

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for indoxacarb in various crops¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Spain received an application from the Spanish Federation of Associations of Producers and Exporters of Fruits, Vegetables, Flowers and Live Plants (FEPEX) to modify the existing MRLs for the active substance indoxacarb in raspberries and strawberries. In accordance with Article 6 of Regulation (EC) No 396/2005, The Netherlands received an application from DuPont Danmark to modify the existing MRLs for the active substance indoxacarb in several crops. Spain and The Netherlands drafted the evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to EFSA. For reasons of efficiency EFSA combined both applications in one reasoned opinion. According to EFSA the data are sufficient to derive MRL proposals for the crops under consideration, except for strawberries, raspberries and witloof. The submitted residue data indicate no need to modify the existing EU MRLs for scarole and soya beans. Adequate analytical enforcement methods are available to control the residues of indoxacarb and its R-isomer on the commodities for which a MRL is proposed at the validated LOQ of 0.02 mg/kg. Based on the risk assessment results, EFSA concludes that the proposed uses of indoxacarb on Chinese cabbage, lamb's lettuce, scarole, beans with pods, cardoons, fennel, rhubarb and soya beans will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

© European Food Safety Authority, 2012

KEY WORDS

Indoxacarb, strawberries and raspberries, Chinese cabbage and leaf vegetables, fresh beans and soya beans, stem vegetables, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, oxadiazine insecticide, R-isomer.

¹ On request from European Commission, Question No EFSA-Q-2011-01265 and Q-2012-00027, approved on 09 July 2012.

² Correspondence: pesticides.mrl@efsa.europa.eu

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Spain, hereafter referred to as the evaluating Member State (EMS-ES), received an application from the Spanish Federation of Associations of Producers and Exporters of Fruits, Vegetables, Flowers and Live Plants (FEPEX) to modify the existing MRLs for the active substance indoxacarb in raspberries and strawberries. In order to accommodate for the intended uses, Spain proposed to raise the existing MRLs from 0.5 mg/kg in raspberries and from the limit of quantification (0.02 mg/kg) in strawberries to 0.6 mg/kg. Spain drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 29 November 2011.

In accordance with Article 6 of Regulation (EC) No 396/2005, The Netherlands, hereafter referred to as the evaluating Member State (EMS-NL), received an application from DuPont Danmark to modify the existing MRLs for the active substance indoxacarb in several crops. In order to accommodate for the intended uses, The Netherlands proposed the following MRLs: 0.5 mg/kg in beans with pods, 3 mg/kg in Chinese cabbage, 40 mg/kg in lamb's lettuce and 2 mg/kg in cardoons, fennel and rhubarb, whereas no MRL amendment was found to be necessary for scarole and soya beans. The EMS-NL considered the intended use on witloof as not supported. The Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 6 January 2012.

For reasons of efficiency EFSA combined both applications in one reasoned opinion. EFSA bases its assessment on the evaluation reports submitted by the EMS-ES and EMS-NL, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the Commission Review Report on indoxacarb, the JMPR Evaluation reports as well as the conclusions from previous EFSA opinions on indoxacarb, including the EFSA reasoned opinion on the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of indoxacarb was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.006 mg/kg bw per day and an ARfD of 0.125 mg/kg bw.

The metabolism of indoxacarb in primary crops was investigated in three different crop groups following foliar application. The review of the existing MRLs for indoxacarb performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is indoxacarb (S-enantiomer) and its R-enantiomer. EFSA proposed to reword the residue definition as "sum of indoxacarb and its R-enantiomer". For the uses on crops under consideration EFSA concludes that the metabolism of indoxacarb in primary crops is sufficiently addressed and that the residue definitions as proposed during the MRL review are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals for the crops under consideration, except for strawberries, raspberries and witloof. The submitted residue data indicate no need to modify the existing EU MRLs for scarole and soya beans. Adequate analytical enforcement methods are available to control the residues of indoxacarb and its R-isomer on the commodities for which a MRL is proposed at the validated LOQ of 0.02 mg/kg.

The peer review concluded that the indoxacarb and its R-enantiomer are hydrolytically stable under conditions representative of pasteurisation and baking/boiling and for processed commodities that are not subject to sterilisation the same residue definition as for raw agricultural commodities (RAC) is applicable. The nature of residues under conditions simulating sterilisation was not investigated and is considered required. Considering that the residue levels in raw agricultural commodities (RAC) exceeded the trigger value of 0.1 mg/kg in most of the crops and the total theoretical maximum daily intake (TMDI) amounts to more than 10 % of the ADI, it would be desirable to have additional processing studies.

Based on the available information on the occurrence of indoxacarb residues in rotational crops, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP (Good Agricultural Practice).

Since no amendment of the existing MRL on soya bean (the only product which is also used as feed item) is proposed, no further investigations on the nature and magnitude of residues in livestock are necessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of indoxacarb at EU level and the existing acceptable CXLs supported by data. EFSA now updates this risk assessment with the median residue value as derived from the supervised residue trials on beans with pods, Chinese cabbage, lamb's lettuce, celery (extrapolated to cardoons, fennel and rhubarb). The acute exposure assessment was performed only with regard to the commodities for which a change of the existing MRL is proposed. The estimated exposure was then compared with the derived toxicological reference values.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for indoxacarb under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for 75 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. No acute consumer risk was identified in relation to the MRL proposals.

EFSA concludes that the proposed uses of indoxacarb on Chinese cabbage, lamb's lettuce, scarole, beans with pods, cardoons, fennel, rhubarb and soya beans will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

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

Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of indoxacarb and its R-enantiomer^(b) (F)				
0152000	Strawberries	0.02*	No new proposal	The submitted outdoor data are not appropriate to derive MRL proposals for the intended uses under protected conditions. Evidence should be provided that the outdoor residue trials are representative for the intended uses (plastic tunnel).
0153030	Raspberries	0.5	No new proposal	
243010	Chinese cabbage	0.2	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended indoor use. No residue data are available for the intended outdoor use in NEU.
251010	Lamb's lettuce	1	30	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended indoor use.
251030	Scarole	2/1 ^(c)	No change	The submitted data support the intended use in SEU and demonstrate that it is not

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
				necessary to amend the MRL of 1 mg/kg recommended under the Article 12 review.
0255000	Witloof	0.02*	No new proposal	The submitted residue data are not sufficient to derive a MRL proposal.
260010	Beans (with pods) (Green bean)	0.02*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended outdoor use in NEU. The submitted residue data do not support a MRL proposal for the intended indoor use and the outdoor use in SEU.
270020	Cardoons	0.02*	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses. The MRLs are derived by extrapolation from celery.
270040	Fennel	0.02*	3	
270070	Rhubarb	0.02*	3	
401070	Soya bean	0.5	No change	The existing MRL covers the intended use and does not need to be amended.

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): As proposed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

(c): A lower MRL of 1 mg/kg is proposed for scarole in the framework of the MRL review (EFSA, 2011).

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

(F): Fat-soluble pesticide.

TABLE OF CONTENTS

Abstract	1
Summary	2
Table of contents	5
Background	6
Terms of reference.....	6
The active substance and its use pattern.....	7
Assessment	8
1. Method of analysis.....	8
1.1. Methods for enforcement of residues in food of plant origin	8
1.2. Methods for enforcement of residues in food of animal origin	8
2. Mammalian toxicology.....	9
3. Residues.....	9
3.1. Nature and magnitude of residues in plant.....	9
3.1.1. Primary crops.....	9
3.1.2. Rotational crops.....	14
3.2. Nature and magnitude of residues in livestock	14
4. Consumer risk assessment	15
Conclusions and recommendations	17
References	19
Appendices	21
A. Good Agricultural Practice (GAPs).....	21
B. Pesticide Residues Intake Model (PRIMo).....	24
C. Existing EU maximum residue levels (MRLs).....	26
D. List of available median residue values for chronic risk assessment.....	30
Abbreviations	31

BACKGROUND

Regulation (EC) No 396/2005³ establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC⁴, repealed by Regulation (EC) No 1107/2009⁵, shall submit to a Member State, when appropriate, an application to set/modify a MRL in accordance with the provisions of Article 7 of that Regulation.

Spain, hereafter referred to as the evaluating Member State (EMS-ES), received an application from the Spanish Federation of Associations of Producers and Exporters of Fruits, Vegetables, Flowers and Live Plants (FEPEX)⁶ to modify the existing MRLs for the active substance indoxacarb in raspberries and strawberries. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS-ES in accordance with Article 8 of the Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS-NL), received an application from the company DuPont Danmark ApS⁷ to modify the existing MRLs for the active substance indoxacarb in green beans, Chinese cabbage, scarole, lamb's lettuce, witloof (chicory), soya bean, fennel, rhubarb and cardoons. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS-NL in accordance with Article 8 of the Regulation.

After completion, the evaluation reports were submitted to the European Commission who forwarded the applications, the evaluation reports and the supporting dossiers to EFSA on 29 November 2011 and 6 January 2012. The applications were included in the EFSA Register of Questions with the reference numbers EFSA-Q-2011-01265 and Q-2012-00027 and the following subject:

Indoxacarb - Application to modify the existing MRLs in raspberries and strawberries.

Indoxacarb - Application to modify the existing MRLs in various crops.

Spain proposed to raise the existing MRLs of indoxacarb in raspberries and strawberries from 0.5 mg/kg and the LOQ of 0.02 mg/kg, respectively, to 0.6 mg/kg. The Netherlands proposed the following MRLs: 0.5 mg/kg in beans with pods, 3 mg/kg in Chinese cabbage, 40 mg/kg in lamb's lettuce and 2 mg/kg in cardoons, fennel and rhubarb, whereas no MRL amendment was found to be necessary for scarole and soya beans. The EMS-NL considered the intended use on witloof as not supported.

EFSA proceeded with the assessment of the applications and the evaluation reports as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with 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.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) 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.

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

⁵ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

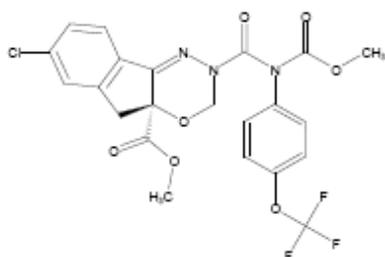
⁶ FEPEX, c/Miguel Ángel 13, 4º, 28010, Madrid, Spain.

⁷ DuPont Danmark ApS, Skøjtevej 26, 2770, Kastrup, Denmark.

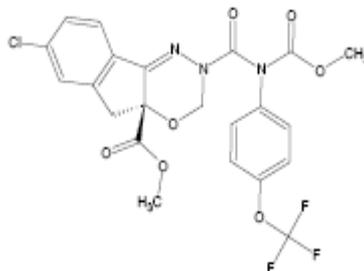
In this particular case the calculated deadlines for providing the reasoned opinion are 29 February 2012 and 6 April 2012.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Indoxacarb is the ISO common name for methyl (*S*)-*N*-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)indeno[1,2-*e*][1,3,4]oxadiazin-2-ylcarbonyl]-4-(trifluoromethoxy)carbanilate or methyl (*S*)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl(4-trifluoromethoxyphenyl)carbamoyl]indeno[1,2-*e*][1,3,4]oxadiazine-4a-carboxylate (IUPAC). The ISO common name indoxacarb refers only to the *S*-enantiomer. The technical material used in the plant protection products is a mixture of the active *S*-isomer and the inactive *R*-isomer.



S-enantiomer



R-enantiomer

Molecular weight: 527.84 g/mol

Indoxacarb is a non-systemic insecticide belonging to the oxadiazine chemical class. Indoxacarb is used on several crops to control a wide range of insects, such as Lepidoptera and other pests in the larval stages. It is active by ingestion and contact routes. The insecticidal activity occurs by blocking the flow of sodium ions in the insect nervous cells.

Indoxacarb was evaluated in the framework of Council Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Commission Directive 2006/10/EC⁸ which entered into force on 1 April 2006 for use as insecticide only. The minimum purity of the technical material specified in the inclusion Directive is equal to 628 g/kg; the content of the inactive isomer has not been specified. In accordance with Commission Implementing Regulation (EU) No 540/2011⁹ indoxacarb is approved under Regulation (EC) No 1107/2009. The representative uses assessed under the peer review were indoor and/or outdoor uses of indoxacarb on brassica vegetables, leaf vegetables and fruiting vegetables. Indoxacarb was not peer reviewed by EFSA.

The EU MRLs are set for the sum of indoxacarb and its *R*-enantiomer in Annex II and Part B of Annex III to Regulation (EC) No 396/2005 (see Appendix C). EFSA recommendations to modify the existing MRLs on various crops (EFSA, 2009a, 2009b, 2009c, 2009d, 2010) have been implemented in four Regulations adopted between 2009 and 2011. EFSA recently issued a reasoned opinion for indoxacarb which reviews all uses authorised at EU level and Codex limits (CXLs) according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011). Modifications of the existing MRLs were proposed for several crops (see Appendix C) which are currently under discussion at the Standing Committee on the Food Chain and Animal Health (draft Regulation SANCO/10392/2012 (Article 12 MRLs) rev3).

The existing EU MRLs for indoxacarb on the crops under consideration are set at the LOQ of 0.02 mg/kg for strawberries, witloof, green beans, cardoons, fennel, rhubarb, 0.2 mg/kg for Chinese cabbage, 0.5 mg/kg for raspberries and soya beans, 1 mg/kg for lamb's lettuce and 2 mg/kg for

⁸ Commission Directive 2006/10/EC of 27 January 2006, OJ L 25, 28.1.2006, p. 24-27.

⁹ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011. OJ L 153, 11.06.2011, p. 1-186.

scarole. Codex Alimentarius has established CXLs for a wide range of commodities. No CXLs have been set for the crops under consideration, except for soya beans for which the CXL is set at 0.5 mg/kg.

The details of the intended GAPs for indoxacarb are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the evaluation reports submitted by the EMS-ES and EMS-NL (Spain, 2011; The Netherlands, 2011), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (The Netherlands, 2000, 2005), the Commission Review Report on indoxacarb (EC, 2005), the JMPR Evaluation reports (FAO, 2005, 2009) as well as the conclusions from previous EFSA opinions on indoxacarb, including the EFSA reasoned opinion on the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2009a, 2009b, 2009c, 2009d, 2010, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹⁰ 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; OECD, 2011).

1. Method of analysis

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

A single residue analytical method using GC-MS and the multi residue DFG S19 method using GC-ECD were assessed during the peer review and were found adequate to determine the residues of indoxacarb and its R-enantiomer in high water (tomatoes, apples, pears, peaches, cabbage, cauliflower, lettuce), high acid (grapes), high fat (cotton seed) content commodities at the combined LOQ of 0.02 mg/kg (The Netherlands, 2005; EFSA, 2011).

The multi-residue QuEChERS method described in the European Standard EN 15662:2008 using HPLC-MS/MS is also applicable for the determination of the residues of the mixture of components in high water content, high acid content and dry commodities with a LOQ of 0.01 mg/kg (CEN, 2008).

Since the commodities under consideration belong to the group of high water and high fat (soya bean) content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for indoxacarb on the crops under consideration are available.

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

There are adequate analytical enforcement methods available to monitor indoxacarb and its R-enantiomer residues in food of animal origin with a combined LOQ of at least 0.01 mg/kg in meat, fat, kidney, liver, milk and eggs (The Netherlands, 2005; EFSA, 2011).

¹⁰ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

2. Mammalian toxicology

The toxicological profile of the active substance indoxacarb was assessed in the framework of the peer review under Directive 91/414/EEC (The Netherlands, 2000; EC, 2005). The toxicological studies submitted in the dossier were performed with indoxacarb and different mixtures of the S- and R isomer. The acceptable daily intake (ADI) was discussed in a toxicological expert meeting organised on 10 June 2001. The experts agreed to derive the ADI from the NOAEL of the chronic rat study performed with the racemic mixture as test material and a safety factor of 100 (EC, 2005). The toxicological reference values derived in the peer review are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Indoxacarb and its R-enantiomers					
ADI	EC	2005	0.006 mg/kg bw per day	2 years, rat ^(a)	100
ARfD	EC	2005	0.125 mg/kg bw	Rat, acute neurotoxicity ^(b)	100

(a): Test item: racemic mixture of S- and R-enantiomers (50:50).

(b): Test item: mixture of S-enantiomers and R-enantiomers (75:25).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of indoxacarb after foliar application was investigated in grapes, tomatoes, lettuce, and cotton, representing the crop groups of fruit and fruiting vegetables, leafy vegetables and oil seed/pulses. The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the review of the existing MRLs (The Netherlands, 2005; EFSA, 2011). The peer review established the residue definition for risk assessment and enforcement as “indoxacarb (sum of R and S isomers)”. In the framework of the MRL review EFSA confirmed the residue definition for enforcement, which is established in Regulation (EC) No 396/2005, but proposed to reword it as “sum of indoxacarb and its R-enantiomer”, since the compound common name indoxacarb refers only to the S-isomer (EFSA, 2011).

For the uses on the crops under consideration, EFSA concludes that the metabolism of indoxacarb is sufficiently addressed and the residue definitions for enforcement and risk assessment as proposed during the MRL review are applicable.

3.1.1.2. Magnitude of residues

All the supervised residue trials were conducted using a 30 WG formulation (DPX-MP062) containing 300 g/kg of indoxacarb (isomer ratio S/R=75/25). The application rate was expressed in terms of the active substance indoxacarb. Residues were measured and expressed as the sum of indoxacarb and its R-enantiomer.

a. Raspberries, Strawberries

Four supervised residue trials (two designed as decline trials) on raspberries and eight supervised residue trials (four designed as decline trials) on strawberries performed in Spain over two seasons are available. Raspberries are a minor crop while strawberries are a major crop in Europe (EC, 2011). The

trials reflect the GAP in terms of rate, number, interval, timing of application and PHI, but were conducted under outdoor conditions. The EMS-ES proposed to use these outdoor SEU trials to estimate the expected residues on raspberries and strawberries grown under protected conditions (high and low plastic tunnels) in Spain, because this particular cultivation, typical of the Southern Europe, shall be considered as a special type of outdoor (field) use (Spain, 2011).

EFSA is of the opinion that the assumption that both situations produce comparable residues shall be confirmed with data. According to the current EU guidance document outdoor applications are not comparable with other uses such as under protected conditions. The climatic conditions in greenhouse or under plastic covers differ from those prevailing under field conditions and usually lead to higher residues (EC, 1997b). In order to propose MRLs on raspberries and strawberries, evidence should be provided that the outdoor residue trials are representative for the intended use (plastic tunnels).

b. Green beans with pods

Beans with pods are a major crop in Europe, therefore a minimum of eight trials is required to support the MRL proposal for each geographical region (EC, 2011).

Outdoor-NEU: eight supervised field residue trials (none designed as decline trial) performed on beans with pods over three seasons are available. The trials reflect the intended GAP. EFSA considers that the data are sufficient to support the MRL proposal of 0.3 mg/kg for the intended outdoor use on green beans with pods in NEU.

Outdoor-SEU: five supervised field residue trials (none designed as decline trial) performed on beans with pods over two seasons are available. The trials reflect the intended GAP. However, the number of trials is not sufficient to derive a MRL proposal (EC, 2011).

Indoor-EU: eight supervised residue trials (four designed as decline trials) performed on beans with pods over two seasons are available. All trials were conducted under glasshouse conditions and comply with the intended critical GAP. Since the trials were all performed during August and the beginning of October, the Netherlands requested the applicant to provide evidence that the period tested in the residue trials represents the worst-case expected under practical conditions leading to the highest residues. Despite this deficiency, the Netherlands proposed a tentative MRL value (The Netherlands, 2011). EFSA is of the opinion that until this data gap is addressed, no MRL proposal can be derived for the intended glasshouse use.

c. Soya bean

Eight supervised residue trials (four designed as decline trials) performed on soya beans in Spain, Italy and Southern France over two seasons are available. Soya beans are a major crop in SEU Europe, therefore a minimum of eight trials is required to support the MRL proposal (EC, 2011). All trials were considered as reflecting the intended GAP. One trial result (residue < LOQ) was disregarded because of possible losses of residues due to rainfall recorded in the first 24 hours. Thus, the number of trials is theoretically not sufficient to support a MRL proposal (EC, 2011). Since the existing MRL of 0.5 mg/kg is sufficiently high to cover the intended use on soya beans in SEU (MRL proposal: 0.07 mg/kg), the small deficiency in the total number of trials is acceptable.

d. Chinese cabbage

Outdoor-NEU: no supervised residue trials are available to support the intended NEU field use.

Indoor-EU: four supervised residue trials (two designed as decline trial) performed on cabbage and pak choi in the Netherlands over two seasons are available. All trials were conducted under glasshouse conditions and were considered representative for the intended GAP although slightly longer intervals between applications (10 days instead of the minimum of 8 days) were noted. Chinese cabbage is a minor crop in the EU, therefore a minimum of four trials is required to support the MRL proposal (EC,

2001). EFSA concludes that the data are sufficient to support the MRL proposal of 3 mg/kg for the intended use on Chinese cabbage grown in glasshouse in the EU.

e. Witloof

Only one supervised residue trial performed on witloof in Spain is available. To verify whether the trial is representative for the intended outdoor GAP, further information on the cultivation conditions of witloof in Spain is required. Witloof is a minor crop in the EU, therefore a minimum of four trials is required to support the MRL proposal (EC, 2001). The data are not sufficient to support the MRL proposal for the intended outdoor use on witloof in SEU.

f. Scarole

Four supervised residue trials (two designed as decline trial) performed on the variety radicchio in Italy and Spain over two seasons are available. The trials were considered as representative for the intended use. Scarole is a minor crop in the EU, therefore a minimum of four trials is required to support the MRL proposal (EC, 2001). EFSA concludes that the data are sufficient to support the MRL proposal for the intended use on scarole in SEU.

g. Lamb's lettuce

Seven supervised residue trials performed on lamb's lettuce over two seasons are available. All trials were conducted under protected conditions (plastic tunnels or plastic greenhouse) and comply with the intended GAP. Lamb's lettuce is a minor crop in the EU, therefore a minimum of four trials is required to support the MRL proposal (EC, 2001). EFSA concludes that the data are sufficient to support the MRL proposal for the intended use on lamb's lettuce under protected conditions.

h. Cardoons, Fennel (bulb), Rhubarb

To support the intended use the applicant referred to the four supervised field residue trials on celery assessed in the framework of the MRL review (EFSA, 2011). Since the studies on celery reflect the intended GAP for cardoons, fennel (bulb) and rhubarb and the extrapolation of residues from celery to these crops is possible (EC, 2011), EFSA concludes that the data on celery are sufficient to support the MRL proposal for the intended use on cardoons, fennel (bulb), rhubarb.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-1.

The storage stability of indoxacarb and its R isomer in primary crops was investigated in the DAR under Directive 91/414/EEC (The Netherlands, 2005). Residues of both isomers were found to be stable for up to 18 months at $\leq -18^{\circ}\text{C}$ in matrices with high water (apples) and high acid (grapes) content and for a period of 11 months at -20°C in matrices with high oil content. Although a minor deficiency was identified by EMS-NL in the residue trials on green beans (the storage temperature was not recorded), it was assumed that the samples were appropriately stored. All other supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (Spain, 2011, The Netherlands, 2011). It is concluded that the residue data are valid with regard to storage stability.

According to the EMS-ES and EMS-NL, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (The Netherlands, 2011; Spain, 2011).

EFSA concludes that the submitted supervised residue trials are sufficient to derive MRL proposals as follow: 0.3 mg/kg in beans with pods (NEU outdoor use only), 30 mg/kg in lamb's lettuce and 3 mg/kg in Chinese cabbage (indoor use only), cardoons, fennel and rhubarb. No MRL amendment is proposed for scarole and soya beans. The intended uses on strawberries, raspberries and witloof are not adequately supported by residue data and no MRL proposals are derived.

Table 3-1: Overview of the available residues 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 (sum of indoxacarb and its R-enantiomer)	Risk assessment (sum of indoxacarb and its R-enantiomer)					
Raspberries	SEU	Outdoor	0.1, 0.11, 0.15, 0.3	0.1, 0.11, 0.15, 0.3	0.13	0.3	-	1	Trials conducted outdoor are considered as not representative for the intended GAP use. Evidence should be provided that the outdoor use is producing comparable residues with the intended use (plastic tunnels).
		Indoor ^(g)	-	-	No data available to support a MRL proposal.				
Strawberries	SEU	Outdoor	0.08, 0.16, 2 x 0.19, 0.20, 0.21, 0.22, 0.27 ^(f)	0.08, 0.16, 2 x 0.19, 0.20, 0.21, 0.22, 0.27 ^(f)	0.19	0.27	-	1	
		Indoor ^(g)	-	-	No data available to support a MRL proposal.				
Green beans (with pods)	NEU	Outdoor	5 x <0.05; 0.07; 0.1; 0.16	5 x <0.05; 0.07; 0.1; 0.16	0.05	0.16	0.3	1	R _{ber} = 0.18 R _{max} = 0.20 MRL _{OECD} = 0.23/0.3
	SEU	Outdoor	4 x <0.05; 0.06	4 x <0.05; 0.06	0.05	0.06	-	1	Number of GAP compliant trials not sufficient to derive a MRL proposal.
	EU	Indoor	0.04; 0.06; 0.07; 0.09; 0.12; 0.13; 0.22; 0.24	0.04; 0.06; 0.07; 0.09; 0.12; 0.13; 0.22; 0.24	0.11	0.24	-	1	All trials were performed during August-October. Evidence should be provided that the tested period represents the worst case residue situation.
Soya bean	SEU	Outdoor	3 x <0.01; 0.01; 2 x 0.02; 0.04	3 x <0.01; 0.01; 2 x 0.02; 0.04	0.01	0.04	0.07	1	R _{ber} = 0.04 R _{max} = 0.05 MRL _{OECD} = 0.06/0.07

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 (sum of indoxacarb and its R-enantiomer)	Risk assessment (sum of indoxacarb and its R-enantiomer)					
Chinese cabbage	NEU	Outdoor	-	-	No data available to support a MRL proposal.				
	EU	Indoor	0.21; 0.34; 0.63; 1.54	0.21; 0.34; 0.63; 1.54	0.49	1.54	3	1	R _{ber} = 2.63 R _{max} = 3.76 MRL _{OECD} = 3.08/3
Witloof	SEU	Outdoor	<0.01	<0.01	Number of trials not sufficient to support a MRL proposal.				
Scarole	SEU	Outdoor	<0.01; 0.06; 0.11; 0.13	<0.01; 0.06; 0.11; 0.13	0.09	0.13	0.3	1	R _{ber} = 0.25 R _{max} = 0.35 MRL _{OECD} = 0.29/0.3
Lamb's lettuce	EU	Indoor ^(g)	2.5; 4.1; 7; 8.6; 9.4; 2 x 15	2.5; 4.1; 7; 8.6; 9.4; 2 x 15	8.6	15	30	1	R _{ber} = 30.0 R _{max} = 25.36 MRL _{OECD} = 28.28/30
Celery→ Cardoons, Fennel, Rhubarb	SEU	Outdoor	0.25; 0.95; 0.98; 1.53	0.25; 0.95; 0.98; 1.53	0.97	1.53	3	1	R _{ber} = 2.78 R _{max} = 3.62 MRL _{OECD} = 3.02/3

(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 residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): The highest values measured at a longer PHI of 5 days.

(g): High or low plastic tunnels for berries; plastic tunnels or plastic greenhouses for lamb's lettuce.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of indoxacarb and its R-enantiomer was assessed during the peer review and in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. The peer review concluded that the indoxacarb and its R-enantiomer are hydrolytically stable under conditions representative of pasteurisation (20 minutes at 90C, pH 4) and baking/boiling (60 minutes at 100C, pH 5) and for processed commodities that are not subject to sterilisation the same residue definition as for raw agricultural commodities (RAC) is applicable (The Netherlands, 2000, 2011, EFSA, 2011). No study simulating sterilisation (20 minutes at 120C, pH 6) was carried out and was considered required (EFSA, 2011). Since the crops under consideration may be subject to sterilisation, this data requirement is reiterated.

Specific studies to assess the magnitude of indoxacarb residues following processing were not submitted in the framework of the current MRL applications. A limited number of processing studies (*e.g.* with canned peaches) which could be considered as representative for processed commodities obtained from the fruits and vegetables under consideration were reported in the framework of the Article 12 review. However, the number of studies was not sufficient to derive reliable processing factors. Considering that the residue levels in raw agricultural commodities (RAC) exceeded the trigger value of 0.1 mg/kg in most of the crops and the total theoretical maximum daily intake (TMDI) amounts to more than 10 % of the ADI (EC, 1997d), it would be desirable to have additional processing studies.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except strawberries and raspberries¹¹ can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of indoxacarb is moderate; the maximum DT₉₀ from field studies is 88 days (EC, 2005), which is below the trigger value of 100 days. Thus, no further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (EC, 1997c).

A rotational crop study assessed during the peer review confirmed that the residue levels in rotational crops were low (The Netherlands, 2005). Based on the available information, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP (Good Agricultural Practice).

3.2. Nature and magnitude of residues in livestock

Soya bean and its by-product are normally fed to livestock. Since the notified GAP does not require an amendment of the existing MRL on soya beans, no further investigations on the nature and magnitude of residues in livestock are considered necessary.

¹¹ According to OECD studies on the residues in rotational crops are generally not required for semi-permanent crops as strawberries and raspberries (OECD, 2007).

4. Consumer risk assessment

In the framework of the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of indoxacarb at EU level and the existing CXLs supported by data. Those food commodities for which no uses of indoxacarb were reported in the framework of Article 12 of Regulation (EC) No 396/2005 were excluded from the exposure calculation assuming that there is no use on these crops (EFSA, 2011). The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population ¹² (EFSA, 2007).

EFSA now updates this risk assessment with the median residue values as derived from the supervised residue trials on beans with pods, Chinese cabbage, lamb's lettuce, celery extrapolated to cardoons, fennel and rhubarb (see Table 3-1). The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at the median residue levels identified in supervised trials. EFSA is of the opinion that if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to the commodities under consideration for which an amendment of the MRL is proposed assuming the consumption of a large portion of the food items as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of indoxacarb and its R-enantiomer				
Green beans with pods	0.05	Median residue (outdoor, NEU)	0.16	Highest residue (outdoor, NEU)
Chinese cabbage	0.49	Median residue	1.54	Highest residue
Lamb's lettuce	8.6	Median residue	15	Highest residue
Cardoons	0.97	Median residue	1.53	Highest residue
Fennel	0.97	Median residue	1.53	Highest residue
Rhubarb	0.97	Median residue	1.53	Highest residue

¹² The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Other commodities of plant and animal origin	See Appendix D		Acute risk assessment was undertaken only with regard to the crops for which an amendment of the MRL is proposed.	

The estimated exposure was then compared with the toxicological reference values derived for indoxacarb and its R-isomer (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for indoxacarb under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011). Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for 75 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The contribution of residues on the crops under consideration to the total consumer exposure was low, accounting with respect to the ADI for a maximum of 1.63 % on Chinese cabbage, 0.96 % on lamb's lettuce, 0.92 % on beans with pods, 0.17 % on cardoons, 1.57 % on fennel and 3.96 % on rhubarb.

No acute consumer risk was identified in relation to the MRL proposals. The calculated maximum exposure in percentage of the ARfD was less than 46 % for Chinese cabbage and rhubarb, 34 % for lamb's lettuce, 32 % for fennel, 13.2 % for cardoons and 1.5 % for beans with pods.

EFSA concludes that the proposed uses of indoxacarb on Chinese cabbage, lamb's lettuce, scarole, beans with pods, cardoons, fennel, rhubarb and soya beans will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of indoxacarb was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.006 mg/kg bw per day and an ARfD of 0.125 mg/kg bw.

The metabolism of indoxacarb in primary crops was investigated in three different crop groups following foliar application. The review of the existing MRLs for indoxacarb performed under Article 12 of Regulation (EC) No 396/2005 confirmed the conclusion of the peer review that the relevant residue for enforcement and risk assessment in all plant commodities treated by foliar application is indoxacarb (S-enantiomer) and its R-enantiomer. EFSA proposed to reword the residue definition as “sum of indoxacarb and its R-enantiomer”. For the uses on crops under consideration EFSA concludes that the metabolism of indoxacarb in primary crops is sufficiently addressed and that the residue definitions as proposed during the MRL review are applicable.

EFSA considers that the submitted supervised residue trials are sufficient to derive MRL proposals for the crops under consideration, except for strawberries, raspberries and witloof. The submitted residue data indicate no need to modify the existing EU MRLs for scarole and soya beans. Adequate analytical enforcement methods are available to control the residues of indoxacarb and its R-isomer on the commodities for which a MRL is proposed at the validated LOQ of 0.02 mg/kg.

The peer review concluded that the indoxacarb and its R-enantiomer are hydrolytically stable under conditions representative of pasteurisation and baking/boiling and for processed commodities that are not subject to sterilisation the same residue definition as for raw agricultural commodities (RAC) is applicable. The nature of residues under conditions simulating sterilisation was not investigated and is considered required. Considering that the residue levels in raw agricultural commodities (RAC) exceeded the trigger value of 0.1 mg/kg in most of the crops and the total theoretical maximum daily intake (TMDI) amounts to more than 10 % of the ADI, it would be desirable to have additional processing studies.

Based on the available information on the occurrence of indoxacarb residues in rotational crops, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on the crops under consideration according to the proposed GAP (Good Agricultural Practice).

Since no amendment of the existing MRL on soya bean (the only product which is also used as feed item) is proposed, no further investigations on the nature and magnitude of residues in livestock are necessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of indoxacarb at EU level and the existing acceptable CXLs supported by data. EFSA now updates this risk assessment with the median residue value as derived from the supervised residue trials on beans with pods, Chinese cabbage, lamb's lettuce, celery (extrapolated to cardoons, fennel and rhubarb). The acute exposure assessment was performed only with regard to the commodities for which a change of the existing MRL is proposed. The estimated exposure was then compared with the derived toxicological reference values.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for indoxacarb under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for 75 % of the ADI (DE child diet). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. No acute consumer risk was identified in relation to the MRL proposals.

EFSA concludes that the proposed uses of indoxacarb on Chinese cabbage, lamb's lettuce, scarole, beans with pods, cardoons, fennel, rhubarb and soya beans will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a consumer health risk.

RECOMMENDATIONS

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: sum of indoxacarb and its R-enantiomer^(b) (F)				
0152000	Strawberries	0.02*	No new proposal	The submitted outdoor data are not appropriate to derive MRL proposals for the intended uses under protected conditions. Evidence should be provided that the outdoor residue trials are representative for the intended uses (plastic tunnel).
0153030	Raspberries	0.5	No new proposal	
243010	Chinese cabbage	0.2	3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended indoor use. No residue data are available for the intended outdoor use in NEU.
251010	Lamb's lettuce	1	30	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended indoor use.
251030	Scarole	2/1 ^(c)	No change	The submitted data support the intended use in SEU and demonstrate that it is not necessary to amend the MRL of 1 mg/kg recommended under the Article 12 review.
0255000	Witloof	0.02*	No new proposal	The submitted residue data are not sufficient to derive a MRL proposal.
260010	Beans (with pods) (Green bean)	0.02*	0.3	The MRL proposal is sufficiently supported by data and no risk for consumers was identified for the intended outdoor use in NEU. The submitted residue data do not support a MRL proposal for the intended indoor use and the outdoor use in SEU.
270020	Cardoons	0.02*	3	The MRL proposals are sufficiently supported by data and no risk for consumers was identified for the intended uses. The MRLs are derived by extrapolation from celery.
270040	Fennel	0.02*	3	
270070	Rhubarb	0.02*	3	
401070	Soya bean	0.5	No change	The existing MRL covers the intended use and does not need to be amended.

(a): According to Annex I of Regulation (EC) No 396/2005.

(b): As proposed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011).

(c): A lower MRL of 1 mg/kg is proposed for scarole in the framework of the MRL review (EFSA, 2011).

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

(F): Fat-soluble pesticide.

REFERENCES

- CEN (European Committee for Standardisation), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662.2008. November 2008.
- EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.
- EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2005. Review report for the active substance indoxacarb. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 23 September 2005 in view of the inclusion of indoxacarb in Annex I of Council Directive 91/414/EEC. SANCO/1408/2001 – rev.3, 23 September 2005, 49 pp.
- EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu/efsajournal
- EFSA (European Food Safety Authority), 2009a. Reasoned opinion on the modification of the existing MRL(s) for indoxacarb in Brussels sprouts. *EFSA Scientific Report* (2009) 225, 1-27.
- EFSA (European Food Safety Authority), 2009b. Reasoned opinion on the modification of the existing MRL(s) for indoxacarb in raspberries and blackberries. *EFSA Scientific Report* (2009) 246, 1-23.
- EFSA (European Food Safety Authority), 2009c. Reasoned opinion on the modification of the existing MRL(s) for indoxacarb in certain small fruits and berries. *EFSA Scientific Report* (2009) 275, 1-26.

- EFSA (European Food Safety Authority), 2009d. Reasoned opinion on the modification of the existing MRL(s) for indoxacarb in cherries and sugar beets. *EFSA Scientific Report* (2009) 324, 1-30.
- EFSA (European Food Safety Authority), 2010. Scientific and technical support for preparing an EU position in the 42nd Session of the Codex Committee on Pesticide Residues (CCPR). *EFSA Journal* (2010); 8(11):1560, 1-51.
- EFSA (European Food Safety Authority), 2011. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for indoxacarb according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2011;9(8):2343. [83 pp.]
- FAO (Food and Agriculture Organization of the United Nations), 2005. Indoxacarb. In: Pesticide residues in food – 2005. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 183, 142-176.
- FAO (Food and Agriculture Organization of the United Nations), 2009. Indoxacarb. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 196, 209-216.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany. Available from: http://www.jki.bund.de/fileadmin/dam_uploads/veroeff/bbch/BBCH-Skala_englisch
- OECD (Organization for Economic Co-operation and Development), 2007. Test No 504: Residues in rotational crops (limited field studies). In: Pesticide Publications/Publications on Pesticide Residues/Guidance documents. Guidelines for the Testing of Chemicals, Section 5: Other Test Guidelines. 8 January 2007. Available from: <http://www.oecd.org/env/pesticides>
- OECD (Organization for Economic Co-operation and Development), 2008. Test No 508: Magnitude of pesticide residues in processed commodities. In: Pesticide Publications/Publications on Pesticide Residues/Guidance documents. Guidelines for the Testing of Chemicals, Section 5: Other Test Guidelines. 3 October 2008. Available from: <http://www.oecd.org/env/pesticides>
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: <http://www.oecd.org/env/pesticides>
- Spain, 2011. Evaluation report on the setting of MRLs for indoxacarb in raspberries and strawberries prepared by the evaluating Member State Spain under Article 8 of Regulation (EC) No 396/2005, November 2011, 38 pp.
- The Netherlands, 2000. Draft assessment report on the active substance indoxacarb prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, January 2000.
- The Netherlands, 2001. Addendum to the draft assessment report on the active substance indoxacarb prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, February 2001.
- The Netherlands, 2005. Addendum to the draft assessment report on the active substance indoxacarb prepared by the rapporteur Member State The Netherlands in the framework of Council Directive 91/414/EEC, January 2005.
- The Netherlands, 2011. Evaluation report on the setting/modification of MRLs for indoxacarb in green beans, Chinese cabbage, scarole, lamb's lettuce, witloof (Chicory). Soya bean, fennel, rhubarb and cardoons prepared by the evaluating Member State The Netherlands under Article 8 of Regulation (EC) No 396/2005, 19 December 2011, 61 pp.

APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Raspberries	ES	P ⁽¹⁾	<i>H. armigera</i> , <i>S. exigua</i> , <i>S. littoralis</i>	WG	300 g/kg indoxacarb	High pressure mist blower	When pests are present	1-2	10 d	-	600-1000	0.0375	3	Product: DPX-MP062 30 WG
Strawberries	ES	P ⁽¹⁾	<i>H. armigera</i> , <i>S. exigua</i> , <i>S. littoralis</i> , <i>Chalcites</i> spp., <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	High pressure mist blower	When pests are present	1-2	10 d	-	600-1000	0.0375	3	Product: DPX-MP062 30 WG
Green bean (with pods)	NEU	F	<i>H. armigera</i> , <i>S. exigua</i> , <i>C. chalcites</i> , <i>M. brassicae</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, high pressure mist blower	When pests are present	1-4	10-14 d	-	200-1000	0.0375	3	Product: DPX-MP062 30 WG
	SEU	F	<i>H. armigera</i> , <i>S. exigua</i> , <i>C. chalcites</i> , <i>M. brassicae</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, high pressure mist blower	When pests are present	1-4	10-14 d	-	200-1000	0.0375	3	Product: DPX-MP062 30 WG
	EU	G ⁽²⁾	<i>H. armigera</i> , <i>S. exigua</i> , <i>C. chalcites</i> , <i>M. brassicae</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, high pressure mist blower	When pests are present	1-4	10-14 d	-	200-1000	0.0375	3	

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
	NL	G	<i>H. armigera</i> , <i>S. exigua</i> , <i>C. chalcites</i> , <i>M. brassicae</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, high pressure mist blower	When pests are present	1-4	10-14 d	-	200-1500	0.0375 -0.057	1	Dose rate is 25.5 g a.s./ha per 1 m of plant height. Minimum rate for crops below 1.5 m is 37.5 g a.s./ha. Product: DPX- MP062 30 WG
Chinese cabbage (Pak choi)	NEU	F	<i>Pieris</i> spp., <i>M. brassicae</i> , <i>C. chalcites</i> , <i>S. exigua</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>P. xylostella</i> , <i>E. forficalis</i> , <i>C. spectrana</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, sprayer	When pests are present	1-3	8-14 d	-	200-1000	0.0255	1	Max. 3 appl./ crop, max. 6 appl./year. Product: DPX- MP062 30 WG
Chinese cabbage	(N)EU	G	<i>Pieris</i> spp., <i>M. brassicae</i> , <i>C. chalcites</i> , <i>S. exigua</i> , <i>L. oleracea</i> , <i>A. gamma</i> , <i>P. xylostella</i> , <i>E. forficalis</i> , <i>C. spectrana</i> , <i>Plusia</i> spp.	WG	300 g/kg indoxacarb	Broadcast, sprayer	When pests are present	1-3	8-14 d	-	200-1000	0.0255	1	Max. 3 appl./ crop, max. 6 appl./year. Product: DPX- MP062 30 WG
Soya bean	SEU	F	<i>S. exigua</i> , <i>H. armigera</i>	WG	300 g/kg indoxacarb	High pressure mist blower	When pests are present typically BBCH 51-79	1-2	10-14 d	-	300-700	0.0375	14	Product: DPX- MP062 30 WG
Scarole (Radicchio)	SEU	F	<i>S. exigua</i> , <i>H. armigera</i>	WG	300 g/kg indoxacarb	Hydraulic ground directed boom	When pests are present	3-6	7-10 d	-	300-700	0.0375i	1	Product: DPX- MP062 30 WG

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Lamb's lettuce	S(EU)	P ⁽¹⁾	<i>S. exigua</i> , <i>H. armigera</i>	WG	300 g/kg indoxacarb	Hydraulic ground directed boom	When pests are present	3-6	7-10 d	-	300-700	0.0375	1	Product: DPX-MP062 30 WG
Witloof	SEU	F	<i>S. exigua</i> , <i>H. armigera</i>	WG	300 g/kg indoxacarb	Hydraulic ground directed boom	When pests are present	3-6	7-10 d	-	300-700	0.0375	1	Product: DPX-MP062 30 WG
Cardoons, Fennel, Rhubarb	South zone, except FR	F	<i>S. exigua</i>	WG	300 g/kg indoxacarb	Hydraulic ground directed boom	When pests are present	1-3	7 d	-	300-700	0.0375	1	Product: DPX-MP062 30 WG

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (1) Protected conditions (P). High or low plastic tunnel for berries and plastic tunnels or plastic greenhouse for lamb's lettuce.
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)
 - (2) The GAP highlighted in grey colour is less critical and was not assessed in the framework of this reasoned opinion.

NOTE

Product DPX-MP062 30 WG refers to a 75:25 mixture of S- and R-enantiomers.

In the table the dose rate is expressed in terms of the active substance indoxacarb (S-enantiomer).

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Indoxacarb									
Status of the active substance:		Included		Code no.					
LOQ (mg/kg bw):				proposed LOQ:					
Toxicological end points									
ADI (mg/kg bw/day):		0.006		ARfD (mg/kg bw):		0.125			
Source of ADI:		EC		Source of ARfD:		EC			
Year of evaluation:		2005		Year of evaluation:		2005			
Chronic risk assessment - refined calculations									
				TMDI (range) in % of ADI minimum - maximum					
				6 --- 75					
				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)	
75.0	DE child	42.2	Apples	8.8	Milk and milk products: Cattle	6.8	Table grapes		
63.1	NL child	22.2	Apples	18.1	Milk and milk products: Cattle	4.8	Spinach		
39.8	WHO Cluster diet B	9.6	Wine grapes	5.4	Tomatoes	3.5	Apples		
36.8	FR infant	15.9	Milk and milk products: Cattle	8.8	Apples	5.8	Spinach		
34.3	IE adult	6.7	Wine grapes	4.0	Rhubarb	2.9	Apples		
31.7	FR all population	21.3	Wine grapes	1.7	Apples	1.7	Milk and milk products: Cattle		
28.6	FR toddler	9.2	Spinach	9.2	Apples	1.4	Tomatoes		
25.5	ES child	7.7	Milk and milk products: Cattle	4.0	Apples	3.6	Lettuce		
25.2	WHO cluster diet E	8.6	Wine grapes	3.0	Apples	1.8	Milk and milk products: Cattle		
24.2	PT General population	13.3	Wine grapes	3.7	Apples	1.6	Tomatoes		
23.8	UK Toddler	9.9	Sugar beet (root)	6.0	Apples	1.3	Table grapes		
21.9	SE general population 90th percentile	7.6	Milk and milk products: Cattle	3.7	Apples	1.6	Chinese cabbage		
21.8	NL general	4.1	Apples	4.0	Milk and milk products: Cattle	3.4	Wine grapes		
21.5	WHO regional European diet	3.3	Lettuce	2.9	Milk and milk products: Cattle	2.3	Apples		
20.3	ES adult	4.6	Lettuce	3.0	Milk and milk products: Cattle	2.7	Apples		
19.3	WHO cluster diet D	2.9	Milk and milk products: Cattle	2.3	Apples	1.9	Wine grapes		
18.3	DK child	8.1	Apples	2.4	Pears	1.6	Cucumbers		
17.1	WHO Cluster diet F	3.2	Wine grapes	2.6	Lettuce	2.4	Milk and milk products: Cattle		
16.4	IT adult	3.3	Lettuce	2.8	Apples	2.0	Tomatoes		
16.1	UK Infant	5.5	Apples	4.4	Sugar beet (root)	1.1	Bananas		
15.7	IT kids/toddler	3.1	Apples	2.5	Lettuce	2.5	Tomatoes		
14.1	LT adult	6.5	Apples	2.4	Milk and milk products: Cattle	1.1	Tomatoes		
14.1	DK adult	7.4	Wine grapes	2.7	Apples	0.7	Tomatoes		
14.1	UK vegetarian	4.3	Wine grapes	2.1	Apples	1.6	Sugar beet (root)		
14.0	PL general population	7.2	Apples	1.7	Table grapes	1.5	Tomatoes		
13.1	UK Adult	5.8	Wine grapes	1.7	Sugar beet (root)	1.4	Apples		
6.2	FI adult	1.6	Wine grapes	1.4	Apples	0.7	Tomatoes		
Conclusion:									
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Indoxacarb is unlikely to present a public health concern.									

Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations						
The acute risk assessment is based on the ARfD.												
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.												
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.												
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.												
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.												
Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1		*)	**)	IESTI 2		*)	**)	IESTI 1		*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	45.7	Chinese cabbage	1.54 / -	45.7	Chinese cabbage	1.54 / -	44.0	Chinese cabbage	1.54 / -	44.0	Chinese cabbage	1.54 / -
	45.5	Rhubarb	1.53 / -	33.7	Lamb's lettuce	15 / -	32.0	Fennel	1.53 / -	23.3	Fennel	1.53 / -
	33.7	Lamb's lettuce	15 / -	32.7	Rhubarb	1.53 / -	22.6	Lamb's lettuce	15 / -	22.6	Lamb's lettuce	15 / -
	24.9	Fennel	1.53 / -	24.9	Fennel	1.53 / -	13.2	Cardoons	1.53 / -	9.7	Cardoons	1.53 / -
	1.5	Beans (with pods)	0.16 / -	1.5	Beans (with pods)	0.16 / -	12.0	Rhubarb	1.53 / -	9.6	Rhubarb	1.53 / -
							0.7	Beans (with pods)	0.16 / -	0.7	Beans (with pods)	0.16 / -
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	***) pTMRL/ threshold MRL (mg/kg)
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.												
**) pTMRL: provisional temporary MRL												
***) pTMRL: provisional temporary MRL for unprocessed commodity												
Conclusion:												
For Indoxacarb IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.												
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.												
For processed commodities, no exceedance of the ARfD/ADI was identified.												

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 18/06/2012 16:56))

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(d)
100000	1. FRUIT FRESH OR FROZEN; NUTS		
110000	(j) Citrus fruit	0,02*	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*	0,02*
110030	Lemons (Citron, lemon)	0,02*	0,02*
110040	Limes	0,02*	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*	0,02*
110990	Others	0,02*	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*	0,02*
120010	Almonds	0,05*	0,02*
120020	Brazil nuts	0,05*	0,02*
120030	Cashew nuts	0,05*	0,02*
120040	Chestnuts	0,05*	0,02*
120050	Coconuts	0,05*	0,02*
120060	Hazelnuts (Filbert)	0,05*	0,02*
120070	Macadamia	0,05*	0,02*
120080	Pecans	0,05*	0,02*
120090	Pine nuts	0,05*	0,02*
120100	Pistachios	0,05*	0,02*
120110	Walnuts	0,05*	0,02*
120990	Others	0,05*	0,02*
130000	(iii) Pome fruit		
130010	Apples (Crab apple)	0,5	0,5
130020	Pears (Oriental pear)	0,3	0,5
130030	Quinces	0,3	0,02*
130040	Medlar	0,3	0,02*
130050	Loquat	0,3	0,02*
130990	Others	0,3	0,02*
140000	(iv) Stone fruit	1	1
140010	Apricots	1	1
140020	Cherries (sweet cherries, sour cherries)	1	1
140030	Peaches (Nectarines and similar hybrids)	1	1
140040	Plums (Damson, greengage, mirabelle)	1	1
140990	Others	1	1

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(d)
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	2	2
151010	Table grapes	2	2
151020	Wine grapes	2	2
152000	(b) Strawberries	0,02*	0,02*
153000	(c) Cane fruit		
153010	Blackberries	0,5	0,5
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*	0,02*
153030	Raspberries (Wineberries)	0,5	0,5
153990	Others	0,02*	0,02*
154000	(d) Other small fruit & berries	1	
154010	Blueberries (Bilberries cowberries (red bilberries))	1	0,8
154020	Cranberries	1	1
154030	Cumants (red, black and white)	1	0,8
154040	Gooseberries (Including hybrids with other ribes species)	1	0,8
154050	Rose hips	1	0,8
154060	Mulberries (arbutus berry)	1	0,8
154070	Azarole (mediterranean medlar)	1	0,8
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	1	0,8
154990	Others	1	0,8
160000	(vi) Miscellaneous fruit		
161000	(a) Edible peel	0,02*	0,02*
161010	Dates	0,02*	0,02*
161020	Figs	0,02*	0,02*
161030	Table olives	0,02*	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*	0,02*
161050	Carambola (Bilimbi)	0,02*	0,02*
161060	Persimmon	0,02*	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomeac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*	0,02*
161990	Others	0,02*	0,02*
162000	(b) Inedible peel, small	0,02*	0,02*
162010	Kiwi	0,02*	0,02*
162020	Lychee (Litchi) (Pulasan,	0,02*	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(d)
	rambutan (hairy litchi))		
162030	Passion fruit	0,02*	0,02*
162040	Prickly pear (cactus fruit)	0,02*	0,02*
162050	Star apple	0,02*	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*	0,02*
162990	Others	0,02*	0,02*
163000	(c) Inedible peel, large		
163010	Avocados	0,02*	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,2	0,2
163030	Mangoes	0,02*	0,02*
163040	Papaya	0,02*	0,02*
163050	Pomegranate	0,02*	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*	0,02*
163070	Guava	0,02*	0,02*
163080	Pineapples	0,02*	0,02*
163090	Bread fruit (Jackfruit)	0,02*	0,02*
163100	Durian	0,02*	0,02*
163110	Soursop (guanabana)	0,02*	0,02*
163990	Others	0,02*	0,02*
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables		
211000	(a) Potatoes	0,02*	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*	0,02*
212020	Sweet potatoes	0,02*	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*	0,02*
212040	Arrowroot	0,02*	0,02*
212990	Others	0,02*	0,02*
213000	(c) Other root and tuber vegetables except sugar beet		
213010	Beetroot	0,02*	0,02*
213020	Carrots	0,02*	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
213030	Celeriac	0,02*	0.02*
213040	Horseradish	0,02*	0.02*
213050	Jerusalem artichokes	0,02*	0.02*
213060	Parsnips	0,02*	0.02*
213070	Parsley root	0,02*	0.02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2	0.3
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,02*	0.02*
213100	Swedes	0,02*	0.02*
213110	Turnips	0,02*	0.02*
213990	Others	0,02*	0.02*
220000	(ii) Bulb vegetables	0,02*	0.02*
220010	Garlic	0,02*	0.02*
220020	Onions (Silverskin onions)	0,02*	0.02*
220030	Shallots	0,02*	0.02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*	0.02*
220990	Others	0,02*	0.02*
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes,)	0,5	0.5
231020	Peppers (Chilli peppers)	0,3	0.3
231030	Aubergines (egg plants) (Pepino)	0,5	0.5
231040	Okra, lady's fingers	0,02*	0.02*
231990	Others	0,02*	0.02*
232000	(b) Cucurbits - edible peel	0,5	0.5
232010	Cucumbers	0,5	0.5
232020	Gherkins	0,5	0.5
232030	Courgettes (Summer squash, marrow (patisson))	0,5	0.5
232990	Others	0,5	0.5
233000	(c) Cucurbits-inedible peel	0,5	0.5
233010	Melons (Kiwano)	0,5	0.5
233020	Pumpkins (Winter squash)	0,5	0.5
233030	Watermelons	0,5	0.5
233990	Others	0,5	0.5
234000	(d) Sweet corn	0,02*	0.02*
239000	(e) Other fruiting vegetables	0,02*	0.02*
240000	(iv) Brassica vegetables		
241000	(a) Flowering brassica	0,3	0.3
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,3	0.3
241020	Cauliflower	0,3	0.3
241990	Others	0,3	0.3
242000	(b) Head brassica		
242010	Brussels sprouts	0,1	0.06
242020	Head cabbage (Pointed head)	3	0.2

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
	cabbage, red cabbage, savoy cabbage, white cabbage)		
242990	Others	0,02*	0.02*
243000	(c) Leafy brassica		0.4
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,2	0.4
243020	Kale (Borecole (curly kale), collards)	0,2	0.4
243990	Others	0,02*	0.4
244000	(d) Kohlrabi	0,02*	0.02*
250000	(v) Leaf vegetables & fresh herbs		
251000	(a) Lettuce and other salad plants including Brassicaceae		
251010	Lamb's lettuce (Italian comsalad)	1	2
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	2	1
251040	Cress	0,02*	0.02*
251050	Land cress	0,02*	0.02*
251060	Rocket, Rucola (Wild rocket)	0,02*	2
251070	Red mustard	0,02*	0.02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	1	2
251990	Others	0,02*	0.02*
252000	(b) Spinach & similar (leaves)		
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	2	2
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*	0.02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*	0.02*
252990	Others	0,02*	0.02*
253000	(c) Vine leaves (grape leaves)	2	0.02*
254000	(d) Water cress	0,02*	0.02*
255000	(e) Witloof	0,02*	0.02*
256000	(f) Herbs		
256010	Chervil	2	2
256020	Chives	2	2
256030	Celery leaves (fennel leaves ,	2	2

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
	Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)		
256040	Parsley	2	2
256050	Sage (Winter savory, summer savory,)	2	2
256060	Rosemary	2	2
256070	Thyme (marjoram, oregano)	2	2
256080	Basil (Balm leaves, mint, peppermint)	15	15
256090	Bay leaves (laurel)	2	2
256100	Tarragon (Hyssop)	2	2
256990	Others	2	2
260000	(vi) Legume vegetables (fresh)	0,02*	0.02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*	0.02*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,02*	0.02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*	0.02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*	0.02*
260050	Lentils	0,02*	0.02*
260990	Others	0,02*	0.02*
270000	(vii) Stem vegetables (fresh)		
270010	Asparagus	0,02*	0.02*
270020	Cardoons	0,02*	0.02*
270030	Celery	2	2
270040	Fennel	0,02*	0.02*
270050	Globe artichokes	0,1	0.2
270060	Leek	0,02*	0.02*
270070	Rhubarb	0,02*	0.02*
270080	Bamboo shoots	0,02*	0.02*
270090	Palm hearts	0,02*	0.02*
270990	Others	0,02*	0.02*
280000	(viii) Fungi	0,02*	0.02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*	0.02*
280020	Wild (Chanterelle, Truffle, Morel,)	0,02*	0.02*
280990	Others	0,02*	0.02*
290000	(ix) Sea weeds	0,02*	0.02*
300000	3. PULSES, DRY		
300010	Beans (Broad beans, navy beans,	0,1	0.2

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
	flageoletts, jack beans, lima beans, field beans, cowpeas)		
300020	Lentils	0,02*	0.01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*	0.01*
300040	Lupins	0,02*	0.01*
300990	Others	0,02*	0.01*
400000	4. OILSEEDS AND OILFRUITS		
401000	(i) Oilseeds		
401010	Linseed	0,05*	0.02*
401020	Peanuts	0,05*	0.02*
401030	Poppy seed	0,05*	0.02*
401040	Sesame seed	0,05*	0.02*
401050	Sunflower seed	0,05*	0.02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*	0.04
401070	Soya bean	0,5	0,5
401080	Mustard seed	0,05*	0.02*
401090	Cotton seed	0,05*	1
401100	Pumpkin seeds	0,05*	0.02*
401110	Safflower	0,05*	0.02*
401120	Borage	0,05*	0.02*
401130	Gold of pleasure	0,05*	0.02*
401140	Hempseed	0,05*	0.02*
401150	Castor bean	0,05*	0.02*
401990	Others	0,05*	0.02*
402000	(ii) Oilfruits	0,02*	0,02*
402010	Olives for oil production	0,02*	0,02*
402020	Palm nuts (palmoil kernels)	0,02*	0,02*
402030	Palmfruit	0,02*	0,02*
402040	Kapok	0,02*	0,02*
402990	Others	0,02*	0,02*
500000	5. CEREALS	0,02*	0.01*
500010	Barley	0,02*	0.01*
500020	Buckwheat	0,02*	0.01*
500030	Maize	0,02*	0.01*
500040	Millet (Foxtail millet, teff)	0,02*	0.01*
500050	Oats	0,02*	0.01*
500060	Rice	0,02*	0.01*
500070	Rye	0,02*	0.01*
500080	Sorghum	0,02*	0.01*
500090	Wheat (Spelt/Triticale)	0,02*	0.01*
500990	Others	0,02*	0.01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA		0.01*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
620000	(ii) Coffee beans	0,05*	0.01*
630000	(iii) Herbal infusions (dried)	10	0.01*
631000	(a) Flowers	10	0.01*
631010	Camomille flowers	10	0.01*
631020	Hybiscus flowers	10	0.01*
631030	Rose petals	10	0.01*
631040	Jasmine flowers	10	0.01*
631050	Lime (linden)	10	0.01*
631990	Others	10	0.01*
632000	(b) Leaves	10	0.01*
632010	Strawberry leaves	10	0.01*
632020	Rooibos leaves	10	0.01*
632030	Maté	10	0.01*
632990	Others	10	0.01*
633000	(c) Roots	10	0.01*
633010	Valerian root	10	0.01*
633020	Ginseng root	10	0.01*
633990	Others	10	0.01*
639000	(d) Other herbal infusions	10	0.01*
640000	(iv) Cocoa (fermented beans)	0,05*	0.01*
650000	(v) Carob (st johns bread)	0,05*	0.01*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*	0.01*
800000	8. SPICES	0,05*	0.01*
810000	(i) Seeds	0,05*	0.01*
810010	Anise	0,05*	0.01*
810020	Black caraway	0,05*	0.01*
810030	Celery seed (Lovage seed)	0,05*	0.01*
810040	Coriander seed	0,05*	0.01*
810050	Cumin seed	0,05*	0.01*
810060	Dill seed	0,05*	0.01*
810070	Fennel seed	0,05*	0.01*
810080	Fenugreek	0,05*	0.01*
810090	Nutmeg	0,05*	0.01*
810990	Others	0,05*	0.01*
820000	(ii) Fruits and berries	0,05*	0.01*
820010	Allspice	0,05*	0.01*
820020	Anise pepper (Japan pepper)	0,05*	0.01*
820030	Caraway	0,05*	0.01*
820040	Cardamom	0,05*	0.01*
820050	Juniper berries	0,05*	0.01*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*	0.01*
820070	Vanilla pods	0,05*	0.01*
820080	Tamarind	0,05*	0.01*
820990	Others	0,05*	0.01*
830000	(iii) Bark	0,05*	0.01*
830010	Cinnamon (Cassia)	0,05*	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ^(a)
830990	Others	0,05*	0.01*
840000	(iv) Roots or rhizome	0,05*	0.01*
840010	Liquorice	0,05*	0.01*
840020	Ginger	0,05*	0.01*
840030	Turmeric (Curcuma)	0,05*	0.01*
840040	Horseradish	0,05*	0.01*
840990	Others	0,05*	0.01*
850000	(v) Buds	0,05*	0.01*
850010	Cloves	0,05*	0.01*
850020	Capers	0,05*	0.01*
850990	Others	0,05*	0.01*
860000	(vi) Flower stigma	0,05*	0.01*
860010	Saffron	0,05*	0.01*
860990	Others	0,05*	0.01*
870000	(vii) Aril	0,05*	0.01*
870010	Mace	0,05*	0.01*
870990	Others	0,05*	0.01*
900000	9. SUGAR PLANTS		
900010	Sugar beet (root)	0,1	0,1
900020	Sugar cane	0,02*	0,02*
900030	Chicory roots	0,02*	0,02*
900990	Others	0,02*	0,02*
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	2	2
1011020	Fat free of lean meat	2	2
1011030	Liver	0,05	0,05
1011040	Kidney	0,05	0,05
1011050	Edible offal	0,05	0.01*
1011990	Others	0,01*	0,01*
1012000	(b) Bovine		
1012010	Meat	2	2
1012020	Fat	2	2
1012030	Liver	0,05	0,05
1012040	Kidney	0,05	0,05
1012050	Edible offal	0,05	0.01*
1012990	Others	0,01*	0,01*
1013000	(c) Sheep		
1013010	Meat	2	2
1013020	Fat	2	2

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ⁽⁴⁾
1013030	Liver	0,05	0,05
1013040	Kidney	0,05	0,05
1013050	Edible offal	0,05	0.01*
1013990	Others	0,01*	0,01*
1014000	(d) Goat		
1014010	Meat	2	2
1014020	Fat	2	2
1014030	Liver	0,05	0,05
1014040	Kidney	0,05	0,05
1014050	Edible offal	0,05	0.01*
1014990	Others	0,01*	0,01*
1015000	(e) Horses, asses, mules or hinnies		
1015010	Meat	2	2
1015020	Fat	2	2
1015030	Liver	0,05	0,05
1015040	Kidney	0,05	0,05
1015050	Edible offal	0,05	0.01*
1015990	Others	0,01*	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon		0.01*
1016010	Meat	0,3	0.01*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ⁽⁴⁾
1016020	Fat	0,3	0.01*
1016030	Liver	0,01*	0,01*
1016040	Kidney	0,01*	0,01*
1016050	Edible offal	0,01*	0,01*
1016990	Others	0,01*	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)		
1017010	Meat	2	2
1017020	Fat	2	2
1017030	Liver	0,05	0,05
1017040	Kidney	0,05	0,05
1017050	Edible offal	0,05	0.01*
1017990	Others	0,01*	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	0,1	0,1
1020010	Cattle	0,1	0,1
1020020	Sheep	0,1	0,1
1020030	Goat	0,1	0,1
1020040	Horse	0,1	0,1

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R (F)	Sum of indoxacarb and its R-enantiomer (F) ⁽⁴⁾
1020990	Others	0,1	0,1
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	0,02	0.01*
1030010	Chicken	0,02	0.01*
1030020	Duck	0,02	0.01*
1030030	Goose	0,02	0.01*
1030040	Quail	0,02	0.01*
1030990	Others	0,02	0.01*
1040000	(iv) Honey (Royal jelly, pollen)	0,02	0.01*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,02	0.01*
1060000	(vi) Snails	0,02	0.01*
1070000	(vii) Other terrestrial animal products	0,02	0.01*

(*) Indicates lower limit of analytical determination.
(F) = Fat soluble

⁽⁴⁾ The enforcement residue definition and the MRL value as proposed by EFSA in its reasoned opinion on the review of the existing maximum residue levels for indoxacarb (EFSA, 2011) and not yet voted by the SCFCAH. For details on the derived MRLs see the table footnotes of the reasoned opinion.

D. LIST OF AVAILABLE MEDIAN RESIDUE VALUES FOR CHRONIC RISK ASSESSMENT

Existing uses and intended use assessed under Article 12 (EFSA, 2011)

Commodity	Input value (mg/kg)	Comments
Apples	0.21	Median residue
Pears	0.21	Median residue
Apricots	0.17	STMR
Cherries	0.17	STMR
Peaches	0.17	STMR
Table grapes	0.32	Median residue
Wine grapes	0.32	Median residue
Blackberries	0.26	Median residue
Raspberries	0.26	Median residue
Blueberries	0.11	Median residue
Cranberries	0.15	STMR
Currants	0.11	Median residue
Gooseberries	0.11	Median residue
Rose hips	0.11	Median residue
Mulberries	0.11	Median residue
Azarole	0.11	Median residue
Elderberries	0.11	Median residue
Bananas	0.04	Median residue
Potatoes	0.01	STMR
Radishes	0.02	Median residue

Commodity	Input value (mg/kg)	Comments
Tomatoes	0.11	STMR
Peppers	0.06	Median residue
Aubergines	0.11	STMR
Cucumbers, edible peel	0.06	STMR
Cucumbers, inedible peel	0.06	STMR
Sweet corn	0.01	Median residue
Broccoli	0.08	Median residue (tentative)
Cauliflower	0.08	Median residue (tentative)
Brussels sprouts	0.02	Median residue
Head cabbage	0.02	Median residue (fall-back MRL)
Kale	0.05	Median residue
Lettuce	0.52	Median residue (fall-back MRL)
Scarole	0.27	Median residue
Rocket, Rucola	0.52	Median residue (tentative)

Commodity	Input value (mg/kg)	Comments
Leaves and sprouts of Brassica spp	0.52	Median residue (tentative)
Spinach	0.78	Median residue
Chervil	0.52	Median residue
Chives	0.38	Median residue
Celery leaves	0.52	Median residue
Parsley	0.52	Median residue
Sage	0.378	Median residue
Rosemary	0.38	Median residue
Thyme	0.38	Median residue
Basil	3.5	STMR
Bay leaves	0.38	Median residue
Tarragon	0.38	Median residue
Celery	0.85 ^(a)	Median residue
Globe artichokes	0.04	Median residue
Beans (dry)	0.02	STMR
Peanuts	0.01	STMR
Rape seed	0.01	Median residue
Soya bean	0.03	Median residue

Commodity	Input value (mg/kg)	Comments
Cotton seed	0.36	STMR
Maize grain	0.01	Median residue
Sugarbeet (root)	0.03	Median residue
Maize forage	0.130	
Swine meat	0.01	STMR
Swine fat	0.38	STMR
Swine liver and kidneys	0.01	STMR
Ruminant meat	0.01	STMR
Ruminant fat	0.38	STMR
Ruminant liver, kidneys	0.01	STMR
Milk	0.04	STMR
Poultry meat ^(b)	0.06	Median residue*CF (tentative)
Poultry fat ^(b)	0.06	Median residue*CF (tentative)
Poultry liver ^(b)	0.02	Median residue*CF (tentative)
Birds' Eggs ^(b)	0.02	Median residue*CF (tentative)

(a): The median residue value of 0.85 mg/kg derived from the residue trials on celery based on a PHI of 3 days and assessed under Article 12 review (EFSA, 2011).

(b): Proposed risk assessment residue definition: sum of indoxacarb, its R enantiomer and IN-JT333, expressed as indoxacarb (EFSA, 2011).

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i>)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
cGAP	critical GAP
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
DT ₉₀	period required for 90 % dissipation (define method of estimation)
EC	European Community
ECD	electron capture detector
EFSA	European Food Safety Authority
<i>e.g.</i>	for example (<i>exempli gratia, Latin</i>)
EMS	evaluating Member State
ES	Spain
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
<i>i.e.</i>	that is (<i>id est, Latin</i>)
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
LOQ	limit of quantification

MRL	maximum residue level
MS	Member States
MS	mass spectrometry
MS/MS	tandem mass spectrometry
NEU	northern European Union
NOAEL	no observed adverse effect level
NL	The Netherlands
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
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
RAC	raw agricultural commodity
RMS	rapporteur Member State
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WG	water dispersible granule
WHO	World Health Organisation