REASONED OPINION OF EFSA

Modification of the residue definition for isoxaflutole[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-739)

Issued on 03 July 2009

SUMMARY

According to Article 6(1) of Regulation (EC) No 396/2005, the Netherlands received an application from Bayer CropScience to amend the enforcement residue definition for isoxaflutole which is currently defined as isoxaflutole (sum of isoxaflutole, RPA 202248[2] and RPA 203328[3], expressed as isoxaflutole). The applicant requested to exclude the metabolite RPA 203328 from the residue definition. The evaluation report prepared by the Netherlands on this application was forwarded to EFSA in October 2008.

Based on the above mentioned evaluation report and the Draft Assessment Report (DAR) prepared by the Rapporteur Member State under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application.

Metabolism of isoxaflutole was investigated in maize grown in soil treated with radiolabelled isoxaflutole. The study revealed that RPA 203328 is the major metabolite in maize whereas RPA 202248 is found in significantly lower concentrations compared with RPA 203328. No parent compound is expected in harvested maize grain.

The assessment of the toxicological data provided in the framework of the peer review under Directive 91/414/EEC and in support of this application demonstrated that the biologically inactive metabolite RPA 203328 is of low concern compared to the parent compound and the biologically active metabolite RPA 202248. Thus, from a toxicological point of view it is not necessary to include this metabolite in the residue definition.

The applicant provided an analytical method based on HPLC/MS/MS to measure residues of isoxaflutole and the metabolite RPA 202248. The method was validated in tomatoes, rape seed, oranges and wheat grain. The analytical method is capable to enforce the proposed residue definition (sum of isoxaflutole and RPA 202248, expressed as isoxaflutole) with a LOQ of 0.02 mg/kg in the commodities with high water content, high oil content, high acid content and dry matrices.

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the residue definition for isoxaflutole. *EFSA Scientific Report* (2009) 323, 1-26

[2] RPA 202248 is 2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl) propane-1,3-dione

[3] RPA 203328: 2-methanesulfonyl-4-trifluoromethylbenzoic acid

In view of the higher sensitivity of the analytical method proposed for the new residue definition, the Evaluating Member State proposed to lower the MRLs established at the LOQ of 0.05 mg/kg to 0.02 mg/kg. MRLs currently established at the LOQ of 0.1 mg/kg for commodities with high fat content and other matrices which contain a high amount of natural compounds interfering with analytical detection systems (e.g. tea, coffee, herbal infusions, cocoa, hops, spices) are proposed to be lowered to 0.05 mg/kg.

Supervised field trials in maize show that no residues above the LOQ of 0.013 mg/kg according to the currently established residue definition are expected in maize. If the residue definition is changed as proposed, the MRL for maize could be established at the level of 0.02 mg/kg which corresponds with the LOQ of the enforcement method developed for the proposed new residue definition.

For other crops no authorised uses have been notified by the manufacturer of the active substance. The lowering of the LOQ value as proposed by the Evaluating Member State would not require the re-evaluation of any residue trials.

The proposed change of the residue definition and the lowering of the LOQ values would not have a negative impact on the consumer safety. The long-term consumer exposure resulting from residues in maize at the level of 0.02 g/kg (corresponding to the LOQ) is less than 0.5% of the ADI.

The recommendations resulting from the assessment are summarised in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Change the residue definition to : **Isoxaflutole (sum of isoxaflutole and RPA 202248, expressed as isoxaflutole)**			
Maize	0.05*	0.02*	MRL proposal is supported by supervised field trials data. A validated method is available to enforce this MRL. No consumer health risk was identified.
Fruit Vegetables Pulses Oilseeds and oilfruits Other cereals (except maize) Sugar plants	0.05* 0.05* 0.05* 0.1*/0.05* 0.05*	0.02*	When changing the residue definition risk managers may consider the lowering of the LOQ to 0.02*mg/kg for all crops for which no GAPs are authorised. A validated analytical method is available for the mentioned crop groups.
Tea, coffee, herbal infusitons and cocoa Hops Spices	0.1* 0.1* 0.1*	0.1* or 0.05*	No validation of the analytical method is available for these crop groups. In case enforcement laboratories have experiences in analysing the commodities belonging to these crop groups, the lowering of the LOQ may be considered.

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

It should be noted that MRLs established for isoxaflutole will be subject to a full review under Article 12(2) of Regulation 396/2005.

Key words: Isoxaflutole, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, 2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethyl-phenyl) propane-1,3-dione (RPA 202248), 2-methanesulfonyl-4-trifluoro-methylbenzoic acid (RPA 203328)

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from the company Bayer CropScience [4] to modify the residue definition for the active substance isoxaflutole. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA in October 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-739 and the following subject:

Isoxaflutole - Application to modify the residue definition for MRL setting from isoxaflutole to the sum of isoxaflutole and RPA 202248, expressed as isoxaflutole.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

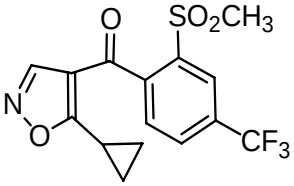
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 26 March 2009.

[4] Bayer CropScience B.V., Energieweg 1, 3641 RT Mijdrecht, Netherlands

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Isoxaflutole is the ISO common name for 5-cyclopropyl-1,2-oxazol-4-yl a,a,a-trifluoro-2-mesyl-p-tolyl ketone (IUPAC).



Isoxaflutole is a systemic herbicide used against broad leaved weed and grasses in maize. It inhibits the carotenoid biosynthesis and causes chlorosis in new growth. In plants and in soil the active substance is rapidly metabolised by opening the isoxazole ring to form a diketonitrile–metabolite which is responsible for the mode of action.

Isoxaflutole has been evaluated in the framework of Directive 91/414/EEC as a new active substance with the Netherlands being the designated Rapporteur Member State (RMS). The active substance was included in Annex I of Directive 91/414/EEC by Directive 2003/68/EC which entered into force on 1 October 2003. Since EFSA was not yet involved in the peer review at that time, no EFSA conclusion is available for this active substance.

The supported use of isoxaflutole in the framework of the peer review was the use in maize (application after sowing, pre-emergence) with a dose rate of 100 g a.s./ha against a broad spectrum of broad leaf and grassy weeds. The GAP supported in the DAR is identical with the GAP provided by the applicant in support of the current application (see Appendix A).

MRLs for cereals, fruit and vegetables have been established at EU level first in 2005 by Directive 2005/37/EC. These MRLs (all at the LOQ of 0.05 or 0.1 mg/kg) have been transferred without amendment to Annex II of Regulation 396/2005 (Appendix B). For crops not covered by the previous legislation additional MRLs (all at the LOQ) have been included in Annex IIIB. For products of animal origin, no MRLs are currently set at EU level. Codex Alimentarius did not establish CXLs for this active substance.

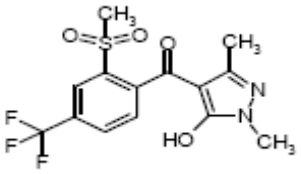
The Netherlands received an application from the manufacturer of the active substance isoxaflutole to amend the enforcement residue definition which is currently defined as isoxaflutole (sum of isoxaflutole, RPA 202248[5] and RPA 203328[6], expressed as isoxaflutole). The applicant requests to exclude the metabolite RPA 2033328 from the residue definition because it is a common metabolite which may also result from the use of pyrasulfotole. According to the applicant, the use of pyrasulfotole to cereals may lead to residues of RPA 203328 up to 0.5 mg/kg. The presence of this metabolite resulting from the use of pyrasulfotole would cause an MRL exceedance with regard to the MRLs established for isoxaflutole.

A full review of the MRLs established will be performed in the framework of Article 12(2) of Regualtion 396/2005 within the next months.

5 RPA 202248 is 2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl) propane-1,3-dione
6 RPA 203328: 2-methanesulfonyl-4-trifluoromethylbenzoic acid

The EMS proposed that in the course of amending the residue definition, also the LOQ could be lowered. As a consequence, it is proposed that the MRLs established at the LOQ of 0.05 mg/kg should be lowered to 0.02 mg/kg. For commodities belonging to the crop group with high fat content and dry commodities the new MRLs should be established at the LOQ of 0.05 mg/kg instead of 0.1 mg/kg.

Pyrasulfotole is the ISO common name for (5-hydorxyl-1,3-dimethyl-1H-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone. Pyrasulfotole is currently not authorised in the EU and no application for including the active substance in Annex I of Directive 91/414/EEC has been made. It is used in the United States as herbicide in cereals.



For pyrasulfotole import tolerances have been established in Annex IIIA of Regulation 396/2005 to accommodate for the use in the United States. All MRLs are set at the LOQ of 0.01 or 0.02 mg/kg except for oats (0.2 mg/kg), bovine liver (1 mg/kg) and bovine kidney (0.2 mg/kg). The residue definition comprises the parent compound only (see Appendix B).

ASSESSMENT

1. Methods of analysis

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

The applicant provided analytical methods based on HPLC/MS/MS to measure residues of isoxaflutole and the metabolite RPA 202248. The method was validated (including ILV) in commodities with high water content (tomatoes), high oil content (rape seed), high acid content (oranges) and dry matrices (wheat grain). The LOQ for each analyte is 0.01 mg/kg. Thus, the overall LOQ for the four crop groups for which validation data were presented is 0.02 mg/kg.

In conclusion, an analytical method is available to enforce the new residue definition proposed for enforcement.

It should be noted that in the framework of the peer review a common moiety method determining parent isoxaflutole, RPA 201148[7] and RPA 203328 as RPA 203328 was evaluated. This method was validated for maize (grain, forage, fodder and foliage) and a LOQ of 0.05 mg/kg was proposed for regulatory practice.

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

Currently no MRLs are established for products of animal origin.

The availability of analytical methods for enforcement of residues in feed of animal origin was not investigated because the application to amend the residue definition for plant products has no impact on the MRL setting for products of animal origin.

[7] 2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl) propane-1,3-dione

2. Mammalian toxicology

The toxicological properties of isoxaflutole have been evaluated in the DAR prepared under Directive 91/414/EEC (NL, 1997). The following health based guidance values have been derived:

Table 2-1. **Overview of the toxicological reference values**

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Parent compound isoxaflutole					
ADI	COM	2003	0.02	2 yr rat	100
ARfD	COM	2003		Not necessary	

The toxicological relevance of the metabolites RPA 202248 and RPA 203328 was discussed. The metabolite RPA 203328 was found to be of no concern from a toxicological point of view (NL, 1998) whereas for metabolite RPA 202248 it was concluded that it is a toxicologically relevant metabolite.

Additional studies provided after the Annex I inclusion (90 day toxicity study in rats, genotoxicity studies (in vitro and in vivo), and a teratogenicity study) which have been evaluated in the Evaluation Report (NL, 2008) present a rough comparison of the toxicity of isoxaflutole *vs.* the metabolite RPA 203328. The studies demonstrated the absence of genotoxic potential and that the metabolite RPA 203328 is less toxic than isoxaflutole.

It is concluded that the metabolite RPA 203328 is of low concern compared to the parent compound. Thus, from a toxicological point of view it is not necessary to include this metabolite in the residue definition.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

In the DAR (NL, 1997) prepared for isoxaflutole, a metabolism study in maize was evaluated. Maize plants were grown in soil on which ^{14}C-labelled isoxaflutole had been applied at a dose rate of 209 g a.s./ha (2N) and 657 g. a.s./ha before or just after sowing. Less than 2% of the radiolabelled herbicide applied was absorbed by the plants. The TRR at harvest was 0.044 mg/kg in grain and 0.149 mg/kg in fodder in the trial with the 2N application rate. The application of 657 g a.s./ha (6N) lead to 0.152 mg/kg isoxaflutole equivalents in grain and to 0.661 mg/kg isoxaflutole equivalents in fodder.

83-99% of the TRR were extractable residues. RPA 202248 and RPA 203328 accounted for about 10% and 90% of the extractable residues, respectively. The parent compound was not detected in any part of the plant.

The study reveals that RPA 203328 is the prevalent metabolite in maize. RPA 202248 is present at significantly lower concentrations compared with RPA 203328. No parent compound is expected in harvested maize grain.

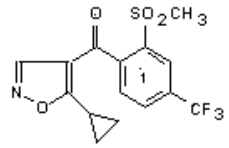
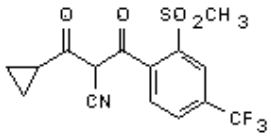
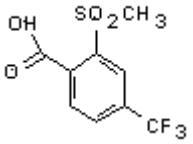
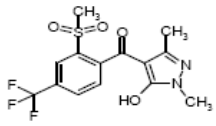
In the peer review the following residue definition for plant products was agreed: sum of isoxaflutole, RPA 202248 and RPA 203328, expressed as isoxaflutole.

Although RPA 203328 is a biologically inactive metabolite it was included in the residue definition as a residue marker because it was identified as the major metabolite. The same residue definition was included in the MRL legislation (Directive 2005/37/EC).

From the available metabolism data it can be concluded that for crops belonging to the crop group “cereals” the residue definition for both risk assessment and enforcement can be established as sum of isoxaflutole and RPA 202248, expressed as isoxaflutole.

The omission of the metabolite RPA 203328 from the residue definitions is justified since it is of no toxicological concern. Since maize is currently the only crop supported by the applicant, no further metabolism studies are required for other crop groups. The validity of the residue definition for other crops than cereals is not confirmed by studies.

Metabolism studies for pyraslfotole are not available to EFSA. However, the EMS mentioned in the evaluation report that RPA 203328 was identified in cereals treated with this structurally similar active substance.

Parent compound/ metabolite	Name	Chemical structure
parent compound isoxaflutole RPA 201772	5-cyclopropyl-1,2-oxazol-4-yl a,a,a-trifluoro-2-mesyl-p-tolyl ketone	
RPA 202248	2-cyano-3-cyclopropyl-1-(2-methylsulfonyl-4-trifluoromethylphenyl) propane-1,3-dione	
RPA 203328	2-methanesulfonyl-4-trifluoromethylbenzoic acid	
Pyrasulfotole	(5-hydorxyl-1,3-dimethyl-1H-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone	

3.1.1.2. Magnitude of residues

Results of supervised field trials on maize are reported in the DAR (NL, 1997). The analytical method used in these studies converted the residues of isoxaflutole and its metabolites RPA 202248 to RPA 203328 which was derivatized to form the methyl ester. Thus, no detailed infomration on the respective concentration of the parent compound and the metabolites is available.

These trials in maize (grain) demonstrate that no residues above the LOQ of 0.013 mg/kg (sum of isoxaflutole, RPA 202248 and 203328, expressed as isoxaflutole) occur if isoxaflutole is applied according the GAP. This conclusion is valid for the Southern and the Northern EU GAPs. The no-residue situation is confirmed by further studies in which the active substance was applied in dose rates 1.5 to 3 times higher than the GAP.
The MRLs for maize is currently established at the level of 0.05 mg/kg which is the LOQ of the analytical method proposed for the enforcement of the residue definition which comprises both metabolites.

