox. Hens were dosed with 0.35 or 2.0 mg/kg bw per d of imazamox, corresponding to approximately 87 or 500 times the dietary burden for poultry. The majority of the radioactivity was observed in the excreta 85.5 % and 84.8 %, respectively in the low and high dose groups. The transfer of residues to tissues is insignificant with TRR levels at ≤0.01 mg/kg imazamox equivalents. No radioactive residues were detected in eggs.

The metabolism studies on both ruminant and poultry show that imazamox is rapidly excreted with insignificant levels of residue being determined in milk, eggs or animal tissues. The residue in commodities of animal origin is therefore defined as imazamox by default, both for enforcement and risk assessment purposes.

3.2.3. Magnitude of residues

According to the above mentioned ruminant metabolism study, it is concluded that, after exposure to the maximum dietary burden (about 6 times lower than the dose level in the ruminant metabolism study; see also section 3.2.1), residues levels in livestock commodities (excluding poultry) are expected to remain below the default MRL of 0.01 mg/kg in milk, muscle/meat, fat, liver and kidney. Hence, no livestock feeding study is needed but in the absence of an analytical method of analysis for enforcement of imazamox in food of animal origin with a validated LOQ it is considered that the MRL be established at the default value of 0.01 mg/kg.

MRLs for poultry products are not required because poultry are not expected to be exposed to significant levels of imazamox residues.

4. Consumer risk assessment

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The (tentative) median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: imazamox		
Beans (fresh with pods)	0.05*	Median residue (tentative) [(a)]
Peas (fresh without pods)	0.05*	Median residue (tentative) [(a)]
Beans (dry)	0.05*	Median residue (tentative) [(a)]
Peas (dry)	0.05*	Median residue (tentative) [(a)]
Lentils (dry)	0.05*	Median residue (tentative) [(a)]
Sunflower seed	0.05	Median residue (tentative) [(a)]
Rapeseed	0.05	Median residue (tentative) [(a)]
Soya bean	0.05	Median residue (tentative) [(a)]
Maize	0.05*	Median residue (tentative) [(a)]

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Rice	0.05*	EU MRL [(b)]
Swine meat	0.01	Default MRL (tentative) [(c)]
Swine fat (free of lean meat)	0.01	Default MRL (tentative) [(c)]
Swine liver	0.01	Default MRL (tentative) [(c)]
Swine kidney	0.01	Default MRL (tentative) [(c)]
Ruminant meat	0.01	Default MRL (tentative) [(c)]
Ruminant fat	0.01	Default MRL (tentative) [(c)]
Ruminant liver	0.01	Default MRL (tentative) [(c)]
Ruminant kidney	0.01	Default MRL (tentative) [(c)]
Ruminant milk	0.01	Default MRL (tentative) [(c)]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations (also assuming the existing residue definition).
(b): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations (also assuming the existing residue definition).
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for imazamox (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B. The highest chronic exposure was calculated for Dutch children, representing 0.005 % of the ADI.

Based on the above calculations, EFSA concludes that major uncertainties remain due to the data gaps identified in section 3, in particular with regard to the residue definition, but considering tentative MRLs or the existing EU MRL in the exposure calculation did not indicate a risk to consumers.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of plant or livestock metabolism on the isomer ratio of imazamox. Considering however that toxicological reference values were derived for the mixture of isomers and that the exposure calculations represent less than 0.005% of the ADI, EFSA concludes that the potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of imazamox would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of imazamox was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 9.0 mg/kg bw per d. An ARfD was not deemed necessary.

Metabolism of imazamox was investigated for soil application, pre-emergence treatment (via incorporation to soil) and by foliar application post emergence on cereals (maize) and on pulses and oilseeds (soya bean, pea and oilseed rape), using 6-pyridine-^{14}C labelled-imazamox. The fate of the imidazolinone moiety was not addressed in the submitted plant metabolism studies and needs to be further addressed. Nevertheless, in the absence of significant residues of parent imazamox and any degradation products (using the pyridine label), it is considered that the residue for enforcement and

risk assessment in pulses and oilseeds and cereal grain is tentatively defined as parent imazamox only, which is sufficient to cover the authorised uses. Analytical methods for enforcement of the proposed residue definition in high water content, acidic and dry commodities are available but a confirmatory method and a validated analytical method for enforcement of residue in high oil content commodities are still required. With regard to the authorisation of further uses confirmation that the hydroxymethyl metabolite does not occur in practice will be required. In fodder the levels of the hydroxymethyl metabolite and the glucoside metabolite, were greater than that for the parent imazamox. The residue for risk assessment in fodder commodities is therefore tentatively proposed as the sum of imazamox and its hydroxymethyl metabolite free and conjugated expressed as imazamox. This residue definition is also proposed for enforcement purposes in view of the future need to set MRLs in feed items and a validated analytical method for enforcement of the proposed future residue definition in forage crops may still be required by risk managers in the future.

Regarding the magnitude of residues in crops, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for rice where the available data were insufficient to derive tentative MRLs. MRL proposals are in any case considered on a tentative basis only due to the lack of a metabolism study with labelling of the imidazolinone ring and due to the analytical method deficiencies for enforcement in oilseeds (see above).

As residues of imazamox exceeding 0.1 mg/kg are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Occurrence of imazamox residues in rotational crops was investigated. It is concluded that significant residues in rotational crops are not expected, provided that imazamox is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant exposures to imazamox are expected for dairy and meat ruminants and pigs. A metabolism study for goat confirms an expectation that residue levels in livestock commodities (excluding poultry) are expected to remain below the enforcement LOQ of 0.01 mg/kg and a residue definition of parent imazamox only is proposed for dairy and meat ruminants and pigs. However validated analytical methods for enforcement of the proposed residue definition in food of animal origin are not available. In the absence of an analytical method of analysis for enforcement of imazamox in food of animal origin with a validated LOQ it is considered that the MRL be established at the default value of 0.01 mg/kg. MRLs for poultry products are not required because they are not expected to be exposed to significant levels of imazamox residues.

Chronic consumer exposure resulting from the uses authorised in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 0.005 % of the ADI (Dutch children). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, tentative MRLs need to be confirmed by the following data:

- 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 (will be considered as part of the active substance renewal program scheduled for 2014);

- 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);

- representative plant metabolism studies with imazamox labelled at the imidazolinone ring (will be considered as part of the active substance renewal program scheduled for 2014);

- 7 additional residues trials supporting the southern outdoor GAP on rice;

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

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

- information on the storage conditions for all residues trials samples reported in the framework of this review.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: imazamox				
260010	Beans (fresh, with pod)	0.05*	0.05*	Further consideration needed [(a)]
260040	Peas (fresh, without pod)	0.05*	0.05*	Further consideration needed [(a)]
300010	Beans (dry)	0.05*	0.05*	Further consideration needed [(a)]
300020	Lentils (dry)	0.05*	0.05*	Further consideration needed [(a)]
300030	Peas (dry)	0.05*	0.05*	Further consideration needed [(a)]
401050	Sunflower seed	0.05*	0.05	Further consideration needed [(a)]
401060	Rapeseed	0.05*	0.05	Further consideration needed [(a)]
401070	Soya bean	0.05*	0.05	Further consideration needed [(a)]
500030	Maize	0.05*	0.05*	Further consideration needed [(a)]
500060	Rice	0.05*	0.05*	Further consideration needed [(b)]
1011010	Swine meat	-	0.01	Further consideration needed [(a)]
1011020	Swine fat (free of lean meat)	-	0.01	Further consideration needed [(a)]
1011030	Swine liver	-	0.01	Further consideration needed [(a)]
1011040	Swine kidney	-	0.01	Further consideration needed [(a)]
1012010	Bovine meat	-	0.01	Further consideration needed [(a)]
1012020	Bovine fat	-	0.01	Further consideration needed [(a)]
1012030	Bovine liver	-	0.01	Further consideration needed [(a)]

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
1012040	Bovine kidney	-	0.01	Further consideration needed [(a)]
1013010	Sheep meat	-	0.01	Further consideration needed [(a)]
1013020	Sheep fat	-	0.01	Further consideration needed [(a)]
1013030	Sheep liver	-	0.01	Further consideration needed [(a)]
1013040	Sheep kidney	-	0.01	Further consideration needed [(a)]
1014010	Goat meat	-	0.01	Further consideration needed [(a)]
1014020	Goat fat	-	0.01	Further consideration needed [(a)]
1014030	Goat liver	-	0.01	Further consideration needed [(a)]
1014040	Goat kidney	-	0.01	Further consideration needed [(a)]
1020010	Cattle milk	-	0.01	Further consideration needed [(a)]
1020020	Sheep milk	-	0.01	Further consideration needed [(a)]
1020030	Goat milk	-	0.01	Further consideration needed [(a)]
-	Other products of plant and animal origin	See App C	-	Further consideration needed [(c)]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix D).
(b): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix D).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on imazamox prepared by the rapporteur Member State France in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 11 June 2009. Last updated on 19 October 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																			
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Beans (with pods)	*Phaseolus vulgaris,*	NEU	Outdoor	FR	weeds	EC	22.4	g/L	Foliar treatment - spraying	12	25		1				28.00	g a.i./ha	42	
Peas (without pods)	*Pisum sativum*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	63	Application Method : High volume overall spray. Application growth stage : preemergence (3 to 4 days after sowing). UK requests the same GAP but without PHI.
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	63	Application method : High Volume overall spray. Application growth stage : preemergence. UK requests the same GAP but without PHI.
Lentils (dry)	*Lens culinaris syn. L. esculenta*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				37.00	g a.i./ha	63	Application method : High volume overall spray. Application growth stage : preemergence.
Peas (dry)	*Pisum sativum*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	63	High Volume overall spray. Application growth stage : preemergence and early post emergence. UK requests the same GAP but witout PHI.
Sunflower seed	*Helianthus annuus*	NEU	Outdoor	FR	weeds	SL	40.0	g/L	Foliar treatment - spraying	13	14		1				50.00	g a.i./ha	90	
Rape seed	*Brassica napus*	NEU	Outdoor	UK	weeds	SL	40.0	g/L	Foliar treatment - general (see also comment field)		18		1			20.00	70.00	g a.i./ha	120	
Soya bean	*Glycine max*	NEU	Outdoor	HU	weeds	SL	40.0	g/L	Foliar treatment - spraying	13	16		1				40.00	g a.i./ha	n.a.	
Maize	*Zea mays*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	n.a.	Application Method : High volume overall spray.
Alfalfa	*Medicago Sativa*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Foliar treatment - general (see also comment field)	1	15		1				67.00	g a.i./ha	28	Application Method : High volume overall spray.
Maize (for forage)	*Zea mays*	NEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	90	Application Method : High volume overall spray.

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Beans (with pods)	*Phaseolus vulgaris,*	SEU	Outdoor	IT	weeds	SL	40.0	g/L	Foliar treatment - general (see also comment field)	13	16		1			30.00	40.00	g a.i./ha	35	Application Method : Normal volume spraying.
Peas (without pods)	*Pisum sativum*	SEU	Outdoor	FR	weeds	EC	16.7	g/L	Soil treatment - spraying	0	7		1				75.00	g a.i./ha	63	Application method : High volume overall spray. Application growth stage : preemergence (3 to 4 days after sowing).
Sunflower seed	*Helianthus annuus*	SEU	Outdoor	FR	weeds	SL	40.0	g/L	Foliar treatment - spraying	13	14		1				50.00	g a.i./ha	90	
Rape seed	*Brassica napus*	SEU	Outdoor	FR	weeds	SC	17.5	g/L	Foliar treatment - general (see also comment field)	10	18		1				35.00	g a.i./ha	n.a.	Application method : High volume overall spray.
Soya bean	*Glycine max*	SEU	Outdoor	FR	weeds	SL	40.0	g/L	Foliar treatment - spraying	13	14		1				50.00	g a.i./ha	90	
Maize	*Zea mays*	SEU	Outdoor	FR	weeds	EC	16.7	g/L	Foliar treatment - general (see also comment field)	12	15		1				75.00	g a.i./ha	90	Application Method: High Volume overall spray; GAP ES: 0,05 - 0,07kg a.i./ha; PHI = 90; Growth stage of application = BBCH18
Rice	*Oryza sativa*	SEU	Outdoor	IT	weeds	SL	40.0	g/L	Foliar treatment - general (see also comment field)	13	22		1				70.00	g a.i./ha		Method application : normal volume spraying broadcast. Another GAP (IT, EL, ES) : 2*35 g a.i/ha from BBCH 13 untill BBCH 24
Alfalfa	*Medicago Sativa*	SEU	Outdoor	FR	weeds	EC	16.7	g/L	Foliar treatment - general (see also comment field)	1	15		1				67.00	g a.i./ha	28	Application method : High volume overall spray.
Maize (for forage)	*Zea mays*	SEU	Outdoor	FR	weeds	EC	16.7	g/L	Foliar treatment - general (see also comment field)	12	15		1				75.00	g a.i./ha	90	Application Method : High volume overall Spray. GAP ES : 0,05 - 0,07kg a.i./ha; PHI = 90; Growth stage of application = BBCH18

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Imazamox			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	9	ARfD (mg/kg bw):	n.n.
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2002	Year of evaluation:	2002

