REASONED OPINION OF EFSA

Modification of the existing MRLs for indoxacarb in cherries and sugar beets[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00635)

Issued on 7 July 2009

SUMMARY

The Netherlands received an application from DuPont Danmark ApS to modify the existing MRLs for indoxacarb in cherries and sugar beets based on the new intended GAP in Italy. In order to accommodate for a new use of indoxacarb on these crops, the applicant proposes to raise the existing MRL of 0.02 mg/kg to 0.5 mg/kg in cherries and 0.1 mg/kg in sugar beets. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

EFSA derives the following conclusions regarding the application, based on the above mentioned 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 commodities of plant origin. The residue definition for risk assessment and enforcement is set as "indoxacarb (sum of *R* and *S* isomers)". Consequently, the MRL application for crops under consideration does not require additional metabolism studies. Analytical methods are available to enforce the proposed MRL in cherries and sugar beets.

Submitted supervised residue field trials indicate that the current MRLs of 0.02 mg/kg do not accommodate the intended GAPs in Italy and higher MRLs as proposed by the EMS (0.5 mg/kg for cherries and 0.1 mg/kg for sugar beet) would be necessary.

Since sugar beets can be grown in crop rotation, the occurrence of indoxacarb or its metabolites in rotational crops was also investigated. EFSA concluded that significant residue

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for indoxacarb in cherries and sugar beets. *EFSA Scientific Report* (2009) 324, 1-30

levels in rotational crops are not expected provided that indoxacarb is applied according to the proposed GAP.

The livestock dietary burden was calculated considering the existing MRLs for indoxacarb and the proposed MRL in sugar beets. The impact of sugar beets to the total livestock dietary burden is insignificant therefore the need to modify the existing MRLs for commodities of animal origin was not further investigated. It should be noted that indoxacarb MRLs will be reconsidered by EFSA in the framework of Article 12 (2) of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with the revision 2 of the EFSA PRIMo. For chronic intake assessment the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on cherries and sugar beet were use as input values. In addition, for several other crops the STMR values were available to refine the consumer intake calculations. Acute intake assessment was performed only with regard to cherries and sugar beets using the HR values as obtained for the intended use on these crops.

The chronic dietary intake calculations did not reveal any consumer intake concerns. The intake values ranged from 10 to 72% of the ADI. No acute intake risk was identified for crops under consideration.

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)			
Cherries	0.02*	0.5	The MRL proposals are supported by data and no risk for consumers was identified for the proposed uses. The MRL proposals are based on the Southern European use only.
Sugar beet	0.02*	0.1	

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

EFSA concludes that the proposed use of indoxacarb on cherries and sugar beets in Southern European Member Sates is sufficiently supported by data and no risk for consumer health was identified. It should, however, be mentioned that currently no information is available to EFSA if an application for the authorization of the use of indoxacarb has already been submitted in Italy.

Regarding 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.

Key words: Indoxacarb, cherries, sugar beet, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, indeno-oxadizine insecticide

TABLE OF CONTENTS

BACKGROUND

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

The Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from DuPont Danmark ApS[2] to modify the existing MRLs for indoxacarb in cherries and sugar beets. 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 29 May 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00635 and the following subject:

Indoxacarb - Application to set new MRLs for indoxacarb (sum of R and S isomers) in cherries at 0.5 mg/kg and in sugar beet (root) at 0.1 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.

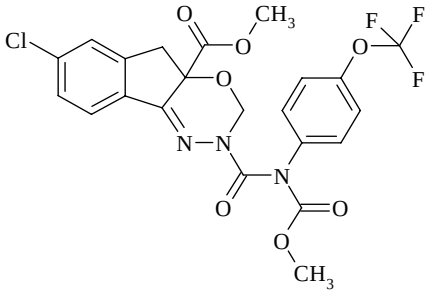
In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

[2] DuPont Danmark ApS, Sköjtevej 26, DK-2770, Kastrup, Danmark

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. 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.

Indoxacarb was peer reviewed under Directive 91/414/EEC and is included in the Annex I to this Directive by the Commission Directive 2006/10/EC which entered into force of 1 April 2006 for the use 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, grapes, brassica vegetables, stone fruit, fruiting vegetables and leafy vegetables. Indoxacarb was not peer reviewed by EFSA.

In the European Community the MRLs for indoxacarb were first set by Directive 2007/21/EC. After the entry into force of Regulation (EC) No 396/2005, the MRLs established under Directives 86/362/EEC and 90/642/EEC were transferred to Annex II to Regulation (EC) No 396/2005. In Annex III to the Regulation temporary MRLs were established for crops that were not covered by previous Community MRL legislation. The current MRLs are established in Annexes II and IIIB of the Regulation (EC) No 396/2005 and are summarized in Appendix B. For Brussels sprouts, raspberries and blackberries and certain small fruits and berries the MRL proposals were recently assessed by EFSA (EFSA, 2009a, 2009b, 2009c) and recommendations made by EFSA were voted in the SCoFCAH on 30 March 2009 and 3 July 2009. The current MRLs for cherries and sugar beet (roots) are set at the LOQ of 0.02 mg/kg. Codex Alimentarius has set CXLs for a wide range of commodities, but no CXLs are set for cherries and sugar beet. The MRLs for commodities of animal origin are set at the LOQ of 0.01 mg/kg, except 0.3 mg/kg for fat.

The GAP for which an authorization is requested in Italy refers to an outdoor application of the active substance on cherries (BBCH 69) 1-2 times at an application rate of 0.05-0.075 kg a.s./ha and on sugar beets (BBCH 39) 1-3 times at an application rate of 0.0375 kg a.s./ha. For both intended uses the minimum waiting period is 14 days. The details of the GAP can be found in Appendix A.

Currently no information is available to EFSA if an application for the authorization of use of indoxacarb has already been submitted in Italy.

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 were reported in the DAR 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. A modified DFG S19 method is also available being validated at 0.01 mg/kg for commodities with high acid, high water and high fat content.

The single residue method, using GC-MS, 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.

In addition, QuEChERS method is sufficiently validated at the LOQ of 0.01 mg/kg for the determination of indoxacarb in commodities with high acid, high water content and dry commodities.

It is concluded that adequate analytical methods are available for the enforcement of the proposed MRLs for commodities with high water content.

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

The availability of analytical methods for enforcement of residues in the foodstuffs of animal origin was not investigated as the uses supported in the framework of this application are not expected to affect the dietary burden of livestock to indoxacarb residues.

2. Mammalian toxicology

The toxicological reference values for indoxacarb have been reported in the DAR (The Netherlands, 2005) and are summarized in Table 2-1.

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

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

In addition, the Netherlands as the RMS reported that recently they have submitted a post-inclusion addendum to re-evaluate the ADI of indoxacarb. A new ADI of 0.01 mg/kg bw/day was suggested complying with the ADI which is set for indoxacarb by Codex Alimentarius Commission. Pending evaluation of proposed ADI, in the evaluation report as well as in the current EFSA opinion the ADI of 0.006 mg/kg bw/day is used.

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 of indoxacarb in plants 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

In support of the proposed GAP the applicant submitted five supervised residue field trials on cherries and seven supervised field trials on sugar beets. One additional trial on sugar beets evaluated by the EMS was disregarded since applications were made at much later growth stage (BBCH 77-85 instead of BBCH 39-49). The data on residue levels in sugar beet leaves are also available and were used to derive the input values for livestock dietary burden calculations. Most of residue trials were designed as decline studies. In one cherry trial the residue levels within a trial were higher at longer PHI (21 day) and this value was included n the database for deriving the MRL proposal. EFSA also calculated an MRL proposal for sugar beet leaves, which should be considered if MRLs will be set in the future for feed items.

Trials data are summarized in Table 3-1.

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 of indoxacarb 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. Before analysis the supervised field trial samples of cherries and sugar beets were stored deep frozen for 8 and 9 months respectively, meaning that the demonstrated storage stability period of indoxacarb was not exceeded.

Analytical methods used for analyzing supervised field trial samples are considered 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 [(d)]	Comments
			Enforcement	Risk assessment					
Indoxacarb (sum of *R* and *S* isomers)									
Cherries	SEU	Outdoor	0.10; 0.12; 0.15; 0.18; 0.3*	0.10; 0.12; 0.15; 0.18; 0.3*	0.15	0.3	0.5	1.0	Rber=0.48 mg/kg Rmax=0.5 mg/kg
Sugar beet roots	SEU	Outdoor	2 x <0.01; 0.013; 0.026; 0.031; 0.04; 0.06	2 x <0.01; 0.013; 0.026; 0.031; 0.04; 0.06	0.026	0.06	0.1	1.0	Rber=0.08 mg/kg Rmax=0.09 mg/kg
Sugar beet leaves	SEU	Outdoor	0.16; 0.21; 0.33; 0.41; 0.69; 0.83*; 0.99	0.16; 0.21; 0.33; 0.41; 0.69; 0.83*; 0.99	0.41	0.99	2.0	1.0	Rber=1.7 mg/kg Rmax=1.6 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 residue value was obtained from longer PHI of 21 day

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 positions in the molecule, 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 cherries and such are not considered necessary since the contribution of cherries to the total dietary intake is low. Even though it is not expected that residues in sugar beet will result in measurable residues in sugar, a sugar beet processing study is recommended.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Sugar beet can be grown in crop rotation. 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 37.5 g a.s./ha on sugar beets, indoxacarb residues are not expected in rotational crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden

According to the EU Guidance document on livestock feeding studies Appendix G (Document 7031/VI/95 rev.4), sugar beet are potential feed item for chicken, dairy ruminants, meat ruminants and pig (European Commission, 1996).

The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator. For sugar beet leaves and roots the input values were as obtained from the supervised residue field trials (Table 3-1). Commodities for which the MRL values

are set above the LOQ in the Regulation (EC) No 396/2005 and which are potential livestock feed input values were considered in these calculations, e.g., apples, head cabbage, kale and soya bean. Other commodities that might be used as feed items but for which the existing MRLs are set at the LOQ were not considered in the calculation. The input values are summarized in Table 3-2.

Table 3-2. **Input values for the dietary burden calculation**

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: indoxacarb, sum of *R* and *S* isomers				
Sugar beet root	0.03	STMR	0.06	STMR
Sugar beet leaves	0.41	STMR	1.0	STMR
Apple pomace	0.74	P-STMR (The Netherlands, 2006a)	0.74	P-STMR (The Netherlands, 2006a)
Cabbage	0.44	STMR (The Netherlands, 2006a)	2.7	HR (The Netherlands, 2006a)
Kale	0.05	STMR (Germany, 2006)	0.13	HR (Germany, 2006)
Soya bean	0.027	STMR(The Netherlands, 2006a)	0.45	HR (The Netherlands, 2006a)
Soya bean meal	0.027	STMR (The Netherlands, 2006a)	0.027	STMR (The Netherlands, 2006a)

In order to estimate the contribution of sugar beets to the total livestock dietary burden, EFSA first performed dietary burden calculations for all commodities excluding sugar beet (Table 3-3) and compared them to the second dietary burden calculation, which was performed including sugar beet (Table 3-4).

Table 3-3. **Results of the dietary burden calculation (excluding sugar beet)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Intake of residues (mg/kg/DM)	Dietary burden triggered?
Risk assessment residue definition: Indoxacarb, sum of *R* and *S* isomers					
Dairy ruminants	0.2459	0.0403	Cabbage	6.76	Yes
Meat ruminants	0.2897	0.0476	Cabbage	6.76	Yes
Poultry	0.0611	0.0101	Cabbage	0.97	Yes
Pigs	0.1160	0.0191	Cabbage	2.89	Yes

Table 3-4. **Results of the dietary burden calculation (including sugar beet)**

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Intake of residues (mg/kg/DM)	Dietary burden triggered?
Risk assessment residue definition: Indoxacarb, sum of *R* and *S* isomers					
Dairy ruminants	0.2491	0.0420	Cabbage	6.85	Yes
Meat ruminants	0.2971	0.0511	Cabbage	6.93	Yes
Poultry	0.0649	0.0120	Cabbage	1.03	Yes
Pigs	0.1232	0.0294	Sugar beet leaves	3.08	Yes

The calculated dietary burdens in both cases exceed the trigger value of 0.1 mg/kg DM for all relevant livestock species, but are mainly driven by the existing MRLs for cabbage. Adding sugar beet leaves increases the livestock residue intake for a maximum of 7%. The current MRLs for animal commodities are supposed to reflect the residues in feed (excluding sugar beets) and the additional dietary burden related to sugar beet leaves and roots would not significantly change the MRL values, therefore the modification of the existing MRLs in food of animal origin was not further investigated in the framework of this application.

Nevertheless, a full risk assessment of indoxacarb MRLs will be performed by EFSA in the framework if Article 12 (2) of the Regulation (EC) No 396/2005.

4. Consumer risk assessment

The consumer risk assessment is performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For chronic intake assessment the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on cherries and sugar beet were use as input values. In addition, for several crops the STMR values were used as obtained in the previously issued EFSA reasoned opinions on the modification of the existing MRLs for indoxacarb (EFSA, 2009a, 2009b, 2009c). EFSA also 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.

Acute intake assessment was performed only with regard to cherries and sugar beets using the HR values as obtained for the intended use on these crops.

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)				
Cherries	0.15	STMR	0.3	HR
Sugar beet (root)	0.03	STMR	0.06	HR

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Blueberries, cranberries, rose hips, mulberries, azarole, elderberries	0.11	STMR (EFSA, 2009c)	The acute risk assessment was performed only with regard to cherries and sugar beets.	
Raspberries, blackberries	0.26	STMR (EFSA, 2009b)		
Brussels sprouts	0.02	STMR (EFSA, 2009a)		
Apples	0.21	STMR (The Netherlands, 2006a)		
Pears, quinces, medlar, loquat	0.10	STMR(The Netherlands, 2006a)		
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)		
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 calculations can be found in Appendix C.

The chronic dietary intake calculations did not reveal any consumer intake concerns. The calculated total intake values ranged from 10 to 72% of the ADI. The estimated long term exposure amounted for up to 0.8% and 11% of the ADI for cherries (DE child diet) and sugar beets (UK Toddler diet) respectively.

No acute intake risk was identified for cherries (2.9% of the ARfD) and sugar beet (3.1% of the ARfD).

EFSA concludes that the intended use of indoxacarb on cherries and sugar beet is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

The Netherlands received an application from DuPont Danmark ApS to modify the existing MRLs for indoxacarb in cherries and sugar beets based on the new intended GAP in Italy. In order to accommodate for a new use of indoxacarb on these crops, the applicant proposes to raise the existing MRL of 0.02 mg/kg to 0.5 mg/kg in cherries and 0.1 mg/kg in sugar beets. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

EFSA derives the following conclusions regarding the application, based on the above mentioned 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 commodities of plant origin. The residue definition for risk assessment and enforcement is set as "indoxacarb (sum of *R* and *S* isomers)". Consequently, the MRL application for crops under consideration does not require additional metabolism studies. Analytical methods are available to enforce the proposed MRL in cherries and sugar beets.

Submitted supervised residue field trials indicate that the current MRLs of 0.02 mg/kg do not accommodate the intended GAPs in Italy and higher MRLs as proposed by the EMS (0.5 mg/kg for cherries and 0.1 mg/kg for sugar beet) would be necessary.

Since sugar beets can be grown in crop rotation, the occurrence of indoxacarb or its metabolites in rotational crops was also investigated. EFSA concluded that significant residue levels in rotational crops are not expected provided that indoxacarb is applied according to the proposed GAP.

The livestock dietary burden was calculated considering the existing MRLs for indoxacarb and the proposed MRL in sugar beets. The impact of sugar beets to the total livestock dietary burden is insignificant therefore the need to modify the existing MRLs for commodities of animal origin was not further investigated. It should be noted that indoxacarb MRLs will be reconsidered by EFSA in the framework of Article 12 (2) of Regulation (EC) No 396/2005.

The consumer risk assessment was performed with the revision 2 of the EFSA PRIMo. For chronic intake assessment the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on cherries and sugar beet were use as input values. In addition, for several other crops the STMR values were available to refine the consumer intake calculations. Acute intake assessment was performed only with regard to cherries and sugar beets using the HR values as obtained for the intended use on these crops.

The chronic dietary intake calculations did not reveal any consumer intake concerns. The intake values ranged from 10 to 72% of the ADI. No acute intake risk was identified for crops under consideration.

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)			
Cherries	0.02*	0.5	The MRL proposals are supported by data and no risk for consumers was identified for the proposed uses. The MRL proposals are based on the Southern European use only.
Sugar beet	0.02*	0.1	

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

EFSA concludes that the proposed use of indoxacarb on cherries and sugar beets in Southern European Member Sates is sufficiently supported by data and no risk for consumer health was identified. It should, however, be mentioned that currently no information is available to EFSA if an application for the authorization of the use of indoxacarb has already been submitted in Italy.

Regarding 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.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for indoxacarb in cherries and sugar beet prepared by The Netherlands under Regulation (EC) No 396/2005. Submitted to EFSA on 29 May 2009.

REFERENCES

European Commission, 2005. SANCO/1408/2001-rev3. Review report for the active substance indoxacarb.

European Commission, 1996. Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.

EFSA, 2009a. 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.

EFSA, 2009b. Reasoned Opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for indoxacarb in raspberries and blackberries. EFSA Scientific Report (2009) 246, 1-23.

EFSA, 2009c. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for indoxacarb in certain small fruits and berries. *EFSA Scientific Report* (2009) 275324, 1-26

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 (a)	Country and/or region	Product name	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d - f)	Conc. of as (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Cherry	IT	DPX MP06230 WG	F	*A. orana* *Archips spp.*	WG	30%	High pressure mist blower	BBCH 69	1-2 (interval 10-14d)	5.0 g/hl when > 1000 li water/ha	500-1500	0.050-0.0750	14	
Sugar beet	IT	DPX MP06230 WG	F	*S. exigua* *H. armigera* *M. brasicae*	WG	30%	High pressure mist blower	BBCH 39	1-3	0.005-0.0125	300-700	0.0375	14	

(a) For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and 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 plants - 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) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

APPENDIX B – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,3
130030	Quinces	0,3
130040	Medlar	0,3
130050	Loquat	0,3
130990	Others	0,3
140000	(iv) Stone fruit	
140010	Apricots	0,3
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,3
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02* [0.5][a]
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,02*
153030	Raspberries (Wineberries)	0,02* [0.5][a]
153990	Others	0,02*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*[1.0][a]
154020	Cranberries	0,02*
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	0,02*[1.0][a]
154060	Mulberries (arbutus berry)	0,02*[1.0][a]
154070	Azarole (mediteranean medlar)	0,02*[1.0][a]

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*[1.0][a]
154990	Others	0,02*[1.0][a]
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,2
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,2
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,5
231020	Peppers (Chilli peppers)	0,3
231030	Aubergines (egg plants) (Pepino)	0,5
231040	Okra, lady s fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,2
232010	Cucumbers	0,2
232020	Gherkins	0,2
232030	Courgettes (Summer squash, marrow (patisson))	0,2
232990	Others	0,2
233000	(c) Cucurbits-inedible peel	0,1
233010	Melons (Kiwano)	0,1
233020	Pumpkins (Winter squash)	0,1
233030	Watermelons	0,1
233990	Others	0,1
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,3
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,3
241020	Cauliflower	0,3
241990	Others	0,3
242000	(b) Head brassica	
242010	Brussels sprouts	0,02* [0.1][a]
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	3
242990	Others	0,02*
243000	(c) Leafy brassica	

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,2
243020	Kale (Borecole (curly kale), collards)	0,2
243990	Others ( )	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	1
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	2
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	1
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens	2
	(turnip tops))	
252020	Purslane (Winter purslane (miner s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	2
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	2
256010	Chervil	2
256020	Chives	2
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	2
256040	Parsley	2
256050	Sage (Winter savory, summer savory,)	2
256060	Rosemary	2
256070	Thyme (marjoram, oregano)	2
256080	Basil (Balm leaves, mint, peppermint)	2
256090	Bay leaves (laurel)	2
256100	Tarragon (Hyssop)	2
256990	Others	2
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean,	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
	slicing bean, yardlong beans)	
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	2
270040	Fennel	0,02*
270050	Globe artichokes	0,1
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild Chanterelle, Truffle, Morel ,)	0,02*
280990	Others	0,02*
290000	(ix). Sea weeds	
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
	peas, chickling vetch)	
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,5
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	0,02*
500010	Barley	0,02*
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,02*
500990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horse-radish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,3
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	
1012010	Meat	0,01*
1012020	Fat	0,3
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	
1013010	Meat	0,01*
1013020	Fat	0,3
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	
1014010	Meat	0,01*
1014020	Fat	0,3
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	0,01*
1015020	Fat	0,3
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0,01*
1016020	Fat	0,3
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,01*
1017020	Fat	0,3
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02 (ft)
1020010	Cattle	0,02
1020020	Sheep	0,02
1020030	Goat	0,02
1020040	Horse	0,02

Code number	Groups and examples of individual products to which the MRLs apply	Indoxacarb as sum of the isomers S and R
1020990	Others	0,02
1030000	(iii) Birds eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

[a]- MRL proposals as voted in the SCoFCAH on 30 April 2009 and 3 July, but not adopted in legislation by 7 July 2009.

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

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**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	10 72
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)
72.3	DE child	42.2	Apples	6.3	Table grapes	4.8	Milk and cream,	
61.3	NL child	22.2	Apples	9.8	Milk and cream,	4.8	Spinach	
45.2	FR toddler	13.2	Milk and cream,	9.2	Spinach	9.2	Apples	
45.0	WHO Cluster diet B	9.0	Wine grapes	5.7	Tomatoes	3.5	Apples	
35.9	UK Toddler	11.4	Sugar beet (root)	6.9	Milk and cream,	6.0	Apples	
33.2	IE adult	6.3	Wine grapes	2.9	Apples	1.8	Celery	
32.9	UK Infant	12.9	Milk and cream,	5.5	Apples	5.0	Sugar beet (root)	
30.7	FR infant	8.8	Apples	8.6	Milk and cream,	5.8	Spinach	
30.3	FR all population	20.0	Wine grapes	1.7	Apples	1.1	Wheat	
28.3	WHO cluster diet E	8.0	Wine grapes	3.0	Apples	1.9	Head cabbage	
26.2	PT General population	12.4	Wine grapes	3.7	Apples	1.8	Potatoes	
25.3	DK child	8.1	Apples	4.2	Milk and cream,	1.8	Wheat	
24.3	WHO regional European diet	3.3	Lettuce	2.7	Head cabbage	2.3	Apples	
23.8	ES child	4.2	Milk and cream,	4.0	Apples	3.6	Lettuce	
23.3	SE general population 90th percentile	4.6	Head cabbage	4.1	Milk and cream,	3.7	Apples	
23.2	NL general	4.1	Apples	3.1	Wine grapes	2.2	Milk and cream,	
20.7	WHO Cluster diet F	3.0	Wine grapes	2.6	Lettuce	2.3	Apples	
20.1	WHO cluster diet D	2.3	Apples	2.2	Wheat	1.9	Tomatoes	
19.6	ES adult	4.6	Lettuce	2.7	Apples	2.1	Wine grapes	
17.4	UK vegetarian	4.1	Wine grapes	2.1	Apples	1.9	Sugar beet (root)	
16.7	IT kids/toddler	3.1	Apples	2.6	Tomatoes	2.5	Lettuce	
16.7	DK adult	7.0	Wine grapes	2.7	Apples	1.8	Milk and cream,	
16.5	PL general population	7.2	Apples	2.7	Head cabbage	1.6	Tomatoes	
16.5	LT adult	6.5	Apples	2.9	Head cabbage	1.3	Milk and cream,	
16.0	IT adult	3.3	Lettuce	2.8	Apples	2.1	Tomatoes	
15.8	UK Adult	5.4	Wine grapes	2.0	Sugar beet (root)	1.4	Apples	
10.0	FI adult	1.9	Milk and cream,	1.5	Wine grapes	1.4	Apples	

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)
3.1	Sugar beet (root)	0.06 / -	3.1	Sugar beet (root)	0.06 / -	1.2	Sugar beet (root)	0.06 / -	1.2	Sugar beet (root)	0.06 / -
2.9	Cherries	0.3 / -	2.9	Cherries	0.3 / -	1.0	Cherries	0.3 / -	1.0	Cherries	0.3 / -
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 / -
12.8	Elderberry juice	1 / -		0.8	Tomato (preserved-	0.5 / -
8.1	Cuurant juice	1 / -		0.6	Raisins	2 / -
7.0	Tomato juice	0.5 / -		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
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
EC	European Community
ECD	electron capture detection
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State

SCoFCAH	Standing Committee on Food Chain and Animal Health
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation