

## REASONED OPINION OF EFSA

### Modification of the existing MRLs for indoxacarb in raspberries and blackberries<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00213)

Issued on 11 March 2009

#### SUMMARY

Germany received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify an existing MRL for indoxacarb in raspberries and blackberries. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report, the Draft Assessment Report prepared by The Netherlands in the framework of Directive 91/414/EEC as well as MRL proposals prepared by several Member States under the former MRL legislation:

The toxicological profile of indoxacarb was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.006 mg/kg bw/d and an ARfD value of 0.125 mg/kg bw/d.

The metabolism of indoxacarb in primary crops is elucidated in several crop categories and residue definitions have been derived for all plant commodities. The residue definition for risk assessment and enforcement is set as “indoxacarb (sum of R and S isomers)”. Consequently, the MRL application for raspberries and blackberries does not require additional metabolism studies.

Analytical methods are available to enforce an MRL in raspberries and blackberries.

Submitted supervised field trials indicate that the current MRL of 0.02 mg/kg does not accommodate the intended GAP in Germany and a higher MRL of 0.5 mg/kg would be necessary.

Since blackberries and raspberries are perennial crops and usually not grown in rotation, no rotational crop studies are relevant for the current application.

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<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for indoxacarb in raspberries and blackberries. *EFSA Scientific Report* (2009) 246, 1-23

Residues in commodities of animal origin were not assessed in the framework of this application considering that berries are not usually fed to livestock.

The consumer risk assessment was performed with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR and STMR values derived for the intended use on raspberries and blackberries. In addition, for several other crops the STMR values were available to refine the intake calculations.

The chronic dietary intake calculation did not reveal any consumer intake concerns. The TMDI values ranged from 9.8 to 70.9% of the ADI. The highest contribution of raspberries and blackberries was 0.5% of the ADI for the NL child diet and 0.5% of the ADI for IE adult diet, respectively. No acute intake risk was identified for raspberries and blackberries. Regarding the risk assessment of the current MRLs for indoxacarb, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September 2009.

### Overview of the proposed EC MRL

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Indoxacarb (sum of R and S isomers)			
Blackberries, raspberries	0.02*	0.5	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

EFSA concludes that the proposed use of indoxacarb on raspberries and blackberries can be supported as no risk for consumer safety was identified.

**Key words: Indoxacarb, raspberries, blackberries, MRL application, Regulation (EC) No 396/2005, indeno-oxadizine insecticide**

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## **BACKGROUND**

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

Germany, hereafter referred to as the Evaluating Member State (EMS), received an application from Landwirtschaftliches Technologiezentrum Augustenberg<sup>2</sup> to modify the existing MRL for indoxacarb in raspberries and blackberries. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission, who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00213 and the following subject:

*Indoxacarb - Application to modify the existing MRL for indoxacarb (sum of R and S isomers) in raspberries from 0.02\* mg/kg to 0.5 mg/kg and in blackberries from 0.02\* mg/kg to 0.5 mg/kg.*

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

## **TERMS OF REFERENCE**

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

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

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

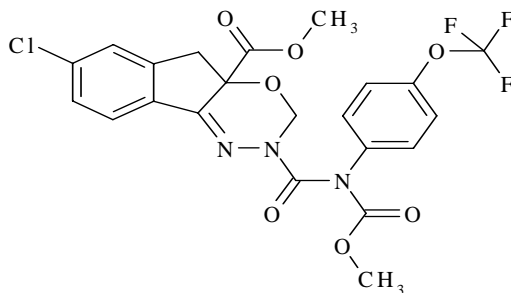
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<sup>2</sup> Landwirtschaftliches Technologiezentrum Augustenberg, Außenstelle Stuttgart, Reinsburgstraße 107, 70197, Stuttgart, Germany

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Indoxacarb is the ISO common name for (S)-7-chloro-3- [methoxycarbonyl-(4-trifluoromethoxy-phenyl)-carbamoyl]-2,5-dihydro-indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylic acid methyl ester (IUPAC). Indoxacarb as defined by ISO refers only to S enantiomer of the active substance which is a racemic mixture of S and R isomers.

The active substance in the formulated products contains the S and R isomers in the ratio 3:1 respectively.