Prepare workbook for refined calculations

Undo refined calculations

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)
0.0045	NL child	0.00326	Milk and milk products: Cattle	0.00028	Beans (with pods)	0.0	Peas (without pods)	
0.0036	FR infant	0.00286	Milk and milk products: Cattle	0.00047	Beans (with pods)	0.0	Peas (without pods)	
0.0034	WHO Cluster diet B	0.00137	Maize	0.00041	Sunflower seed	0.0	Soya bean	
0.0027	ES child	0.00139	Milk and milk products: Cattle	0.00027	Rice	0.0	Maize	
0.0025	IE adult	0.00128	Maize	0.00031	Milk and milk products: Cattle	0.0	Peas	
0.0021	WHO cluster diet E	0.00033	Milk and milk products: Cattle	0.00033	Rape seed	0.0	Soya bean	
0.0021	DE child	0.00159	Milk and milk products: Cattle	0.00015	Rice	0.0	Maize	
0.0019	WHO cluster diet D	0.00053	Milk and milk products: Cattle	0.00031	Rice	0.0	Maize	
0.0017	SE general population 90th percentile	0.00138	Milk and milk products: Cattle	0.00022	Rice	0.0	Beans (with pods)	
0.0016	WHO Cluster diet F	0.00044	Milk and milk products: Cattle	0.00036	Soya bean	0.0	Rape seed	
0.0016	UK Infant	0.00057	Maize	0.00035	Rice	0.0	Peas (without pods)	
0.0015	WHO regional European diet	0.00053	Milk and milk products: Cattle	0.00014	Swine: Meat	0.0	Bovine: Meat	
0.0013	NL general	0.00073	Milk and milk products: Cattle	0.00014	Beans (with pods)	0.0	Peas (without pods)	
0.0013	FR toddler	0.00061	Beans (with pods)	0.00020	Rice	0.0	Peas (without pods)	
0.0013	ES adult	0.00055	Milk and milk products: Cattle	0.00013	Rice	0.0	Beans (with pods)	
0.0012	PT General population	0.00044	Rice	0.00026	Maize	0.0	Soya bean	
0.0010	UK Toddler	0.00043	Beans	0.00032	Rice	0.0	Peas (without pods)	
0.0008	LT adult	0.00044	Milk and milk products: Cattle	0.00012	Rice	0.0	Swine: Meat	
0.0007	FR all population	0.00030	Milk and milk products: Cattle	0.00018	Sunflower seed	0.0	Beans (with pods)	
0.0006	UK vegetarian	0.00021	Rice	0.00020	Beans	0.0	Peas (without pods)	
0.0004	UK Adult	0.00020	Rice	0.00012	Beans	0.0	Peas (without pods)	
0.0003	IT kids/toddler	0.00011	Rice	0.00006	Peas (without pods)	0.0	Beans (with pods)	
0.0003	IT adult	0.00010	Rice	0.00008	Beans (with pods)	0.0	Peas (without pods)	
0.0002	DK adult	0.00006	Bovine: Meat	0.00005	Peas (without pods)	0.0	Rice	
0.0001	FI adult	0.00006	Rice	0.00002	Beans (with pods)	0.0	Beans	
0.0001	DK child	0.00006	Rice	0.00001	Bovine: Liver	0.0	Beans (with pods)	
0.0000	PL general population	0.00002	Beans	0.00001	Peas	0.0	Sunflower seed	

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.

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS)

(Pesticides - Web Version - EU MRLs - File created on 23/11/2012 12:18)

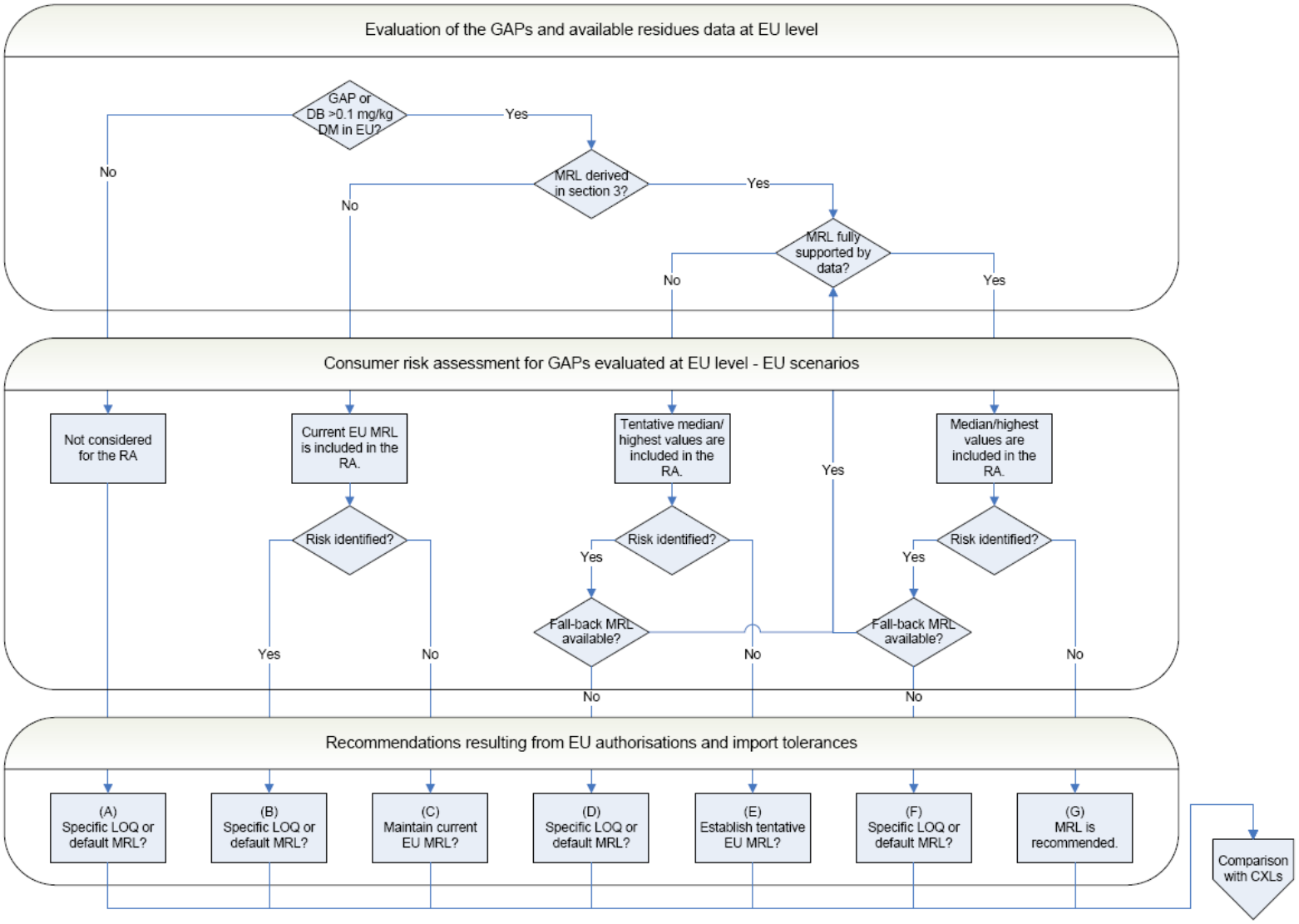
Code number	Groups and examples of individual products to which the MRLs apply [a]	imazamox
100000	1. FRUIT FRESH OR FROZEN; NUTS	0.05*
110000	(i) Citrus fruit	0.05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.05*
110030	Lemons (Citron, lemon)	0.05*
110040	Limes	0.05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.05*
110990	Others	0.05*
120000	(ii) Tree nuts (shelled or unshelled)	0.05*
120010	Almonds	0.05*
120020	Brazil nuts	0.05*
120030	Cashew nuts	0.05*
120040	Chestnuts	0.05*
120050	Coconuts	0.05*
120060	Hazelnuts (Filbert)	0.05*
120070	Macadamia	0.05*
120080	Pecans	0.05*
120090	Pine nuts	0.05*
120100	Pistachios	0.05*
120110	Walnuts	0.05*
120990	Others	0.05*
130000	(iii) Pome fruit	0.05*
130010	Apples (Crab apple)	0.05*
130020	Pears (Oriental pear)	0.05*
130030	Quinces	0.05*
130040	Medlar	0.05*
130050	Loquat	0.05*
130990	Others	0.05*
140000	(iv) Stone fruit	0.05*
140010	Apricots	0.05*
140020	Cherries (sweet cherries, sour cherries)	0.05*
140030	Peaches (Nectarines and similar hybrids)	0.05*
140040	Plums (Damson, greengage, mirabelle)	0.05*
140990	Others	0.05*
150000	(v) Berries & small fruit	0.05*
151000	(a) Table and wine grapes	0.05*
151010	Table grapes	0.05*
151020	Wine grapes	0.05*
152000	(b) Strawberries	0.05*
153000	(c) Cane fruit	0.05*
153010	Blackberries	0.05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0.05*
153030	Raspberries (Wineberries)	0.05*
153990	Others	0.05*
154000	(d) Other small fruit & berries	0.05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.05*
154020	Cranberries	0.05*
154030	Currants (red, black and white)	0.05*
154040	Gooseberries (Including hybrids with other ribes species)	0.05*
154050	Rose hips	0.05*
154060	Mulberries (arbutus berry)	0.05*
154070	Azarole (mediteranean medlar)	0.05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.05*
154990	Others	0.05*
160000	(vi) Miscellaneous fruit	0.05*
161000	(a) Edible peel	0.05*
161010	Dates	0.05*
161020	Figs	0.05*
161030	Table olives	0.05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.05*
161050	Carambola (Bilimbi)	0.05*
161060	Persimmon	0.05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.05*
161990	Others	0.05*
162000	(b) Inedible peel, small	0.05*
162010	Kiwi	0.05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.05*
162030	Passion fruit	0.05*
162040	Prickly pear (cactus fruit)	0.05*
162050	Star apple	0.05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.05*
162990	Others	0.05*
163000	(c) Inedible peel, large	0.05*
163010	Avocados	0.05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.05*
163030	Mangoes	0.05*
163040	Papaya	0.05*
163050	Pomegranate	0.05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.05*
163070	Guava	0.05*
163080	Pineapples	0.05*
163090	Bread fruit (Jackfruit)	0.05*
163100	Durian	0.05*
163110	Soursop (guanabana)	0.05*
163990	Others	0.05*
200000	2. VEGETABLES FRESH OR FROZEN	0.05*
210000	(i) Root and tuber vegetables	0.05*
211000	(a) Potatoes	0.05*
212000	(b) Tropical root and tuber vegetables	0.05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.05*
212020	Sweet potatoes	0.05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.05*
212040	Arrowroot	0.05*
212990	Others	0.05*
213000	(c) Other root and tuber vegetables except sugar beet	0.05*
213010	Beetroot	0.05*
213020	Carrots	0.05*
213030	Celeriac	0.05*
213040	Horseradish	0.05*
213050	Jerusalem artichokes	0.05*
213060	Parsnips	0.05*
213070	Parsley root	0.05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.05*
213100	Swedes	0.05*
213110	Turnips	0.05*
213990	Others	0.05*
220000	(ii) Bulb vegetables	0.05*
220010	Garlic	0.05*
220020	Onions (Silverskin onions)	0.05*
220030	Shallots	0.05*
220040	Spring onions (Welsh onion and similar varieties)	0.05*
220990	Others	0.05*
230000	(iii) Fruiting vegetables	0.05*
231000	(a) Solanacea	0.05*
231010	Tomatoes (Cherry tomatoes,)	0.05*
231020	Peppers (Chilli peppers)	0.05*
231030	Aubergines (egg plants) (Pepino)	0.05*
231040	Okra, lady's fingers	0.05*
231990	Others	0.05*

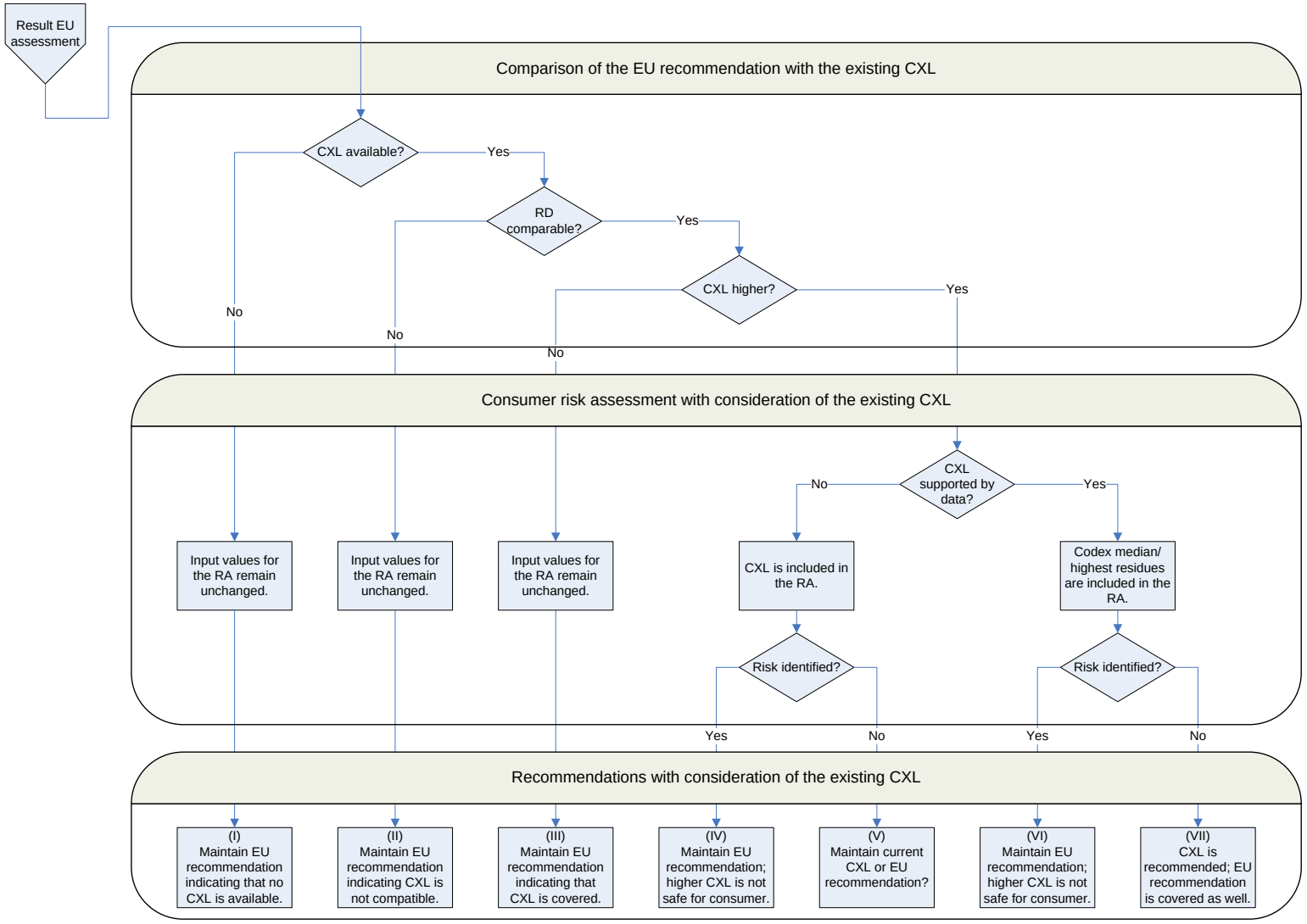
Code number	Groups and examples of individual products to which the MRLs apply [a]	imazamox
232000	(b) Cucurbits - edible peel	0.05*
232010	Cucumbers	0.05*
232020	Gherkins	0.05*
232030	Courgettes (Summer squash, marrow (patisson))	0.05*
232990	Others	0.05*
233000	(c) Cucurbits-inedible peel	0.05*
233010	Melons (Kiwano)	0.05*
233020	Pumpkins (Winter squash)	0.05*
233030	Watermelons	0.05*
233990	Others	0.05*
234000	(d) Sweet corn	0.05*
239000	(e) Other fruiting vegetables	0.05*
240000	(iv) Brassica vegetables	0.05*
241000	(a) Flowering brassica	0.05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.05*
241020	Cauliflower	0.05*
241990	Others	0.05*
242000	(b) Head brassica	0.05*
242010	Brussels sprouts	0.05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.05*
242990	Others	0.05*
243000	(c) Leafy brassica	0.05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.05*
243020	Kale (Borecole (curly kale), collards)	0.05*
243990	Others	0.05*
244000	(d) Kohlrabi	0.05*
250000	(v) Leaf vegetables & fresh herbs	0.05*
251000	(a) Lettuce and other salad plants including Brassicacea	0.05*
251010	Lamb´s lettuce (Italian cornsalad)	0.05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce,	0.05*
	romaine (cos) lettuce)	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0.05*
251040	Cress	0.05*
251050	Land cress	0.05*
251060	Rocket, Rucola (Wild rocket)	0.05*
251070	Red mustard	0.05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0.05*
251990	Others	0.05*
252000	(b) Spinach & similar (leaves)	0.05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0.05*
252030	Beet leaves (chard) (Leaves of beetroot)	0.05*
252990	Others	0.05*
253000	(c) Vine leaves (grape leaves)	0.05*
254000	(d) Water cress	0.05*
255000	(e) Witloof	0.05*
256000	(f) Herbs	0.05*
256010	Chervil	0.05*
256020	Chives	0.05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0.05*
256040	Parsley	0.05*
256050	Sage (Winter savory, summer savory,)	0.05*
256060	Rosemary	0.05*
256070	Thyme (marjoram, oregano)	0.05*
256080	Basil (Balm leaves, mint, peppermint)	0.05*
256090	Bay leaves (laurel)	0.05*
256100	Tarragon (Hyssop)	0.05*
256990	Others	0.05*
260000	(vi) Legume vegetables (fresh)	0.05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.05*
260030	Peas (with pods) (Mangetout (sugar peas))	0.05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.05*
260050	Lentils	0.05*
260990	Others	0.05*
270000	(vii) Stem vegetables (fresh)	0.05*
270010	Asparagus	0.05*
270020	Cardoons	0.05*
270030	Celery	0.05*
270040	Fennel	0.05*
270050	Globe artichokes	0.05*
270060	Leek	0.05*
270070	Rhubarb	0.05*
270080	Bamboo shoots	0.05*
270090	Palm hearts	0.05*
270990	Others	0.05*
280000	(viii) Fungi	0.05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0.05*
280990	Others	0.05*
290000	(ix) Sea weeds	0.05*
300000	3. PULSES, DRY	0.05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.05*
300020	Lentils	0.05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.05*
300040	Lupins	0.05*
300990	Others	0.05*
400000	4. OILSEEDS AND OILFRUITS	0.05*
401000	(i) Oilseeds	0.05*
401010	Linseed	0.05*
401020	Peanuts	0.05*
401030	Poppy seed	0.05*
401040	Sesame seed	0.05*
401050	Sunflower seed	0.05*
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*
401070	Soya bean	0.05*
401080	Mustard seed	0.05*
401090	Cotton seed	0.05*
401100	Pumpkin seeds	0.05*
401110	Safflower	0.05*
401120	Borage	0.05*
401130	Gold of pleasure	0.05*
401140	Hempseed	0.05*
401150	Castor bean	0.05*
401990	Others	0.05*
402000	(ii) Oilfruits	0.05*
402010	Olives for oil production	0.05*
402020	Palm nuts (palmoil kernels)	0.05*
402030	Palmfruit	0.05*
402040	Kapok	0.05*
402990	Others	0.05*
500000	5. CEREALS	0.05*
500010	Barley	0.05*
500020	Buckwheat	0.05*
500030	Maize	0.05*
500040	Millet (Foxtail millet, teff)	0.05*
500050	Oats	0.05*
500060	Rice	0.05*
500070	Rye	0.05*
500080	Sorghum	0.05*
500090	Wheat (Spelt Triticale)	0.05*
500990	Others	0.05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*

Code number	Groups and examples of individual products to which the MRLs apply [a]	imazamox
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0.05*
900010	Sugar beet (root)	0.05*
900020	Sugar cane	0.05*
900030	Chicory roots	0.05*
900990	Others	0.05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

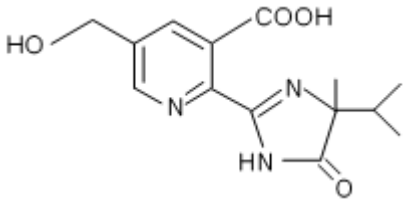
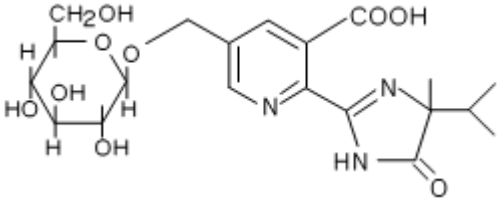
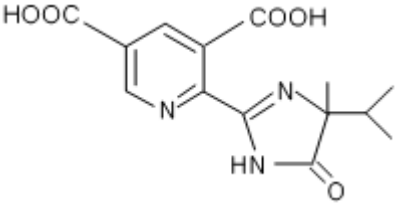
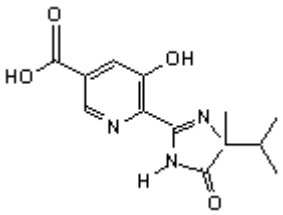
(*) Indicates lower limit of analytical determination
(a): Table footnote

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
Hydroxymethyl metabolite CL263, 284	5-(hydroxymethyl)-2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3-carboxylic acid	
Glucoside metabolite CL 189215	2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)-5-[[3,4,5-trihydroxy-6-(hydroxymethyl)tetrahydropyran-2-yl]oxymethyl]pyridine-3-carboxylic acid	
Di-acid metabolite CL 312622	2-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3,5-dicarboxylic acid	
Hydroxy acid metabolite CL354825	5-hydroxy-6-(4-isopropyl-4-methyl-5-oxo-1H-imidazol-2-yl)pyridine-3-carboxylic acid	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AHAS	acetohydroxyacid synthase
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
ha	hectare
hL	hectolitre
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra-violet detector
ILV	independent laboratory validation

ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation