European Food Safety Authority

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REASONED OPINION OF EFSA

Modification of the existing MRL for indoxacarb in Brussels sprouts[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-731)

Issued on 20 January 2009

SUMMARY

The United Kingdom received an application from the Horticultural Development Council to modify the existing MRL for indoxacarb in Brussels sprouts. The United Kingdom as an Evaluating Member State (EMS) drafted an Evaluation Report which was submitted to the European Commission and forwarded to EFSA on 26 September 2008.

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 Brussels sprouts does not require additional metabolism studies.

Analytical methods are available to enforce an MRL in Brussels sprouts.

The possible occurrence of indoxacarb residues in rotational crops was also investigated. It was concluded that the nature of residues in rotational crops and primary crops is expected to be similar but significant residue levels in rotational crops (exceeding 0.01 mg/kg) will not occur provided that the active substance is applied according to the proposed GAP.

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

[1] For citation purposes: 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

Submitted data on supervised field trials reveal that the current MRL does not accommodate the intended GAP in the United Kingdom and a higher MRL of 0.1 mg/kg would be necessary.

EFSA performed the consumer intake risk assessment with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 for indoxacarb as well as the HR and STMR values derived for the intended use on Brussels sprouts. In addition, EFSA looked for the relevant information in available evaluation reports submitted to EC for MRL proposals during 2006-2008 and used the available STMR values of various commodities in the chronic consumer intake calculations.

The chronic dietary intake calculation did not reveal any consumer intake concerns and no acute intake risk was identified for Brussels sprouts since the IESTI is only 0.3% of the ARfD.

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.

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)			
Brussels sprouts	0.02*	0.1	No consumer risk is associated with the proposed MRL for indoxacarb in Brussels sprouts.

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

EFSA concludes that the proposed MRL of 0.1 mg/kg for indoxacarb in Brussels sprouts can be supported as no risk for consumer safety was identified in relation to the Brussels sprouts.

Key words: Indoxacarb, Brussels sprouts, MRL application, Regulation (EC) No 396/2005, oxadizine

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Chapter II of the Regulation, dealing with the procedure to set new MRLs or to amend existing MRLs, entered into force on 2 September 2008.

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom as an Evaluating Member State (EMS) received an application from the Horticultural Development Council (HDC) on the modification of the existing MRL for indoxacarb in Brussels sprouts. On 26 September 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

After the receipt of the Evaluation Report, EFSA included the application in the EFSA Register of Questions with the number EFSA-Q-2008-731 and the following subject:

*Indoxacarb - Application to modify the existing MRL for indoxacarb (sum of R and S isomers) in Brussels sprouts from 0.02*mg/kg to 0.1 mg/kg.*

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall assess MRL applications and the evaluation reports prepared by the responsible Member State and give a reasoned opinion on the risks to the consumer associated with the setting or modification of MRLs.

TERMS OF REFERENCE

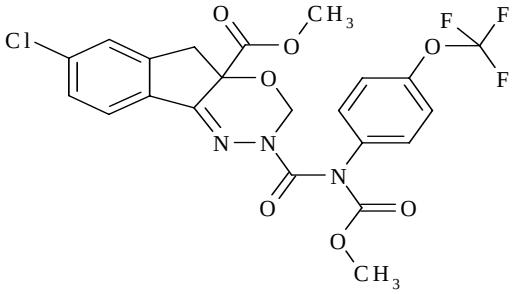
EFSA was requested to provide a reasoned opinion on the risks to consumer associated with the application to modify an MRL for indoxacarb in Brussels sprouts from 0.02* mg/kg to 0.1 mg/kg. The EFSA opinion shall be based in particular on the Evaluation Report prepared by the Evaluating Member State The United Kingdom.

In accordance with Article 11 of Regulation (EC) No 396/2005, the reasoned opinion shall be provided as soon as possible, at the latest within three months from the date of receipt of the application. In this case the deadline for submission of the reasoned opinion was 26 December 2008.

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-oxadizine insecticide. It is active as a larvicide and is taken up by stomach and contact routes after entry into the insect. The importance of stomach versus contact action varies with the species and the crop situation. Data from laboratory and field indicates that 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 leaf 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. The current MRL for Brussels sprouts is set at the limit of quantification and is 0.02 mg/kg.

Codex Alimentarius has established MRLs for indoxacarb in a wide range of commodities but there is no CXL set for Brussels sprouts.

The GAP for which an authorisation is requested in The United Kingdom refers to an outdoor application of indoxacarb on Brussels sprouts. The WG formulation should be applied as a spray for up to 3 times per harvest at an application rate of 25.5 g a.s./ha. The minimum PHI is 1 day.

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 plant commodities 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 water content and can be applicable also for Brussels sprouts.

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for the official control of MRLs have developed their own methods or have included the active substance in the established multi-methods. In the database developed by the Community Reference Laboratories (CRL) for Residues of Pesticides (www.crl-pesticides.eu), in total 345 data sets (status January 2009) have been submitted regarding methods routinely used to determine indoxacarb residues in different matrices. For high water content matrices the validation data have been obtained for several commodities-cucumber, tomatoes, apples, pears, cabbage, spinach, etc. The validation data refer to the QuEChERS method. In the Table 1-1 the validation data for high water content matrices are summarized.

Table 1-1. **Validation data for high water content matrices**[2]

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Water containing	0,14	0,14	105	102	10,6	6	100	1
LC	Water containing	0,01	0,1	96	90	30,5	177	79	7

It is concluded that there are adequate analytical methods available for the enforcement of the MRL for indoxacarb in Brussels sprouts.

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

Brussels sprouts are not used as a livestock feeding stuff, therefore analytical methods for determination of indoxacarb in the food of animal origin are not of relevance for the setting of the MRL in Brussels sprouts.

[2] Source; Website of Community Refrence Laboratories (CRL) for Pesticide Residues www.crl-pesticides.eu January,2009

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 plant origin commodities.

3.1.1.2. Magnitude of residues

Storage stability

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.

The samples of Brussels sprouts from the residue trials were stored frozen for 4-5 months before being analysed (The United Kingdom, 2006). As the storage period of samples did not exceed the demonstrated storage stability of indoxacarb in high water content commodities

(the crop group which Brussels sprouts belong to) the analytical results can be considered reliable with regard to storage stability.

According to the evaluation of the EMS (The United Kingdom, 2006), analytical method applied for the analysis of supervised field trial samples is sufficiently validated and fit for purpose.

Residue trials

The applicant submitted eight supervised field residue trials (The United Kingdom, 2006), but only seven of them support the proposed GAP since one trial does not have a relevant PHI of 1 day for the proposed GAP. All supervised field trials were performed across two seasons in 2004 (4 trials) and 2005 (4 trials) in various regions.

Trials residue data are summarized in Table 3-1. More details regarding residue trials can be found in Appendix B.

The applicant has provided residue decline studies for six trials that demonstrate that the highest level of residues is found in the crop on the day 1 after last application, followed by decrease with longer PHI periods. Taking into account the residue decline studies provided, seven trials can be considered sufficient for the setting of an MRL.

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 [d]	Comments
			Enforcement	Risk assessment					
Brussels sprouts	NEU	Outdoor	0.01; 0.011, 0.014, 0.02; 0.022, 0.03, 0.04	0.01; 0.011, 0.014, 0.02; 0.022, 0.03, 0.04	0.02	0.04	0.1	1.0	R_{ber}= 0.06 R_{max}= 0.058

(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 processing does not result in a formation of toxicologically significant degradation products.

The applicant has not submitted processing studies for Brussels sprouts and such are not considered necessary since the residues of indoxacarb at the harvest are less than 0.1 mg/kg and the contribution of Brussels sprouts in the dietary intake is very low.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Under the peer review the degradation of indoxacarb in soil was evaluated in the field studies (Netherlands, 2005). The studies demonstrate that indoxacarb is extensively degraded under field conditions and after 100 days no soil metabolites exceed 10%.

3.1.2.2. Nature of residues

The metabolism in rotational crops – lettuce, carrots, soybean and wheat - has been evaluated in the DAR. Indoxacarb was applied to the bare soil at an application rate of 300 g a.s./ha. The rotational crops were planted 30, 90 and 120 days after the application. Multiple components, including glucose- and matrix- bound residues, were present in small quantities. In all rotational crop samples, except wheat grain and straw, no single metabolite above 0.01 mg/kg was observed. In grain and straw a single polar metabolite that did not exceed 0.05 mg/kg was observed. The parent compound was not identified in the rotational crop samples. It was concluded that the nature of residues in rotational crops and primary crops is expected to be similar.

3.1.2.3. Magnitude of residues

From the proposed application rate of 76.5 g a.s./ha on Brussels sprouts, indoxacarb residues are not expected in rotational crops.

3.2. Nature and magnitude of residues in livestock

Since Brussels sprouts are not used as livestock feed, nature and magnitude studies of residues in livestock are not of relevance regarding the MRL for Brussels sprouts.

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 Brussels sprouts. In addition, EFSA looked for the relevant information in evaluation reports submitted to the EC 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)				
Brussels sprouts	0.02	STMR (The United Kingdom, 2006)	0.04	HR (The United Kingdom, 2006)
Apples	0.21	STMR (The Netherlands, 2006a)	The acute risk assessment was performed only with regard to Brussels sprouts.	
Pears, quinces, medlar, loquat	0.10	STMR(The Netherlands, 2006a)		
Apricots, peaches	0.11	STMR (The Netherlands, 2006a)		
Table and wine grapes	0.3	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)		
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)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Spinach	0.78	STMR (The Netherlands, 2007d)		
Herbs	0.38	STMR (The Netherlands, 2006b)		
Celery	0.85	STMR(The Netherlands, 2007e)		
Globe artichokes	0.035	STMR (The Netherlands, 2006a)		
Soya bean	0.027	STMR(The Netherlands, 2006a)		

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

The chronic dietary intake calculation did not reveal any consumer intake concerns and no acute intake risk was identified for Brussels sprouts since the IESTI is only 0.3% of the ARfD.

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 proposed MRL of 0.1 mg/kg for indoxacarb in Brussels sprouts can be supported as no risk for consumer safety was identified in relation to Brussels sprouts.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom received an application from the Horticultural Development Council to modify the existing MRL for indoxacarb in Brussels sprouts. The United Kingdom as an Evaluating Member State (EMS) drafted an Evaluation Report which was submitted to the European Commission and forwarded to EFSA on 26 September 2008.

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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 Brussels sprouts does not require additional metabolism studies.

Analytical methods are available to enforce an MRL in Brussels sprouts.

The possible occurrence of indoxacarb residues in rotational crops was also investigated. It was concluded that the nature of residues in rotational crops and primary crops is expected to be similar but significant residue levels in rotational crops (exceeding 0.01 mg/kg) will not occur provided that the active substance is applied according to the proposed GAP.

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

Submitted data on supervised field trials reveal that the current MRL does not accommodate the intended GAP in the United Kingdom and a higher MRL of 0.1 mg/kg would be necessary.

EFSA performed the consumer intake risk assessment with the EFSA PRIMo-rev. 2, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) 396/2005 for indoxacarb as well as the HR and STMR values derived for the intended use on Brussels sprouts. In addition, EFSA looked for the relevant information in available evaluation reports submitted to EC for MRL proposals during 2006-2008 and used the available STMR values of various commodities in the chronic consumer intake calculations.

The chronic dietary intake calculation did not reveal any consumer intake concerns and no acute intake risk was identified for Brussels sprouts since the IESTI is only 0.3% of the ARfD.

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.

Table 5-1. **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)			
Brussels sprouts	0.02*	0.1	No consumer risk is associated with the proposed MRL for indoxacarb in Brussels sprouts.

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

EFSA concludes that the proposed MRL of 0.1 mg/kg for indoxacarb in Brussels sprouts can be supported as no risk for consumer safety was identified in relation to the Brussels sprouts.

REFERENCES

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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.

The United Kingdom, 2006. COP 2008/00206. Residues file note on indoxacarb for use as an insecticide on various brassicas, prepared in the framework of Regulation (EC) No 396/2005, 1-19.

APPENDICES

Appendix A – Good Agricultural Practices (GAPs)

Appendix B – Summary of field residue trials

Appendix C – Pesticide Residues Intake Model (PRIMo)

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	For G (b)	Pest or group of pests controlled c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d-f)	Conc. Of a.s. (i)	method, kind , if other than spray (f-h)	growth stage (j)	number (range)	g a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropriate		
Brussels sprouts	F	Insects	WG	300 g/kg	spray	(see PHI)	3	25.5		-	1	

(a) For crops, the EU and Codex classifications (both) 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.
© *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds.
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e) GCPF Codes – GIFAP Technical Monograph No 2, 1989.
(f) All abbreviations used must be explained.
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench.
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated.
(I) g/kg or g/L.
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
(k) Indicate the minimum and maximum number of application possible under practical conditions of use.
(l) PHI – minimum pre-harvest interval.
(m) Remarks may include: extent of use/economic importance/restrictions.

APPENDIX B –SUMMARY OF FIELD RESIDUE TRIALS

Report No. Location (region)	Commodity/Variety (a)	Date of: 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of treatment c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) & last date (d)	Growth stage at last treatment or date (e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (DP no.) (g)	Period stored frozen prior to analysis (days / months)
				kg as/hL	water (L/ha)	g as/ha							
Netherlands (Nieuwerkerk)	Brussels sprouts/ Cyrus	1) 01/05/04 2) – 3) 28/09/04	spray	0.005 0.0051 0.0051	518 498 503	26.3 25.3 25.6	3, 27/09/04	BBCH 47-49	heads	0.025 <u><0.01</u> <0.01 <0.01 <0.01	2 hours 1 3 28 42.	DP 152731	4 months
Netherlands (Zeewolde)	Brussels sprouts/ Cumulus	1) 07/05/04 2) – 3) 28/09/04	spray	0.0051 0.0051 0.0051	500 502 495	25.4 25.5 25.2	3, 27/09/04	BBCH 47-49	heads	0.015 <u>0.014</u> 0.01 <0.01 <0.01	2 hours 1 3 28 42	DP 152731	4 months
Belgium (Gingelom-Borlo)	Brussels sprouts/ Cumulus	1) 07/05/04 2) – 3) 28/09/04	spray	0.0051 0.0051 0.0051	500 502 495	25.4 25.5 25.2	3, 27/09/04	BBCH 47-49	heads	0.015 <u>0.011</u> 0.01 <0.01 <0.01	2 hours 1 3 28 42	DP 152731	4 months
Germany (Weeze)	Brussels sprouts/ Abacus	1) 28/04/04 2) – 3) 01/11/04	spray	0.0064 0.0063 0.0063	406 418 405	25.8 26.5 25.7	3, 20/09/04	BBCH 49	heads	0.026 <u>0.022</u> 0.019 <0.01 <0.01	2 hours 1 3 28 42	DP 152731	4 months
Belgium (Vlaanderen)	Brussels sprouts/ Abacus	1) 28/04/05 2) – 3) 19/09/05	spray	0.005	488 494 506	24.96 25.27 25.90	3, 18/09/05	BBCH 49	heads	<u>0.03</u>	1	DP 152730	5 months

Report No. Location (region)	Commodity/ Variety (a)	Date of: 1) Sowing or Planting 2) Flowering 3) Harvest (b)	Method of treatment c)	Application rate per treatment			Dates of treatment(s) or no. of treatment(s) & last date (d)	Growth stage at last treatment or date (e)	Portion analysed (a)	Residues (mg/kg)	PHI (days) (f)	Remarks (DP no.) (g)	Period stored frozen prior to analysis (days / months)
				kg as/hL	water (L/ha)	g as/ha							
Belgium (Vlaanderen)	Brussels sprouts/ Maximus	1) 19/05/05 2) – 3) 02/11/05	spray						heads			DP 152730	5 months
PLOT 1				0.005	500	25	3, 03/10/05	BBCH 43		0.02	29		
PLOT 2							3, 11/10/05	BBCH 43-45		0.02	21		
PLOT 3							3, 18/10/05	BBCH 45-47		0.02	14		
PLOT 4							3, 25/10/05	BBCH 47		0.03	7		
PLOT 5							3, 01/11/05	BBCH 49		0.02	1		
Netherlands (Limburg)	Brussels sprouts/ Lumet	1) 25/05/05 2) – 3) 04/11/05	spray	0.005	504 500 504	25.68 25.48 25.68	3, 03/11/05	BBCH 49	Heads	0.04	1	DP 152730	5 months
Germany (North-Rhine-westphalia *	Brussels sprouts/ Rodon	1) 13/05/05 2) – 3) 03/11/05	spray	0.005	500	25			heads			DP 152730	5 months
PLOT 1							3, 06/10/05	BBCH 43		0.01	28		
PLOT 2							3, 13/10/05	BBCH 45		0.03	21		
PLOT 3							3, 20/10/05	BBCH 47		0.02	14		
PLOT 4							3, 27/10/05	BBCH 48		0.04	7		
PLOT 5							3, 03/11/05	BBCH 49		0.08	2 hours		

(a) According to Codex (or other *e.g.* EU) classification)
(b) Only if relevant
© High or low volume spraying, spreading, dusting, *etc.*, overall, broadcast, type of equipment used must be indicated
(d) Year must be indicated
(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)
(f) Minimum number of days after last treatment/application (Label pre-harvest interval, PHI, underline)
(g) Remarks may include: inadequacies, climatic conditions, reference to analytical method, information concerning the metabolites included, the method of storage, storage stability, analysis date

***** This trial does not have an relevant PHI for the proposed GAP.

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Input values in EFSA PRIMo

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)	See Table 4-1
Pears (Oriental pear)	See Table 4-1
Quinces	See Table 4-1
Medlar	See Table 4-1
Loquat	See Table 4-1
Others	See Table 4-1
(iv) Stone fruit	
Apricots	See Table 4-1
Cherries (sweet cherries, sour cherries)	0,02*
Peaches (Nectarines and similar hybrids)	See Table 4-1
Plums (Damson, greengage, mirabelle)	0,02*
Others	0,02*
(v) Berries & small fruit	
(a) Table and wine grapes	See Table 4-1
Table grapes	See Table 4-1
Wine grapes	See Table 4-1
(b) Strawberries	0,02*
(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)	See Table 4-1
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*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
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 sapote)	0,02*
Others	0,02*
(c) Inedible peel, large	0,02*
Avocados	0,02*
Bananas (Dwarf banana, plantain, apple banana)	See Table 4-1
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*
2. VEGETABLES FRESH OR FROZEN	
(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)	See Table 4-1
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*
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,)	See Table 4-1
Peppers (Chilli peppers)	See Table 4-1
Aubergines (egg plants) (Pepino)	See Table 4-1
Okra, lady s fingers	0,02*
Others	0,02*
(b) Cucurbits - edible peel	See Table 4-1
Cucumbers	See Table 4-1
Gherkins	See Table 4-1
Courgettes (Summer squash, marrow (patisson))	See Table 4-1
Others	See Table 4-1
(c) Cucurbits-inedible peel	See Table 4-1
Melons (Kiwano)	See Table 4-1

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Pumpkins (Winter squash)	See Table 4-1
Watermelons	See Table 4-1
Others	See Table 4-1
(d) Sweet corn	0,02*
(e) Other fruiting vegetables	0,02*
(iv) Brassica vegetables	
(a) Flowering brassica	See Table 4-1
Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	See Table 4-1
Cauliflower	See Table 4-1
Others	See Table 4-1
(b) Head brassica	
Brussels sprouts	See Table 4-1
Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	See Table 4-1
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)	See Table 4-1
Kale (Borecole (curly kale), collards)	See Table 4-1
Others ( )	0,02*
(d) Kohlrabi	0,02*
(v) Leaf vegetables & fresh herbs	
(a) Lettuce and other salad plants including Brassicacea	
Lamb´s lettuce (Italian cornsalad)	See Table 4-1
Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	See Table 4-1
Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	See Table 4-1
Cress	0,02*
Land cress	0,02*
Rocket, Rucola (Wild rocket)	0,02*
Red mustard	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Leaves and sprouts of Brassica spp (Mizuna)	See Table 4-1
Others	0,02*
(b) Spinach & similar (leaves)	0,02*
Spinach (New Zealand spinach, turnip greens (turnip tops))	See Table 4-1
Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	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	See Table 4-1
Chervil	See Table 4-1
Chives	See Table 4-1
Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	See Table 4-1
Parsley	See Table 4-1
Sage (Winter savory, summer savory,)	See Table 4-1
Rosemary	See Table 4-1
Thyme (marjoram, oregano)	See Table 4-1
Basil (Balm leaves, mint, peppermint)	See Table 4-1
Bay leaves (laurel)	See Table 4-1
Tarragon (Hyssop)	See Table 4-1
Others	See Table 4-1
(vi) Legume vegetables (fresh)	0,02*
Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
Peas (with pods) (Mangetout (sugar peas))	0,02*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
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	See Table 4-1
Fennel	0,02*
Globe artichokes	See Table 4-1
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	See Table 4-1
Mustard seed	0,05*
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*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
Ginseng root	0,05*
Others	0,05*
(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*
Sugar cane	0,02*
Chicory roots	0,02*
Others	0,02*
10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
(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*

Groups and examples of individual products to which the MRLs apply (a)	Indoxacarb as sum of the isomers S and R (F)
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*
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	

Indoxacarb

Status of the active substance:	**included**	Code no.	**#N/A**
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:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Acute RA- HR Brussels sprouts - 0.04 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-0.11 mg/kg, peppers-0.02 mg/kg, aubergines-0.11 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

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
14	87
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)
86.8	DE child	42.2	Apples	12.7	Oranges	6.3	Table grapes	
72.4	NL child	22.2	Apples	10.4	Oranges	9.8	Milk and cream,	
54.5	FR toddler	13.2	Milk and cream,	9.2	Spinach	9.2	Apples	
47.5	WHO Cluster diet B	9.0	Wine grapes	5.7	Tomatoes	3.5	Apples	
40.7	IE adult	6.3	Wine grapes	3.5	Oranges	2.9	Apples	
39.5	UK Toddler	7.6	Sugar beet (root)	6.9	Milk and cream,	6.6	Oranges	
36.2	UK Infant	12.9	Milk and cream,	5.5	Apples	4.3	Oranges	
35.7	FR infant	8.8	Apples	8.6	Milk and cream,	5.8	Spinach	
32.2	FR all population	20.0	Wine grapes	1.7	Apples	1.1	Wheat	
29.7	ES child	7.2	Oranges	4.2	Milk and cream,	4.0	Apples	
29.4	WHO cluster diet E	8.0	Wine grapes	3.0	Apples	1.9	Head cabbage	
28.5	PT General population	12.4	Wine grapes	3.7	Apples	2.0	Oranges	
28.4	NL general	5.0	Oranges	4.1	Apples	3.1	Wine grapes	
27.9	SE general population 90th percentile	4.6	Head cabbage	4.1	Milk and cream,	3.7	Apples	
26.0	DK child	8.1	Apples	4.2	Milk and cream,	1.8	Wheat	
24.7	WHO regional European diet	3.3	Lettuce	2.7	Head cabbage	2.3	Apples	
23.5	WHO Cluster diet F	3.0	Wine grapes	2.9	Oranges	2.6	Lettuce	
23.2	ES adult	4.6	Lettuce	4.3	Oranges	2.7	Apples	
20.1	UK vegetarian	4.1	Wine grapes	2.9	Oranges	2.1	Apples	
20.0	WHO cluster diet D	2.3	Apples	2.2	Wheat	1.9	Tomatoes	
19.2	IT kids/toddler	3.1	Apples	2.6	Tomatoes	2.5	Lettuce	
17.6	IT adult	3.3	Lettuce	2.8	Apples	2.1	Tomatoes	
17.4	DK adult	7.0	Wine grapes	2.7	Apples	1.8	Milk and cream,	
17.4	UK Adult	5.4	Wine grapes	1.9	Oranges	1.4	Apples	
16.8	PL general population	7.2	Apples	2.7	Head cabbage	1.6	Tomatoes	
15.8	LT adult	6.5	Apples	2.9	Head cabbage	1.3	Milk and cream,	
13.5	FI adult	3.2	Oranges	1.9	Milk and cream,	1.5	Wine grapes	

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 variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0.3	Brussels sprouts	0.04 / -	0.3	Brussels sprouts	0.04 / -	0.2	Brussels sprouts	0.04 / -	0.2	Brussels sprouts	0.04 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
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 / -				1.6	Orange juice	0.2 / -			
7.9	Orange juice	0.2 / -				0.8	Tomato (preserved-	0.5 / -			
7.0	Tomato juice	0.5 / -				0.6	Raisins	2 / -			

*) 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

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
DAT	Days After Treatment
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ILV	Independent Laboratory Validation
IESTI	International Estimated Short Term Intake
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue
TMDI	Theoretical Maximum Daily Intake
WG	Wettable Granule