Indoxacarb is an indeno-oxadiazine insecticide. It is active as a larvicide and is taken up by stomach and contact routes. The product is active on all larval stages of Lepidoptera, together with some activity on some other groups (Othoptera, some Hemiptera and Homoptera in some situations). Indoxacarb, when used according to label recommendations, provides effective control of a wide range of insect pests in grapes, pome fruit, peaches, apricots, tomatoes, peppers, cucurbits, brassica vegetables, and lettuce. Major insect pests controlled includes *Lobesia botrana*, *Eupocilia ambiguella*, *Cydia pomonella*, *Adoxophyes orana*, *Eulia pulchelia*, *Pandermis ribeana*, *Pieris brassicae*, *Pieris rapae*, *Mamestra brassicae*, *Spodoptera exigua*, *Helicoverpa armigera*, and *Plusia gamma*.

Indoxacarb has been peer reviewed under the Directive 91/414/EEC and is included in the Annex I of this Directive by the Commission Directive 2006/10/EC for the uses as an insecticide only. The representative uses assessed under the peer review of Directive 91/414/EEC include field use of indoxacarb on pome fruit, berries and small fruit, Brassica vegetables, stone fruit, fruiting vegetables and leafy vegetables. Indoxacarb was not peer reviewed by EFSA.

In the European Community the MRLs for indoxacarb are established in Annexes II and IIIB of the Regulation (EC) No 396/2005 and are summarized in Appendix B. The current MRLs for raspberries and blackberries are set at the LOQ of 0.02 mg/kg.

Codex Alimentarius has established CXLs for indoxacarb in a wide range of commodities but there is no CXL set for raspberries and blackberries. The GAP for which an authorisation is requested in Germany refers to an outdoor application of indoxacarb on raspberries and blackberries. The WG formulation should be applied as a spray once per harvest at an application rate of 0.051 kg a.s./ha. The minimum PHI is 7 days. The details of the GAP can be found in Appendix A.

## ASSESSMENT

### 1. Methods of analysis

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

The analytical methods for the determination of indoxacarb in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (The Netherlands, 2005). Two analytical methods are available for the determination of combined S and R isomers in raw and processed plant commodities.

The DFG method S19, using GC-ECD, with the LOQ of 0.02 mg/kg was sufficiently validated for the determination of indoxacarb in fruit (apples, peaches and grapes), tomatoes, cabbage and cauliflower.

The single residue method, using GC-MSD, was validated for the determination of indoxacarb in small fruit, pome fruit, fruiting vegetables, brassicas and oilseeds, as well as in processed fractions from these crops. The method was validated at the LOQ of 0.02 mg/kg.

The validation data are sufficient for the commodities with high acid content and can be applicable also for raspberries and blackberries.

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

Raspberries and blackberries are not used as a livestock feedingstuff. Therefore analytical methods for determination of indoxacarb in the food of animal origin are not of relevance for the setting of the MRL in raspberries and blackberries.

### 2. Mammalian toxicology

The toxicological reference values for indoxacarb were derived in the peer review under Directive 91/414/EEC and are compiled in the Table 2-1 (European Commission, 2005).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	COM	2005	0.006	2 yr rat	100
ARfD	COM	2005	0.125	Rat, acute neurotoxicity	100

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

Under the peer review of Directive 91/414/EEC the metabolism studies were submitted for the following crop categories (The Netherlands, 2005):

- grapes, tomatoes (fruit and fruiting vegetables)
- lettuce (leafy vegetables)
- cotton (pulses and oilseeds)

These studies cover the foliar use on three crop groups. Metabolism studies indicated that S and R isomers represent the major residue component in all crops. It was concluded that plant metabolism of indoxacarb is not stereo specific. It was proposed that the ratio of both isomers used in different metabolism studies and residue trials is not of concern.

From the results of the metabolism studies on primary crops it was concluded to set a residue definition for both the risk assessment and enforcement as “indoxacarb (sum of R and S isomers)” for all commodities of plant origin.

###### 3.1.1.2. Magnitude of residues

The applicant submitted four supervised residue field trials on raspberries, in support of the proposed GAP. Supervised field trials were performed across two seasons in Northern Europe. Available residue trials are summarized in Table 3-1. The applicant provided residue decline data for two trials. In all trials residues of indoxacarb were in the range of 0.06 – 0.28 mg/kg. The number of supervised residues field trials is sufficient for extrapolation from raspberries to blackberries and the MRL of 0.5 mg/kg would be necessary to accommodate the proposed GAP.