It is concluded that the supervised field trials data show that no residues above the LOQ of 0.013 mg/kg according to the currently established residue definition are expected in maize. If the residue definition is changed to “sum of isoxaflutole and RPA 202248, expressed as isoxaflutole”, the MRL for maize can be established at the level of 0.02 mg/kg which corresponds with the LOQ of the enforcment method developed for the proposed residue definition.

Since the method was validated for commodities with high water content, high oil content, high acid content and dry matrices, the MRLs currently established at the LOQ of 0.05 mg/kg could be adjusted to the LOQ of 0.02 mg/kg. For other crops like tea, coffee, herbal infusions, coffee, hops, spices where the analyis is often impeded by the presence of natural occurring components leading to interferences in the chromatograms, the LOQ should be established at a level of 0.05 mg/kg to avoid difficulties in enforcement practice.

3.1.1.3. Effect of industrial processing and/or household preparation

The proposed amendment of the residue definition does not have an impact on processed commodities and on processing factors.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Lowering the MRL for plant commodities from the current LOQ of 0.05 mg/kg or 0.1 mg/kg to 0.02 mg/kg or 0.05 mg/kg could in theory lead to the detection of residues in crops grown in crop rotation after the primary crop was treated with isoxaflutole. Therefore the issue of rotational crops has to be considered before a decision regarding the change of the residue definition and the lowering of the LOQ is taken. In particular, it has to be ensured that residues of parent compound and RPA 202248 do not exceed the LOQ values in succeeding crops.

From the assessment in the DAR (NL, 1997) it was concluded that RPA 202248 and RPA 203328 are the major metabolites in soil. The DT_{50} values derived in laboratory studies demonstrate that RPA 203328 is quite stable in soil (mean DT_{50lab} (20°C, aerobic) is 529 d). In field studies, this metabolite was not detected in soil after 61 to 275 d. For RPA 202248 a DT_{50lab} of 46 d (mean) and DT_{50f} of 16 to 24 days were reported.

In rotational crop studies evaluated in the DAR both metabolites were detected in trace amounts in the crops investigated (radish, lettuce, mustard, wheat grain and sorghum). The highest concentration of RPA 202248 was found in raddish leaves grown in soil treated 34 day prior to planting (0.005 mg/kg isoxaflutole equivalent). RPA 203328 however, was the major metabolite found in concentrations between 0.002 mg/kg to 0.031 mg/kg (isoxaflutole equivalent). The parent compoind was not present in the plants grown in crop rotation.

It is concluded that no measurable residues of isoxaflutole and/or RPA 202248 are expected in succeeding crops.

3.2. Nature and magnitude of residues in livestock

Currently no MRLs are established for products of animal origin.

It should be noted that in the peer review a residue definition for food of animal origin was proposed which is identical with the residue defintion proposed now for plant products: sum of isoxaflutole and RPA 202248, expressed as isoxaflutole.

The peer review concluded that no residues are expected in products of animal origin if isoxaflutole is used according to the GAP on maize. Therefore no MRLs were proposed at that time.

The current application does not have an impact on residues in livestock.

4. Consumer risk assessment

EFSA performed a chronic consumer risk assessment by means of the EFSA PRIMo rev. 2. The assessment is based only on the proposed lower MRL for maize (0.02* mg/kg), the only crop for which a GAP was notified and for which supporting residue data are available. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 0.2% of the ADI. The detailed results of the intake calculations are reported in Appendix C to this document.

Since the no ARfD was established, no acute risk assessment was necessary.

CONCLUSIONS AND RECOMMENDATIONS

Metabolism of isoxaflutole was investigated in maize grown in soil treatd with radiolabelled isoxaflutole. The study revealed that RPA 203328 is the major metabolite in maize whereas RPA 202248 is found in significantly lower concentrations compared with RPA 203328. No parent compound is not expected in harvested maize grain.

The assessment of the toxicological data provided in the framework of the peer review under Directive 91/414/EEC and in support of this application demonstrated that the biologically inactive metabolite RPA 203328 is of low concern compared to the parent compound and the biologically active metabolite RPA 202248. Thus, from a toxicological point of view it is not necessary to include this metabolite in the residue definition.

The applicant provided an analytical method based on HPLC/MS/MS to measure residues of isoxaflutole and the metabolite RPA 202248.The method was validated in tomatoes, rape seed, oranges and wheat grain. The analytical method is capable to enforce the proposed residue definition (sum of isoxaflutole and RPA 202248, expressed as isoxaflutole) with a LOQ of 0.02 mg/kg in the commodities with high water content, high oil content, high acid content and dry matrices.

In view of the higher sensitivity of the analytical method proposed for the new residue definition, the Evaluating Member State proposed to lower the MRLs established at the LOQ of 0.05 mg/kg to 0.02 mg/kg. MRLs currently established at the LOQ of 0.1 mg/kg for commodities with high fat content and other matrices which contain a high amount natural compounds interfering with analytical detection systems (e.g. tea, coffee, herbal infusions, cocoa, hops, spices) are proposed to be lowered to 0.05 mg/kg.

Supervised field trials in maize show that no residues above the LOQ of 0.013 mg/kg according to the currently established residue definition are expected in maize. If the residue definition is changed as proposed, the MRL for maize could be established at the level of 0.02 mg/kg which corresponds with the LOQ of the enforcement method developed for the proposed new residue definition.

For other crops no authorised uses have been notified by the manufacturer of the active substance. The lowering of the LOQ value as proposed by the Evaluating Member State would not require the re-evaluation of any residue trials.

The proposed change of the residue definition and the lowering of the LOQ values would not have a negative impact on the consumer safety. The long-term consumer exposure resulting from residues in maize at the level of 0.02 g/kg (corresponding to the LOQ) is less than 0.5% of the ADI.

The recommendations resulting from the assessment are summarised in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Change the residue definition to : **Isoxaflutole (sum of isoxaflutole and RPA 202248, expressed as isoxaflutole)**			

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Maize	0.05*	0.02*	MRL proposal is supported by supervised field trials data. A validated method is available to enforce this MRL. No consumer health risk was identified.
Fruit Vegetables Pulses Oilseeds and oilfruits Other cereals (except maize) Sugar plants	0.05* 0.05* 0.05* 0.1*/0.05* 0.05*	0.02*	When changing the residue definition risk managers may consider the lowering of the LOQ to 0.02*mg/kg for all crops for which no GAPs are authorised. A validated analytical method is available for the mentioned crop groups.
Tea, coffee, herbal infusitons and cocoa Hops Spices	0.1* 0.1* 0.1*	0.1* or 0.05*	No validation of the analytical method is available for these crop groups. In case enforcement laboratories have experiences in analysing the commodities belonging to these crop groups, the lowering of the LOQ may be considered.

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

It should be noted that MRLs established for isoxaflutole will be subject to a full review under Article 12(2) of Regulation 396/2006.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report in order to amend the residue definition for isoxaflutole. October 2008. Prepared by CTgB, Netherlands.

REFERENCES

The Netherlands, 1997. Draft Assessment Report on isoxaflutole prepared by the CTgB under Directive 91/414/EEC. June 2006.

The Netherlands, 1998. Addendum to the Draft Assessment Report on isoxaflutole prepared by CTgB, March 1998.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Intended Uses Proposed by the Notifier

1	2	3	4	5	6			7			8	9
Crop and / or situation	F or G	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. Of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
(a)	(b)	(c)	(d – f)	(i)	(f - h)	(j)					(k)	(l)
Maize	F	Broadleaved and grassy weeds	WP, WG	750 g/l	Soil treatment or spraying	Preplant incorporation or pre-emergence	1	0.0038 – 0.0525	200-500	0.075-0.105	-	

APPENDIX B – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 30/06/2009 08:41)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Isoxaflutole (sum of isoxaflutole, RPA 202248 and RPA 203328, expressed as isoxaflutole)	Pyrasulfotole
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*	0,01*
110000	(i) Citrus fruit	0,05*	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*	0,01*
110030	Lemons (Citron, lemon)	0,05*	0,01*
110040	Limes	0,05*	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*	0,01*
110990	Others	0,05*	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*	0,01*
120010	Almonds	0,05*	0,01*
120020	Brazil nuts	0,05*	0,01*
120030	Cashew nuts	0,05*	0,01*
120040	Chestnuts	0,05*	0,01*
120050	Coconuts	0,05*	0,01*
120060	Hazelnuts (Filbert)	0,05*	0,01*
120070	Macadamia	0,05*	0,01*
120080	Pecans	0,05*	0,01*
120090	Pine nuts	0,05*	0,01*
120100	Pistachios	0,05*	0,01*
120110	Walnuts	0,05*	0,01*
120990	Others	0,05*	0,01*
130000	(iii) Pome fruit	0,05*	0,01*
130010	Apples (Crab apple)	0,05*	0,01*
130020	Pears (Oriental pear)	0,05*	0,01*
130030	Quinces	0,05*	0,01*
130040	Medlar	0,05*	0,01*
130050	Loquat	0,05*	0,01*
130990	Others	0,05*	0,01*
140000	(iv) Stone fruit	0,05*	0,01*
140010	Apricots	0,05*	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,05*	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,05*	0,01*
140040	Plums (Damson, greengage, mirabelle)	0,05*	0,01*
140990	Others	0,05*	0,01*
150000	(v) Berries & small fruit	0,05*	0,01*
151000	(a) Table and wine grapes	0,05*	0,01*
151010	Table grapes	0,05*	0,01*
151020	Wine grapes	0,05*	0,01*
152000	(b) Strawberries	0,05*	0,01*
153000	(c) Cane fruit	0,05*	0,01*
153010	Blackberries	0,05*	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*	0,01*
153030	Raspberries (Wineberries)	0,05*	0,01*
153990	Others	0,05*	0,01*
154000	(d) Other small fruit & berries	0,05*	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*	0,01*
154020	Cranberries	0,05*	0,01*
154030	Currants (red, black and white)	0,05*	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*	0,01*
154050	Rose hips	0,05*	0,01*
154060	Mulberries (arbutus berry)	0,05*	0,01*
154070	Azarole (mediteranean medlar)	0,05*	0,01*
154080	Elderberries (Black chokeberry	0,05*	0,01*

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	(appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)		
154990	Others	0,05*	0,01*
160000	(vi) Miscellaneous fruit	0,05*	0,01*
161000	(a) Edible peel	0,05*	0,01*
161010	Dates	0,05*	0,01*
161020	Figs	0,05*	0,01*
161030	Table olives	0,05*	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*	0,01*
161050	Carambola (Bilimbi)	0,05*	0,01*
161060	Persimmon	0,05*	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*	0,01*
161990	Others	0,05*	0,01*
162000	(b) Inedible peel, small	0,05*	0,01*
162010	Kiwi	0,05*	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*	0,01*
162030	Passion fruit	0,05*	0,01*
162040	Prickly pear (cactus fruit)	0,05*	0,01*
162050	Star apple	0,05*	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*	0,01*
162990	Others	0,05*	0,01*
163000	(c) Inedible peel, large	0,05*	0,01*
163010	Avocados	0,05*	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*	0,01*
163030	Mangoes	0,05*	0,01*
163040	Papaya	0,05*	0,01*
163050	Pomegranate	0,05*	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*	0,01*
163070	Guava	0,05*	0,01*
163080	Pineapples	0,05*	0,01*
163090	Bread fruit (Jackfruit)	0,05*	0,01*
163100	Durian	0,05*	0,01*
163110	Soursop (guanabana)	0,05*	0,01*
163990	Others	0,05*	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*	0,01*
210000	(i) Root and tuber vegetables	0,05*	0,01*
211000	(a) Potatoes	0,05*	0,01*
212000	(b) Tropical root and tuber vegetables	0,05*	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*	0,01*
212020	Sweet potatoes	0,05*	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*	0,01*
212040	Arrowroot	0,05*	0,01*
212990	Others	0,05*	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*	0,01*
213010	Beetroot	0,05*	0,01*
213020	Carrots	0,05*	0,01*
213030	Celeriac	0,05*	0,01*
213040	Horseradish	0,05*	0,01*
213050	Jerusalem artichokes	0,05*	0,01*
213060	Parsnips	0,05*	0,01*
213070	Parsley root	0,05*	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*	0,01*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*	0,01*
213100	Swedes	0,05*	0,01*
213110	Turnips	0,05*	0,01*
213990	Others	0,05*	0,01*
220000	(ii) Bulb vegetables	0,05*	0,01*
220010	Garlic	0,05*	0,01*
220020	Onions (Silverskin onions)	0,05*	0,01*
220030	Shallots	0,05*	0,01*

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220040	Spring onions (Welsh onion and similar varieties)	0,05*	0,01*
220990	Others	0,05*	0,01*
230000	(iii) Fruiting vegetables	0,05*	0,01*
231000	(a) Solanacea	0,05*	0,01*
231010	Tomatoes (Cherry tomatoes,)	0,05*	0,01*
231020	Peppers (Chilli peppers)	0,05*	0,01*
231030	Aubergines (egg plants) (Pepino)	0,05*	0,01*
231040	Okra, lady's fingers	0,05*	0,01*
231990	Others	0,05*	0,01*
232000	(b) Cucurbits - edible peel	0,05*	0,01*
232010	Cucumbers	0,05*	0,01*
232020	Gherkins	0,05*	0,01*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*	0,01*
232990	Others	0,05*	0,01*
233000	(c) Cucurbits-inedible peel	0,05*	0,01*
233010	Melons (Kiwano)	0,05*	0,01*
233020	Pumpkins (Winter squash)	0,05*	0,01*
233030	Watermelons	0,05*	0,01*
233990	Others	0,05*	0,01*
234000	(d) Sweet corn	0,05*	0,01*
239000	(e) Other fruiting vegetables	0,05*	0,01*
240000	(iv) Brassica vegetables	0,05*	0,01*
241000	(a) Flowering brassica	0,05*	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*	0,01*
241020	Cauliflower	0,05*	0,01*
241990	Others	0,05*	0,01*
242000	(b) Head brassica	0,05*	0,01*
242010	Brussels sprouts	0,05*	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*	0,01*
242990	Others	0,05*	0,01*
243000	(c) Leafy brassica	0,05*	0,01*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*	0,01*
243020	Kale (Borecole (curly kale), collards)	0,05*	0,01*
243990	Others	0,05*	0,01*
244000	(d) Kohlrabi	0,05*	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,05*	0,01*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*	0,01*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*	0,01*
251040	Cress	0,05*	0,01*
251050	Land cress	0,05*	0,01*
251060	Rocket, Rucola (Wild rocket)	0,05*	0,01*
251070	Red mustard	0,05*	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*	0,01*
251990	Others	0,05*	0,01*
252000	(b) Spinach & similar (leaves)	0,05*	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*	0,01*
252990	Others	0,05*	0,01*
253000	(c) Vine leaves (grape leaves)	0,05*	0,01*
254000	(d) Water cress	0,05*	0,01*
255000	(e) Witloof	0,05*	0,01*
256000	(f) Herbs	0,05*	0,01*
256010	Chervil	0,05*	0,01*
256020	Chives	0,05*	0,01*

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256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*	0,01*
256040	Parsley	0,05*	0,01*
256050	Sage (Winter savory, summer savory,)	0,05*	0,01*
256060	Rosemary	0,05*	0,01*
256070	Thyme (marjoram, oregano)	0,05*	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,05*	0,01*
256090	Bay leaves (laurel)	0,05*	0,01*
256100	Tarragon (Hyssop)	0,05*	0,01*
256990	Others	0,05*	0,01*
260000	(vi) Legume vegetables (fresh)	0,05*	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*	0,01*
260050	Lentils	0,05*	0,01*
260990	Others	0,05*	0,01*
270000	(vii) Stem vegetables (fresh)	0,05*	0,01*
270010	Asparagus	0,05*	0,01*
270020	Cardoons	0,05*	0,01*
270030	Celery	0,05*	0,01*
270040	Fennel	0,05*	0,01*
270050	Globe artichokes	0,05*	0,01*
270060	Leek	0,05*	0,01*
270070	Rhubarb	0,05*	0,01*
270080	Bamboo shoots	0,05*	0,01*
270090	Palm hearts	0,05*	0,01*
270990	Others	0,05*	0,01*
280000	(viii) Fungi	0,05*	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*	0,01*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*	0,01*
280990	Others	0,05*	0,01*
290000	(ix) Sea weeds	0,05*	0,01*
300000	3. PULSES, DRY	0,05*	0,01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*	0,01*
300020	Lentils	0,05*	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*	0,01*
300040	Lupins	0,05*	0,01*
300990	Others	0,05*	0,01*
400000	4. OILSEEDS AND OILFRUITS		0,01*
401000	(i) Oilseeds	0,1*	0,01*
401010	Linseed	0,1*	0,01*
401020	Peanuts	0,1*	0,01*
401030	Poppy seed	0,1*	0,01*
401040	Sesame seed	0,1*	0,01*
401050	Sunflower seed	0,1*	0,01*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*	0,01*
401070	Soya bean	0,1*	0,01*
401080	Mustard seed	0,1*	0,01*
401090	Cotton seed	0,1*	0,01*
401100	Pumpkin seeds	0,1*	0,01*
401110	Safflower	0,1*	0,01*
401120	Borage	0,1*	0,01*
401130	Gold of pleasure	0,1*	0,01*
401140	Hempseed	0,1*	0,01*
401150	Castor bean	0,1*	0,01*
401990	Others	0,1*	0,01*
402000	(ii) Oilfruits		0,01*
402010	Olives for oil production	0,05*	0,01*
402020	Palm nuts (palmoil kernels)	0,1*	0,01*
402030	Palmfruit	0,1*	0,01*
402040	Kapok	0,1*	0,01*
402990	Others	0,1*	0,01*

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500000	5. CEREALS	0,05*	
500010	Barley	0,05*	0,02*
500020	Buckwheat	0,05*	0,02*
500030	Maize	0,05*	0,02*
500040	Millet (Foxtail millet, teff)	0,05*	0,02*
500050	Oats	0,05*	0,2
500060	Rice	0,05*	0,02*
500070	Rye	0,05*	0,02*
500080	Sorghum	0,05*	0,02*
500090	Wheat (Spelt Triticale)	0,05*	0,02*
500990	Others	0,05*	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*	0,02*
620000	(ii) Coffee beans	0,1*	0,02*
630000	(iii) Herbal infusions (dried)	0,1*	0,02*
631000	(a) Flowers	0,1*	0,02*
631010	Camomille flowers	0,1*	0,02*
631020	Hybiscus flowers	0,1*	0,02*
631030	Rose petals	0,1*	0,02*
631040	Jasmine flowers	0,1*	0,02*
631050	Lime (linden)	0,1*	0,02*
631990	Others	0,1*	0,02*
632000	(b) Leaves	0,1*	0,02*
632010	Strawberry leaves	0,1*	0,02*
632020	Rooibos leaves	0,1*	0,02*
632030	Maté	0,1*	0,02*
632990	Others	0,1*	0,02*
633000	(c) Roots	0,1*	0,02*
633010	Valerian root	0,1*	0,02*
633020	Ginseng root	0,1*	0,02*
633990	Others	0,1*	0,02*
639000	(d) Other herbal infusions	0,1*	0,02*
640000	(iv) Cocoa (fermented beans)	0,1*	0,02*
650000	(v) Carob (st johns bread)	0,1*	0,02*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*	0,02*
800000	8. SPICES	0,1*	0,02*
810000	(i) Seeds	0,1*	0,02*
810010	Anise	0,1*	0,02*
810020	Black caraway	0,1*	0,02*
810030	Celery seed (Lovage seed)	0,1*	0,02*
810040	Coriander seed	0,1*	0,02*
810050	Cumin seed	0,1*	0,02*
810060	Dill seed	0,1*	0,02*
810070	Fennel seed	0,1*	0,02*
810080	Fenugreek	0,1*	0,02*
810090	Nutmeg	0,1*	0,02*
810990	Others	0,1*	0,02*
820000	(ii) Fruits and berries	0,1*	0,02*
820010	Allspice	0,1*	0,02*
820020	Anise pepper (Japan pepper)	0,1*	0,02*
820030	Caraway	0,1*	0,02*
820040	Cardamom	0,1*	0,02*
820050	Juniper berries	0,1*	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*	0,02*
820070	Vanilla pods	0,1*	0,02*
820080	Tamarind	0,1*	0,02*
820990	Others	0,1*	0,02*
830000	(iii) Bark	0,1*	0,02*
830010	Cinnamon (Cassia)	0,1*	0,02*
830990	Others	0,1*	0,02*
840000	(iv) Roots or rhizome	0,1*	0,02*
840010	Liquorice	0,1*	0,02*
840020	Ginger	0,1*	0,02*
840030	Turmeric (Curcuma)	0,1*	0,02*
840040	Horseradish	0,1*	0,02*
840990	Others	0,1*	0,02*
850000	(v) Buds	0,1*	0,02*
850010	Cloves	0,1*	0,02*
850020	Capers	0,1*	0,02*
850990	Others	0,1*	0,02*
860000	(vi) Flower stigma	0,1*	0,02*
860010	Saffron	0,1*	0,02*

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860990	Others	0,1*	0,02*
870000	(vii) Aril	0,1*	0,02*
870010	Mace	0,1*	0,02*
870990	Others	0,1*	0,02*
900000	9. SUGAR PLANTS	0,05*	0,01*
900010	Sugar beet (root)	0,05*	0,01*
900020	Sugar cane	0,05*	0,01*
900030	Chicory roots	0,05*	0,01*
900990	Others	0,05*	0,01*
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		0,01*
1012020	Fat		0,01*
1012030	Liver		1
1012040	Kidney		0,2
1012050	Edible offal		0,01*
1012990	Others		0,01*
1013000	(c) Sheep		0,01*
1013010	Meat		0,01*
1013020	Fat		0,01*
1013030	Liver		0,01*
1013040	Kidney		0,01*
1013050	Edible offal		0,01*
1013990	Others		0,01*

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1014000	(d) Goat		0,01*
1014010	Meat		0,01*
1014020	Fat		0,01*
1014030	Liver		0,01*
1014040	Kidney		0,01*
1014050	Edible offal		0,01*
1014990	Others		0,01*
1015000	(e) Horses, asses, mules or hinnies		0,01*
1015010	Meat		0,01*
1015020	Fat		0,01*
1015030	Liver		0,01*
1015040	Kidney		0,01*
1015050	Edible offal		0,01*
1015990	Others		0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon		0,01*
1016010	Meat		0,01*
1016020	Fat		0,01*
1016030	Liver		0,01*
1016040	Kidney		0,01*
1016050	Edible offal		0,01*
1016990	Others		0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)		0,01*
1017010	Meat		0,01*
1017020	Fat		0,01*
1017030	Liver		0,01*
1017040	Kidney		0,01*
1017050	Edible offal		0,01*
1017990	Others		0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd		0,01*
1020010	Cattle		0,01*
1020020	Sheep		0,01*
1020030	Goat		0,01*

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1020040	Horse		0,01*
1020990	Others		0,01*
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		0,01*
1030010	Chicken		0,01*
1030020	Duck		0,01*
1030030	Goose		0,01*
1030040	Quail		0,01*
1030990	Others		0,01*
1040000	(iv) Honey (Royal jelly, pollen)		0,01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)		0,01*
1060000	(vi) Snails		0,01*
1070000	(vii) Other terrestrial animal products		0,01*

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Isoxaflutole			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,02**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**1999**	Year of evaluation:	**1999**

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)
0,2	WHO Cluster diet B	0,2	Maize					0,2
0,2	IE adult	0,2	Maize					0,2
0,1	UK Infant	0,1	Maize					0,1
0,1	WHO cluster diet E	0,1	Maize					0,1
0,1	WHO cluster diet D	0,1	Maize					0,1
0,0	PT General population	0,0	Maize					0,0
0,0	ES child	0,0	Maize					0,0
0,0	DE child	0,0	Maize					0,0
0,0	WHO regional European diet	0,0	Maize					0,0
0,0	NL child	0,0	Maize					0,0
0,0	WHO Cluster diet F	0,0	Maize					0,0
0,0	ES adult	0,0	Maize					0,0
0,0	NL general	0,0	Maize					0,0
0,0	IT kids/toddler	0,0	Maize					0,0
0,0	FI adult	0,0	Maize					0,0
0,0	IT adult	0,0	Maize					0,0
0,0	UK Toddler	0,0	Maize					0,0
0,0	UK vegetarian	0,0	Maize					0,0
0,0	LT adult	0,0	Maize					0,0
0,0	UK Adult	0,0	Maize					0,0
0,0	PL general population	0,0	Maize					0,0

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

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation

ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation
WP	wettable powder