The storage stability of residues in treated crops has been evaluated under the peer review of Directive 91/414/EEC (The Netherlands, 2005). Studies demonstrated storage stability of racemic mixture under frozen storage conditions for at least 6 months in the fractions of processed apples and tomatoes, 10 months in wet grape pomace and lettuce, 12 months in tomatoes and 18 months in grapes and apples. No formation of toxicologically significant metabolites was observed during storage. The supervised residues field trial samples prior analyses were stored frozen (-18C°) for a time period not exceeding 5 months which means that analytical results can be considered valid regarding storage stability.

According to the evaluation of the EMS, the analytical method applied for analysing supervised field trial samples is sufficiently validated and fit for purpose.

Table 3-1. Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Indoxacarb (sum of R and S isomers)									
Raspberries, blackberries	NEU	Outdoor	0.06; 0.24; 0.27; 0.28	0.06; 0.24; 0.27; 0.28	0.255	0.28	0.5	1.0	R <sub>ber</sub> = 0.555 mg/kg R <sub>max</sub> =0.743 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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



### 3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review of Directive 91/414/EEC the effects on the nature of indoxacarb during processing was investigated in hydrolysis study (The Netherlands, 2005). The nature of the residues of indoxacarb, labelled in two different ways, was studied under pasteurisation and baking/boiling conditions. The hydrolysis studies demonstrate that these conditions do not result in a formation of toxicologically significant degradation products.

The applicant has not submitted processing studies for raspberries and blackberries and such are not considered necessary since the contribution of these berries to the dietary intake is very low.

### 3.1.2. Rotational crops

Raspberries and blackberries are perennial crops and are not grown in rotation therefore rotational crop studies are not necessary with regard to this application.

## 3.2. Nature and magnitude of residues in livestock

Since berries are not fed to livestock, studies on nature and magnitude of residues in livestock are not of relevance regarding the current MRL proposal.

## 4. Consumer risk assessment

The consumer risk assessment is performed with the EFSA PRIMo-rev. 2 (Pesticide Residue Intake Model), using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR and STMR values derived for the intended use on raspberries and blackberries. In addition, for Brussels sprouts the STMR value was used as obtained in the EFSA reasoned opinion on the modification of the existing MRLs for indoxacarb in Brussels sprouts (EFSA, 2008). In addition, EFSA looked for the relevant information in evaluation reports submitted to the European Community for the MRL proposals during 2006-2008 and used the available STMR values of various commodities in the chronic consumer intake calculation.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Indoxacarb (sum of R and S isomers)				
Raspberries, blackberries	0.26	STMR (Germany, 2008)	0.28	HR (Germany, 2008)
Brussels sprouts	0.02	STMR (The United Kingdom, 2006)	The acute risk assessment was performed only with regard to raspberries and blackberries.	
Apples	0.21	STMR (The Netherlands, 2006a)		
Pears, quinces, medlar, loquat	0.10	STMR (The Netherlands, 2006a)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apricots, peaches	0.11	STMR (The Netherlands, 2006a)		
Table and wine grapes	0.30	STMR (The Netherlands, 2006a)		
Currants (black, red and white), gooseberries	0.22	STMR (The Netherlands, 2006b)		
Bananas	0.04	STMR (The Netherlands, 2007b)		
Radishes	0.02	STMR (The Netherlands, 2007c)		
Tomatoes, aubergines	0.11	STMR (The Netherlands, 2006a)		
Peppers	0.05	STMR (The Netherlands, 2006a)		
Cucurbits (edible peel)	0.02	STMR (The Netherlands, 2006a)		
Cucurbits (inedible peel)	0.03	STMR (The Netherlands, 2006a)		
Flowering brassica	0.07	STMR (The Netherlands, 2007a)		
Head cabbage	0.44	STMR (The Netherlands, 2006a)		
Brussels sprouts	0.02	STMR (EFSA, 2009)		
Chinese cabbage, kale	0.05	STMR (Germany, 2006)		
Lamb`s lettuce	0.42	STMR (The Netherlands, 2007c)		
Lettuce, scarole	0.52	STMR (The Netherlands, 2006a)		
Leaves and sprouts of Brassica spp.	0.22	STMR (The Netherlands, 2007e)		
Spinach	0.78	STMR (The Netherlands, 2007d)		
Herbs	0.38	STMR (The Netherlands, 2006b)		
Celery	0.85	STMR (The Netherlands, 2007e)		
Globe artichokes	0.04	STMR (The Netherlands, 2006a)		
Soya bean	0.03	STMR (The Netherlands, 2006a)		

The summary of the intake calculation can be found in Appendix D.

The chronic dietary intake calculation did not reveal any consumer intake concerns. The TMDI values ranged from 9.8 to 70.9% of the ADI. The highest TMDI for raspberries was 0.5% of the ADI for the NL child diet and for blackberries the highest TMDI was 0.5% of the ADI for IE adult diet. No acute intake risk was identified for raspberries and blackberries since the IESTI is 2.4% and 1.3% of the ARfD for blackberries and raspberries respectively.

Regarding the risk assessment of current MRLs for indoxacarb, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September 2009.

EFSA concludes that the intended use of indoxacarb on raspberries and blackberries is acceptable with regard to consumer safety.

## CONCLUSIONS AND RECOMMENDATIONS

Germany received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify an existing MRL for indoxacarb in raspberries and blackberries. Germany as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report, the Draft Assessment Report prepared by The Netherlands in the framework of Directive 91/414/EEC as well as MRL proposals prepared by several Member States under the former MRL legislation:

The toxicological profile of indoxacarb was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.006 mg/kg bw/d and an ARfD value of 0.125 mg/kg bw/d.

The metabolism of indoxacarb in primary crops is elucidated in several crop categories and residue definitions have been derived for all plant commodities. The residue definition for risk assessment and enforcement is set as “indoxacarb (sum of R and S isomers)”. Consequently, the MRL application for raspberries and blackberries does not require additional metabolism studies.

Analytical methods are available to enforce an MRL in raspberries and blackberries.

Submitted supervised field trials indicate that the current MRL of 0.02 mg/kg does not accommodate the intended GAP in Germany and a higher MRL of 0.5 mg/kg would be necessary.

Since blackberries and raspberries are perennial crops and usually not grown in rotation, no rotational crop studies are relevant for the current application.

Residues in commodities of animal origin were not assessed in the framework of this application considering that berries are not usually fed to livestock.

The consumer risk assessment was performed with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 as well as the HR and STMR values derived for the intended use on raspberries and blackberries. In addition, for several other crops the STMR values were available to refine the intake calculations.

The chronic dietary intake calculation did not reveal any consumer intake concerns. The TMDI values ranged from 9.8 to 70.9% of the ADI. The highest contribution of raspberries and blackberries was 0.5% of the ADI for the NL child diet and 0.5% of the ADI for IE adult diet, respectively. No acute intake risk was identified for raspberries and blackberries.

Regarding the risk assessment of the current MRLs for indoxacarb, they will be subject to a full risk assessment according to Article 12 (2) of Regulation (EC) No 396/2005 by 2 September 2009.

Table 5-1. Overview of the proposed EC MRL

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Indoxacarb (sum of R and S isomers)			
Blackberries, raspberries	0.02*	0.5	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

EFSA concludes that the proposed use of indoxacarb on raspberries and blackberries can be supported as no risk for consumer safety was identified.

#### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRLs for indoxacarb in raspberries and blackberries according to Regulation 396/2005/EC prepared by the BVL (Germany), 2008.

#### REFERENCES

- European Commission, 2005. SANCO/1408/2001-rev3. Review report for the active substance indoxacarb.
- EFSA, 2009. Reasoned Opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for indoxacarb in Brussels sprouts. EFSA Scientific Report (2009) 225, 1-27.
- Germany, 2006. MRL proposal for Chinese cabbage and kale from November 2006.
- The Netherlands, 2005. Draft Assessment Report on Indoxacarb prepared in the framework of the Directive 91/414/EEC on January 2005.
- The Netherlands, 2006a. MRL proposal for indoxacarb from June 2006. 1-118.
- The Netherlands, 2006b. MRL proposal for indoxacarb from September 2006. Addendum 1, 1-33.
- The Netherlands, 2007a. MRL proposal from the United Kingdom for indoxacarb in flowering brassicas. February 2007, Addendum 3, 1-2.
- The Netherlands, 2007b. MRL proposal from Spain for indoxacarb in bananas. March 2007. Addendum 4.
- The Netherlands, 2007c. MRL proposal from Germany for indoxacarb in radish and lamb's lettuce from June 2007. Addendum 5, 1-7.
- The Netherlands, 2007d. MRL proposal from Italy for indoxacarb in spinach. October 2007. Addendum 6, 1-4.
- The Netherlands, 2007e. MRL proposal from Spain for indoxacarb in celery and leaves and sprouts of Brassica spp. November, 2007. Addendum 7, 1-6.

**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

Crop and / or situation	F, G or I (a)	Pest or group of pests controlled (b)	Formulation		Application			Application rate per treatment			PHI (days) (f)	Remarks: (g)
			Type (c)	Conc. of a.i. (d)	method, kind	growth stage (e)	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
Blackberries, raspberries	F	Bramble shoot moth (Notocelia uddmanniana)	WG	300 g/kg	spraying	At infestation or if first symptoms/pests become visible	1	0,005	1000	0,051	7	

(a) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(b) e.g. biting and sucking insects, soil born insects, foliar fungi

(c) Water Dispersible Granules (WG)

(d) g/kg or g/l

(e) Growth stage at last treatment

(f) PHI = Pre-harvest interval

(g) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

**APPENDIX B – EXISTING EC MRLs**

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
1. FRUIT FRESH OR FROZEN; NUTS	
(i) Citrus fruit	0,02*
Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
Lemons (Citron, lemon )	0,02*
Limes	0,02*
Mandarins (Clementine, tangerine and other hybrids)	0,02*
Others	0,02*
(ii) Tree nuts (shelled or unshelled)	0,05*
Almonds	0,05*
Brazil nuts	0,05*
Cashew nuts	0,05*
Chestnuts	0,05*
Coconuts	0,05*
Hazelnuts (Filbert)	0,05*
Macadamia	0,05*
Pecans	0,05*
Pine nuts	0,05*
Pistachios	0,05*
Walnuts	0,05*
Others	0,05*
(iii) Pome fruit	
Apples (Crab apple)	0,5
Pears (Oriental pear)	0,3
Quinces	0,3
Medlar	0,3
Loquat	0,3
Others	0,3
(iv) Stone fruit	
Apricots	0,3
Cherries (sweet cherries, sour cherries)	0,02*
Peaches (Nectarines and similar hybrids)	0,3
Plums (Damson, greengage, mirabelle)	0,02*
Others	0,02*
(v) Berries & small fruit	
(a) Table and wine grapes	2
Table grapes	2
Wine grapes	2
(b) Strawberries	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
(c) Cane fruit	0,02*
Blackberries	0,02*
Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
Raspberries (Wineberries )	0,02*
Others	0,02*
(d) Other small fruit & berries	
Blueberries (Bilberries cowberries (red bilberries))	0,02*
Cranberries	0,02*
Currants (red, black and white)	1
Gooseberries (Including hybrids with other ribes species)	1
Rose hips	0,02*
Mulberries (arbutus berry)	0,02*
Azarole (mediteranean medlar)	0,02*
Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*
Others	0,02*
(vi) Miscellaneous fruit	0,02*
(a) Edible peel	0,02*
Dates	0,02*
Figs	0,02*
Table olives	0,02*
Kumquats (Marumi kumquats, nagami kumquats)	0,02*
Carambola (Bilimbi)	0,02*
Persimmon	0,02*
Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
Others	0,02*
(b) Inedible peel, small	0,02*
Kiwi	0,02*
Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
Passion fruit	0,02*
Prickly pear (cactus fruit)	0,02*
Star apple	0,02*
American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
sapote)	
Others	0,02*
(c) Inedible peel, large	0,02*
Avocados	0,02*
Bananas (Dwarf banana, plantain, apple banana)	0,2
Mangoes	0,02*
Papaya	0,02*
Pomegranate	0,02*
Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
Guava	0,02*
Pineapples	0,02*
Bread fruit (Jackfruit)	0,02*
Durian	0,02*
Soursop (guanabana)	0,02*
Others	0,02*
<b>2. VEGETABLES FRESH OR FROZEN</b>	
(i) Root and tuber vegetables	0,02*
(a) Potatoes	0,02*
(b) Tropical root and tuber vegetables	0,02*
Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
Sweet potatoes	0,02*
Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
Arrowroot	0,02*
Others	0,02*
(c) Other root and tuber vegetables except sugar beet	0,02*
Beetroot	0,02*
Carrots	0,02*
Celeriac	0,02*
Horseradish	0,02*
Jerusalem artichokes	0,02*
Parsnips	0,02*
Parsley root	0,02*
Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2
Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
Swedes	0,02*
Turnips	0,02*
Others	0,02*
(ii) Bulb vegetables	0,02*
Garlic	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Onions (Silverskin onions)	0,02*
Shallots	0,02*
Spring onions (Welsh onion and similar varieties)	0,02*
Others	0,02*
(iii) Fruiting vegetables	
(a) Solanacea	
Tomatoes (Cherry tomatoes, )	0,5
Peppers (Chilli peppers)	0,3
Aubergines (egg plants) (Pepino)	0,5
Okra, lady s fingers	0,02*
Others	0,02*
(b) Cucurbits - edible peel	0,2
Cucumbers	0,2
Gherkins	0,2
Courgettes (Summer squash, marrow (patisson))	0,2
Others	0,2
(c) Cucurbits-inedible peel	0,1
Melons (Kiwano )	0,1
Pumpkins (Winter squash)	0,1
Watermelons	0,1
Others	0,1
(d) Sweet corn	0,02*
(e) Other fruiting vegetables	0,02*
(iv) Brassica vegetables	
(a) Flowering brassica	0,3
Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,3
Cauliflower	0,3
Others	0,3
(b) Head brassica	
Brussels sprouts	0,02*
Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	3
Others	0,02*
(c) Leafy brassica	
Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,2
Kale (Borecole (curly kale), collards)	0,2
Others ( )	0,02*
(d) Kohlrabi	0,02*
(v) Leaf vegetables & fresh herbs	

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
(a) Lettuce and other salad plants including Brassicacea	
Lamb's lettuce (Italian cornsalad)	1
Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	2
Cress	0,02*
Land cress	0,02*
Rocket, Rucola (Wild rocket)	0,02*
Red mustard	0,02*
Leaves and sprouts of Brassica spp (Mizuna)	1
Others	0,02*
(b) Spinach & similar (leaves)	0,02*
Spinach (New Zealand spinach, turnip greens (turnip tops))	2
Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
Beet leaves (chard) (Leaves of beetroot)	0,02*
Others	0,02*
(c) Vine leaves (grape leaves)	2
(d) Water cress	0,02*
(e) Witloof	0,02*
(f) Herbs	2
Chervil	2
Chives	2
Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	2
Parsley	2
Sage (Winter savory, summer savory, )	2
Rosemary	2
Thyme ( marjoram, oregano)	2
Basil (Balm leaves, mint, peppermint)	2
Bay leaves (laurel)	2
Tarragon (Hyssop)	2
Others	2
(vi) Legume vegetables (fresh)	0,02*
Beans (with pods) (Green bean (french beans, snap beans),	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
scarlet runner bean, slicing bean, yardlong beans)	
Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
Peas (with pods) (Mangetout (sugar peas))	0,02*
Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
Lentils	0,02*
Others	0,02*
(vii) Stem vegetables (fresh)	
Asparagus	0,02*
Cardoons	0,02*
Celery	2
Fennel	0,02*
Globe artichokes	0,1
Leek	0,02*
Rhubarb	0,02*
Bamboo shoots	0,02*
Palm hearts	0,02*
Others	0,02*
(viii) Fungi	0,02*
Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
Wild (Chanterelle, Truffle, Morel )	0,02*
Others	0,02*
(ix). Sea weeds	
3. PULSES, DRY	0,02*
Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
Lentils	0,02*
Peas (Chickpeas, field peas, chickling vetch)	0,02*
Lupins	0,02*
Others	0,02*
4. OILSEEDS AND OILFRUITS	
(i) Oilseeds	
Linseed	0,05*
Peanuts	0,05*
Poppy seed	0,05*
Sesame seed	0,05*
Sunflower seed	0,05*
Rape seed (Bird rapeseed, turnip rape)	0,05*
Soya bean	0,5
Mustard seed	0,05*



Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Cotton seed	0,05*
Pumpkin seeds	0,05*
Safflower	0,05*
Borage	0,05*
Gold of pleasure	0,05*
Hempseed	0,05*
Castor bean	0,05*
Others	0,05*
(ii) Oilfruits	0,02*
Olives for oil production	0,02*
Palm nuts (palmoil kernels)	0,02*
Palmfruit	0,02*
Kapok	0,02*
Others	0,02*
5. CEREALS	0,02*
Barley	0,02*
Buckwheat	0,02*
Maize	0,02*
Millet (Foxtail millet, teff)	0,02*
Oats	0,02*
Rice	0,02*
Rye	0,02*
Sorghum	0,02*
Wheat (Spelt Triticale)	0,02*
Others	0,02*
6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
(ii) Coffee beans	0,05*
(iii) Herbal infusions (dried)	0,05*
(a) Flowers	0,05*
Camomille flowers	0,05*
Hybiscus flowers	0,05*
Rose petals	0,05*
Jasmine flowers	0,05*
Lime (linden)	0,05*
Others	0,05*
(b) Leaves	0,05*
Strawberry leaves	0,05*
Rooibos leaves	0,05*
Maté	0,05*
Others	0,05*
(c) Roots	0,05*
Valerian root	0,05*
Ginseng root	0,05*
Others	0,05*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
(d) Other herbal infusions	0,05*
(iv) Cocoa (fermented beans)	0,05*
(v) Carob (st johns bread)	0,05*
7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
8. SPICES	0,05*
(i) Seeds	0,05*
Anise	0,05*
Black caraway	0,05*
Celery seed (Lovage seed)	0,05*
Coriander seed	0,05*
Cumin seed	0,05*
Dill seed	0,05*
Fennel seed	0,05*
Fenugreek	0,05*
Nutmeg	0,05*
Others	0,05*
(ii) Fruits and berries	0,05*
Allspice	0,05*
Anise pepper (Japan pepper)	0,05*
Caraway	0,05*
Cardamom	0,05*
Juniper berries	0,05*
Pepper, black and white (Long pepper, pink pepper)	0,05*
Vanilla pods	0,05*
Tamarind	0,05*
Others	0,05*
(iii) Bark	0,05*
Cinnamon (Cassia )	0,05*
Others	0,05*
(iv) Roots or rhizome	0,05*
Liquorice	0,05*
Ginger	0,05*
Turmeric (Curcuma)	0,05*
Horse-radish	0,05*
Others	0,05*
(v) Buds	0,05*
Cloves	0,05*
Capers	0,05*
Others	0,05*
(vi) Flower stigma	0,05*
Saffron	0,05*
Others	0,05*
(vii) Aril	0,05*
Mace	0,05*
Others	0,05*
9. SUGAR PLANTS	0,02*
Sugar beet (root)	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Sugar cane	0,02*
Chicory roots	0,02*
Others	0,02*
<b>10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS</b>	
(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	
(a) Swine	
Meat	0,01*
Fat free of lean meat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(b) Bovine	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(c) Sheep	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(d) Goat	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(e) Horses, asses, mules or hinnies	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Others	0,01*
(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(g) Other farm animals (Rabbit, Kangaroo)	
Meat	0,01*
Fat	0,3
Liver	0,01*
Kidney	0,01*
Edible offal	0,01*
Others	0,01*
(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02 (ft)
Cattle	0,02
Sheep	0,02
Goat	0,02
Horse	0,02
Others	0,02
(iii) Birds eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01*
Chicken	0,01*
Duck	0,01*
Goose	0,01*
Quail	0,01*
Others	0,01*
(iv) Honey (Royal jelly, pollen)	
(v) Amphibians and reptiles (Frog legs, crocodiles)	
(vi) Snails	
(vii) Other terrestrial animal products	

## APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Indoxacarb</b>			
Status of the active substance:	<b>Included</b>	Code no.	<b>#N/A</b>
LOQ (mg/kg bw):		proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.006</b>	ARfD (mg/kg bw):	<b>0.125</b>
Source of ADI:	<b>COM</b>	Source of ARfD:	<b>COM</b>
Year of evaluation:	<b>2005</b>	Year of evaluation:	<b>2005</b>

Acute RA- HR raspberries, blackberries - 0.28 mg/kg. For chronic RA- STMR values for pome fruit-0.1 mg/kg, except apple-0.21 mg/kg; apricots, peaches-0.11 mg/kg; table and wine grapes-0.3 mg/kg; currants and gooseberries- 0.22 mg/kg;bananas-0.044 mg/kg;radishes-0.02mg/kg; tomatoes, aubergines -0.11 mg/kg, peppers-0.05 mg/kg; cucurbits(edible peel)-0.02mg/kg; cucurbits(inedible peel)-0.03 mg/kg; flowering brassica-0.07mg/kg; Brussels sprouts-0.02mg/kg; head cabbage-0.44mg/kg; chinese cabbage, kale-0.05 mg/kg; lamb's lettuce-0.42 mg/kg; lettuce and scarole-0.52 mg/kg; leaves and sprouts of Brassica spp -0.22 mg/kg; spinach-0.78 mg/kg;herbs-0.38 mg/kg;celery-0.845mg/kg; globe artichokes-0.035mg/kgsoya bean-0.027mg/kg; raspberries and blackberries- 0.26 mg/kg

### Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		10                      71							
		<b>No of diets exceeding ADI:</b>		---					
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	pTMRs at LOQ (in % of ADI)	
70.9	DE child	42.2	Apples	6.3	Table grapes	4.8	Milk and cream,		
59.5	NL child	22.2	Apples	9.8	Milk and cream,	4.8	Spinach		
44.6	FR toddler	13.2	Milk and cream,	9.2	Spinach	9.2	Apples		
42.4	WHO Cluster diet B	9.0	Wine grapes	5.7	Tomatoes	3.5	Apples		
31.9	UK Toddler	7.6	Sugar beet (root)	6.9	Milk and cream,	6.0	Apples		
31.5	IE adult	6.3	Wine grapes	2.9	Apples	1.8	Celery		
31.0	UK Infant	12.9	Milk and cream,	5.5	Apples	3.4	Sugar beet (root)		
30.2	FR infant	8.8	Apples	8.6	Milk and cream,	5.8	Spinach		
29.8	FR all population	20.0	Wine grapes	1.7	Apples	1.1	Wheat		
26.6	WHO cluster diet E	8.0	Wine grapes	3.0	Apples	1.9	Head cabbage		
26.0	PT General population	12.4	Wine grapes	3.7	Apples	1.8	Potatoes		
24.6	DK child	8.1	Apples	4.2	Milk and cream,	1.8	Wheat		
22.9	SE general population 90th percentile	4.6	Head cabbage	4.1	Milk and cream,	3.7	Apples		
22.5	NL general	4.1	Apples	3.1	Wine grapes	2.2	Milk and cream,		
22.3	ES child	4.2	Milk and cream,	4.0	Apples	3.6	Lettuce		
22.1	WHO regional European diet	3.3	Lettuce	2.7	Head cabbage	2.3	Apples		
19.7	WHO Cluster diet F	3.0	Wine grapes	2.6	Lettuce	2.3	Apples		
18.6	ES adult	4.6	Lettuce	2.7	Apples	2.1	Wine grapes		
18.5	WHO cluster diet D	2.3	Apples	2.2	Wheat	1.9	Tomatoes		
16.6	UK vegetarian	4.1	Wine grapes	2.1	Apples	1.3	Sugar beet (root)		
16.4	DK adult	7.0	Wine grapes	2.7	Apples	1.8	Milk and cream,		
16.4	IT kids/toddler	3.1	Apples	2.6	Tomatoes	2.5	Lettuce		
16.3	PL general population	7.2	Apples	2.7	Head cabbage	1.6	Tomatoes		
15.6	IT adult	3.3	Lettuce	2.8	Apples	2.1	Tomatoes		
15.4	LT adult	6.5	Apples	2.9	Head cabbage	1.3	Milk and cream,		
15.1	UK Adult	5.4	Wine grapes	1.4	Apples	1.3	Sugar beet (root)		
9.8	FI adult	1.9	Milk and cream,	1.5	Wine grapes	1.4	Apples		

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs 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 leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	2.4	Blackberries	0.28 / -	2.4	Blackberries	0.28 / -	0.9	Raspberries	0.28 / -	0.9	Raspberries	0.28 / -
	1.3	Raspberries	0.28 / -	1.3	Raspberries	0.28 / -	0.5	Blackberries	0.28 / -	0.5	Blackberries	0.28 / -
	<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	IESTI 1	*)	***)	IESTI 2	*)	***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	52.6	Grape juice	2 / -	6.2	Wine	2 / -
	20.4	Apple juice	0.5 / -	2.6	Apple juice	0.5 / -
	8.1	Cuurant juice	1 / -	0.8	Tomato (preserved-	0.5 / -
	7.0	Tomato juice	0.5 / -	0.6	Raisins	2 / -
	4.3	Peach juice	0.3 / -	0.5	Peach preserved with	0.3 / -

\*) 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.

## GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/EEC)
DAT	days after treatment
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	European Community
ECD	Electron Capture Detection
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
IESTI	International Estimated Short Term Intake
IE	Ireland
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues

L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NL	The Netherlands
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million ( $10^{-6}$ )
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation