

The review of the existing MRLs for indoxacarb

UK Competent Authority Draft Reasoned Opinion

■ Prepared under Article 12 of Assimilated Regulation 396/2005

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DRAFT

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Summary

This assessment is a draft only and outlines proposed recommendations for the MRLs for the active substance indoxacarb.

According to Article 12 of Assimilated Regulation 396/2005,¹ HSE as a competent authority has reviewed the Maximum Residue Levels (MRLs) currently established in Great Britain (GB) for the pesticide indoxacarb. The review of the MRLs has been undertaken following the non-approval decision of indoxacarb and the withdrawal of all plant protection authorisations in GB. The non-approval decision was delivered following an Article 21(1) review, in which it was concluded that indoxacarb failed to meet the approval criteria as regards Art. 4(3)(b) of Assimilated Regulation 1107/2009.² The following reason was presented for the decision: 'Unacceptable risk to operators, workers, resident, and bystanders from the representative uses'.

Based on the review of the MRLs, HSE prepared a Reasoned Opinion (RO). HSE took into account the DAR (Draft Assessment Report) related to the approval in GB and the Article 21 Review undertaken by HSE. The Article 21 Review took into account the EU RAR (Renewal Assessment Report), the dossier for which was available to HSE, and EFSA Conclusion on the renewal (2018) and therefore these assessments have also been considered for the MRL Review.

Indoxacarb does not meet the requirements outlined in the guidance document SANCO/11188/2013, rev 2 September 2015 and therefore it is not suitable for inclusion in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of indoxacarb in plant commodities, in line with the enforcement residue definition for products of plant origin, are available to support the crop groups considered in the MRL review; an LOQ of 0.01* mg/kg is achievable for all commodity types, this change will be reflected in the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of indoxacarb in animal commodities, in line with the enforcement residue definition for products of animal origin (POAO), are available for all POAO.

¹ [Assimilated Regulation 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#)

² [Assimilated Regulation 1107/2009 concerning the placing of plant protection products on the market](#)

Toxicological reference values were established in the GB review of the approval of indoxacarb: an ADI of 0.005 mg/kg bw/day and an ARfD of 0.005 mg/kg bw.

The metabolism of indoxacarb in primary crops was investigated in fruit and fruiting vegetables (grapes and tomatoes), pulses and oilseeds (cotton) and leafy crops (lettuce) following foliar applications for the approval of the active substance (DAR, 2000). The available information is sufficient to cover the crops considered in this MRL review.

The residue definition for enforcement and risk assessment (RD-Enf and RD-RA) in plants is recommended as:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

Hydrolysis of indoxacarb under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that indoxacarb is stable under standard pasteurisation conditions; however, a number of metabolites (IN-KT413, IN-MP819, IN-MK638, IN-P0036 and IN-TMG00) are formed under standard sterilisation conditions. It is possible that the metabolite 'IN-KT413' may also form under standard baking, brewing and boiling conditions.

IN-P0036 is covered by the toxicological reference values established for indoxacarb; potential exposure to this metabolite is covered by the full consumer risk assessment conducted in section 7.

The genotoxic potential of IN-KT413, IN-MP819, and IN-TMG00 were considered for the EU renewal of the active substance, these compounds were considered unlikely to be genotoxic. As noted, the renewal assessment including all relevant studies were made available to HSE. The genotoxic potential of IN-MK638 has been considered in the framework of the current evaluation. All metabolites are considered unlikely to be genotoxic as a result of QSAR/read across data.

The Cramer Class III TTC value of 1.5 µg/kg bw/d and the acute threshold value of 5 µg/kg bw are considered applicable for IN-KT413, IN-MP819, IN-MK638, IN-TMG00. The potential exposure to the above metabolites through consumption of processed commodities was assessed. A worst case assessment was conducted, assuming that all exposure to indoxacarb is via the consumption of processed commodities. The estimated chronic and estimated acute exposures are lower than the thresholds and therefore no harmful effects on human health are expected.

In addition, a number of metabolites were considered for inclusion in the RD-RA for animal commodities. HSE has reviewed the data submitted for the renewal of the active substance: 5-OH-indoxacarb (free and conjugated), IN-JT333, IN-MN470, and IN-MF014. HSE agrees with the EFSA conclusion (EFSA, 2018) and has concluded that sufficient information is available to conclude that these metabolites are unlikely to be genotoxic, HSE recommends that the TTC Cramer Class III and acute threshold values apply to these metabolites.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that residues in rotational crops are expected to be <0.01 mg/kg for all crops at PBIs of 90 and 125 days and specific residue definitions for rotational crops are not required. There were some deficiencies noted in the studies, relating to poor metabolite identification, and the lack of consideration of soil plateau concentrations in light of the potential persistence of indoxacarb and several soil metabolites. Nonetheless, the available information is sufficient to conclude that the proposed MRLs are unlikely to be affected by possible uptake from soil residues.

A dietary burden (DB) was calculated based on the MRLs which are recommended for plant commodities, and which may be imported as feed items. The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for poultry and mammalian species. Metabolism of indoxacarb in ruminants was considered for the approval of the active substance and, for poultry, during the Article 12 review (DAR, 2000 and EFSA, 2011). The approval assessment concluded that the metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs.

The residue definition for risk assessment for poultry was tentative, and two supplementary requirements were included in the GB MRL Statutory register for poultry commodities:

Supplementary requirement 1

- *Further information on the nature and occurrence of the metabolite F that was encountered in poultry*

Supplementary requirement 2

- *Storage stability data for eggs*

Additional data was provided for the EU renewal of the active substance demonstrating acceptable storage stability in eggs. No further information was made available for metabolite 'F'.

Supplementary requirement 2 is considered addressed, and HSE recommends the footnotes is deleted from the GB Statutory Register. Supplementary requirement 1 is addressed for all poultry matrices except for poultry fat.

HSE has reconsidered the residue definitions for animal commodities in view of the expected occurrence of the compounds based on the metabolism and feeding studies, and the available toxicological information.

As such, HSE recommends the following residue definitions for poultry as outlined below:

Proposed residue definition for risk assessment in poultry (excluding fat):

- Indoxacarb (and its R-enantiomer)

Proposed residue definitions for risk assessment in poultry fat:

- Indoxacarb (and its R-enantiomer)
- Metabolite F (provisional pending additional information to allow formal identification, as well as relevant toxicological information and/or feeding studies to elucidate its occurrence)

Proposed residue definition for enforcement in poultry:

- Indoxacarb (and its R-enantiomer)

All GB MRLs are currently set at the LOQ (0.01* mg/kg) for poultry; on the basis of the calculated DB, this is considered sufficiently protective. Further information on metabolite F is required if a higher MRL is requested in future.

On the basis that the current MRLs are set at the LOQ, HSE recommends that supplementary requirement 1 is also deleted from the GB Statutory Register.

For mammals, based on the available metabolism data, feeding studies, and calculated DB, as well as the relative toxicity of the observed metabolites, HSE recommends the following residue definitions for mammals as outlined below:

Proposed residue definition for risk assessment in ruminant tissues, and enforcement definition in ruminant tissues and milk:

- Indoxacarb (and its R-enantiomer)

Proposed residue definition for risk assessment in milk:

1. Indoxacarb (and its R-enantiomer)

2. IN-MP819 (provisional – pending additional toxicological information; and/or feeding studies which elucidate its occurrence)

Based on the current GB MRL, exposure to IN-MP819 exceeds the TTC CCIII chronic threshold value. In the absence of specific toxicological information, HSE recommends that the MRL for milk is set at 0.01* mg/kg and this will ensure residues of the metabolite will also be <0.01* mg/kg.

It is noted that the current GB MRL for mammalian muscle (2 mg/kg) is set based on the CXL for meat – as indoxacarb is fat soluble, the CXL for meat was based on the residue levels in fat. As the GB MRL for muscle is set independently of residues in fat, it is appropriate to recalculate the GB MRL on a muscle only basis. This results in an MRL (CXL) of 0.05 mg/kg. The STMR/HR used in the consumer risk assessment (all scenarios) are already based on the 80/20 muscle/fat ratio for meat.

In order to set a substantive MRL for milk, additional toxicological data and feeding studies for the metabolite are required.

The above residue definitions may require further consideration with regards to possible metabolites if the dietary burden increases in future. At present, the above residue definitions are suitable for risk assessment and enforcement in animal commodities imported into GB. Should the above residue definitions require further consideration in future, further toxicological data may be required on a number of metabolites. The consumer risk assessments have been undertaken for three different scenarios. Based on the outcome of the refined consumer risk assessments in scenario 3, HSE recommends that a number of MRLs are retained, and that several CXLs are adopted. All other MRLs should be set at the LOQ.

For the retained MRLs and CXLs: The highest UK NEDI was 56% of the ADI (toddler). The highest PRIMo IEDI was 35% of the ADI (NL toddler).

The highest UK NESTI was 17% of the ARfD (infant/pears). The highest IESTI was 28% of the ARfD (child/pears). Therefore, on the basis of the lowered MRLs for a number of commodities, and the adoption of several CXLs, no health effects due to chronic or acute exposure are expected from the consumption of commodities treated with indoxacarb.

A number of the current MRLs for plant commodities have a footnote relating to missing information. No information has been provided for these commodities; however, an acute risk was identified for all affected commodities, as such, HSE recommends that the footnotes are deleted from the GB Statutory Register when the MRLs are set at the LOQ.

The MRLs proposed by HSE are outlined in Table 8.1.

Proposed Recommendations

The MRLs considered within this review, including the CXLs, will not result in consumer exposures exceeding the toxicological reference values. Therefore, harmful effects on human health are not expected. The appropriate level of protection has been met.

The MRLs proposed by HSE are outlined in Table 8.1.

The MRLs should be established on the basis of the following residue definitions:

The residue definition for enforcement (RD-Enf) in plants:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

The residue definition for enforcement (RD-Enf) in animals:

- Indoxacarb (and its R-enantiomer)

The MRLs outlined specifically in Table 0.1 are not fully supported by data. Therefore, HSE recommends that supplementary information is provided within 5 years to support their continued validity; the final data submission deadline should be confirmed in the GB MRL Statutory Register.

Supplementary information requirements for indoxacarb MRLs

The MRLs outlined in Table 0.1 are not fully supported and therefore MRL supplementary information is required.

Table 0.1 MRLs for indoxacarb for which supplementary information is required

Product code	Product	Proposed GB MRL requiring supplementary information (mg/kg)	Proposed MRL if supplementary information is not provided to support the current MRL or an alternative MRL (mg/kg)
0152000	Strawberries	0.6	0.01*
0153030	Raspberries	0.6	0.01*
0154030	Currants (black, red and white)	0.8	0.01*
0154040	Gooseberries (green, red and yellow)	0.8	0.01*

0145060	Mulberries (black and white)	0.8	0.01*
0154070	Azaroles/Mediterranean medlars	0.8	0.01*
0154080	Elderberries	0.8	0.01*
0154990	Others - Other small fruit and berries	0.8	0.01*
0213080	Radishes	0.4	0.01*
0242010	Brussels sprouts	0.06	0.01*
0242020	Head cabbage	0.2	0.01*
0251040	Cresses and other shoots and sprouts	1	0.01*
0251050	Land cresses	1	0.01*
0251070	Red mustards	1	0.01*
0251990	Others – lettuces and other salad plants	1	0.01*
0252020	Purslanes	1	0.01*
0252990	Others – spinaches and similar leaves	1	0.01*
0256000	Herbs and edible flowers	2	0.02*
0260010	Beans with pods	0.5	0.01*
0270050	Globe artichokes	0.2	0.01*
0401080	Mustard seeds	0.05	0.01*
0900010	Sugar beet roots	0.1	0.01*

In accordance with the approaches of international organisations (for example JMPR/CCPR) residue trials data and use patterns should be available to support MRLs. Therefore, in principle the MRLs for the commodities outlined in Table 0.1 should be lowered to the LOQ. In addition, it is important to note that as there is no information on a use pattern and residues data then all aspects of the risk assessment have not been addressed (for example data to address levels in processed commodities) and it has not been confirmed that the appropriate level of protection has been met.

However, the consumer risk assessments undertaken on the basis of the MRL do not lead to exceedances of the TRVs. In particular for each MRL the NESTIs and IESTIs are $\leq 75\%$ of the ARfD for the majority of the retained MRLs. For strawberries, currants (black, red and white), radishes, head cabbage, sugar beet the NESTIs and/or IESTIs are $>75\%$ of the ARfD but $<100\%$ of the ARfD.

On this basis HSE recommends that these MRLs are retained for a period of five years. However, to confirm the MRLs required and confirm that the appropriate level of protection has been met, information on a use pattern and residues data should be provided, including any additional data required to support the risk assessment (for example analytical methods, rotational crop data, storage stability data, processing data). The full list of MRL supplementary information required for each MRL is outlined below. If the MRL supplementary information is not provided or is not sufficient then the MRLs will be lowered to the LOQ.

HSE identified that the MRLs for the commodities listed in table 0.1, are not fully supported by residue trials data. To support these MRLs appropriate information and data must be submitted to HSE. This must include:

- (a) the GAP
- (b) evidence of an authorisation
- (c) Residue trials data complying with the GB extrapolation document ([Technical guidance for the extrapolation of residue trials for plants and residues data for products of animal origin to support the authorisation of PPP and setting of MRLs in Great Britain - Pesticides - HSE](#)) and the OECD guidance/guidelines.
- (d) Additional data, where appropriate, to fully support the MRL and risk assessment (for example a validated analytical method, storage stability data, processing data)

HSE recommends the supplementary information is provided within 5 years of the data of adoption of the new MRLs.

This data is currently necessary to meet existing regulatory requirements. Potential changes to the regulatory regime may impact its relevance and applicability. Consequently, any data generated now may not align with future requirements.

Notification of the proposed MRLs

To meet the UK's international trade obligations, consultation on the proposed MRLs, outlined in this draft RO, is also being conducted by notifying the measures to the World Trade Organization (WTO). The WTO/SPS notification can be found at the following link and searching for indoxacarb and United Kingdom as the notifying member:

[Home - ePing SPS&TBT platform \(wto.org\)](#)

- **There may be a delay between publication of this draft RO and the notification appearing in the Sanitary and Phytosanitary Information Management System**
- **The notification includes the proposed date of adoption/publication and the proposed date of entry in force of the new MRLs.**

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Background

Article 12 of Assimilated Regulation 396/2005 requires the GB Competent authority to undertake a review of the Maximum Residue Levels (MRLs).

A non-approval decision ³ was taken for indoxacarb on 28 June 2024, with the expiry date of approval being brought forward to 31 August 2024 and a final use date for pesticide products in GB of 28 February 2026. The non-approval decision was delivered following an Article 21(1) review, in which it was concluded that indoxacarb failed to meet the approval criteria as regards Art. 4(3)(b) of Assimilated Regulation 1107/2009. The following reason was presented for the decision: 'Unacceptable risk to operators, workers, resident, and bystanders from the representative uses'. A number of dietary exposure concerns were also noted in the Article 21(1) review for the short-term dietary intakes for the following commodities: pears, apples, sweet peppers, cauliflowers and cucumbers.

HSE therefore initiated a review of the current MRLs taking into account the assessment report from the current approval for GB and the GB review under Article 21. The Article 21 Review took into account the EU RAR (Renewal Assessment Report) and EFSA Conclusion on the renewal (2018) and therefore these assessments have also been considered for the MRL review, noting that HSE undertook an independent and objective review of the current scientific and technical knowledge available to support the GB MRLs.

As outlined in Article 12 (3) of Assimilated Regulation 396/2005 the following points have been considered within this review:

- The existing MRLs for indoxacarb are set out in Part 2 or 3 of the GB MRL Statutory Register
- The necessity of setting a new MRL for indoxacarb, or its inclusion in Part 4 of the MRLs register
- Specific processing factors as referred to in Article 20(2) that may be needed for indoxacarb
- MRLs which the competent authority may consider including in Part 2 or 3 of the MRLs register and those MRLs related to indoxacarb which may be deleted

³ [Indoxacarb - decision to withdraw approval](#)

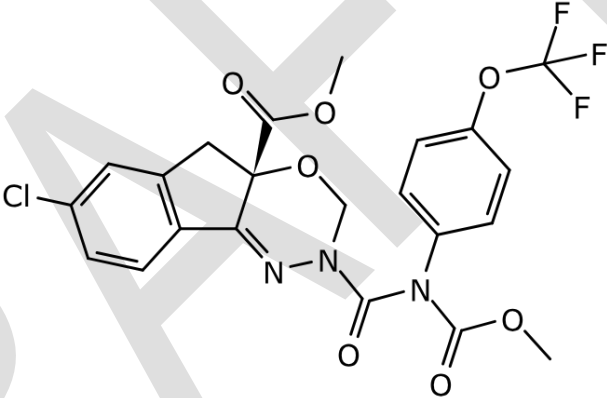
This review is the basis of HSE's draft reasoned opinion. HSE recommends the retention of a number of MRLs, and adoption of the CXLs for beans (dry), maize/corn, peanuts and tree nuts. All other MRLs should be set at the LOQ.

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The active substance and its use pattern

Information on the active substance indoxacarb is outlined in Table 0.2.

Table 0.2 Information on the active substance

Common name (ISO)	Indoxacarb
Chemical name (IUPAC)	Methyl (S)-N-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)indeno[1,2-e][1,3,4]oxadiazin-2-ylcarbonyl]-40-(trifluoromethoxy)carbanilate or methyl (S)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl(4-trifluoromethoxyphenyl)carbamoyl]indeno[1,2-e][1,3,4]oxadiazine-4a-carboxylate
CAS number	173584-44-6
Structural formula	 The chemical structure of Indoxacarb is a complex molecule. It features a central indeno[1,2-e][1,3,4]oxadiazine core. A 7-chlorophenyl group is attached to the indene ring. The oxadiazine ring is substituted with a methoxycarbonyl group at the 4a-position and a carbonyl group at the 2-position. This carbonyl group is part of a carbamate linkage to a 4-(trifluoromethoxy)phenyl group. The trifluoromethoxy group is represented as a phenyl ring with a -OCF₃ group at the para position. The entire molecule is shown in a skeletal structure with stereochemistry indicated at the chiral center.
Molecular formula	C ₂₂ H ₁₇ ClF ₃ N ₃ O ₇
Molecular mass	527.84 g/mol

Indoxacarb is not an approved active substance in GB. A DAR (Draft Assessment Report), the Netherlands 2000, supporting the current approval is available as is an Article 21 review of the current approval (GB, 2022). The Article 21 Review took into account the EU RAR (Renewal Assessment Report) and EFSA Conclusion on the renewal (2018) and therefore these assessments have also been considered for the MRL review, noting that HSE undertook an independent and objective review of the current scientific and technical knowledge available to support the GB MRLs.

MRLs are established for indoxacarb in Part 2 of the GB MRL Statutory Register.

Indoxacarb is an insecticide. It was authorised for use on a range of crops as a foliar spray in both field and protected structures.

Appendix A outlines the GAPs (Good Agricultural Practices) considered in this review.

The following CXLs are available for indoxacarb (Codex Pesticide Residues in food online database). A number of CXLs were adopted by the 46th session of the Codex Alimentarius Commission (CAC); these are also presented table 0.3 and have been considered for adoption as GB MRLs in the current review.

Table 0.3 CXLs for indoxacarb

Codex commodity description	GB commodity description (code)	CXL (mg/kg)	Comments	Year of adoption of CXL
Apple	Apples (0130010)	0.5	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2006
Broccoli	Broccoli (0241010)	0.2	The CXL is lower than the current GB MRL of 0.3 mg/kg, an acute intake concern was identified for the current GB MRL (scenario 1) and for the lower CXL (scenario 2); the CXL cannot be recommended for adoption.	2006
Bushberries, subgroup of	Blueberries (0154010)	2	The CXL is higher than the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2023
Bushberries, subgroup of	Currants (black, red and white) (0154030)	2	The CXL is higher than the current GB MRL of 0.8 mg/kg, the CXL was considered further. The CXL resulted in acute intake concerns (scenario 2); the CXL cannot be recommended for adoption.	2023
Bushberries, subgroup of	Gooseberries (green, red and yellow) (0154040)	2	The CXL is higher than the current GB MRL of 0.8 mg/kg, the CXL was considered further. The CXL resulted in acute intake concerns (scenario 2); the CXL cannot be recommended for adoption.	2023

Bushberries, subgroup of	Rose hips (0154050)	2	The CXL is higher than the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2023
Beans, dry, subgroup of (except cowpea, mung bean and soya bean)	Beans (0300010)	0.09	The CXL is lower than the current GB MRL which is based on the CXL for mung beans. See CXL for mung beans.	2023
Beans with pods, subgroup of (except soya bean)	Beans (with pods) (0260010)	0.9	The CXL is higher than the current GB MRL of 0.5 mg/kg, the CXL was considered further. The CXL resulted in acute intake concerns (scenario 2); the CXL cannot be recommended for adoption.	2023
Beetroot	Beetroot (0213010)	0.5	The CXL is higher than the current GB MRL of 0.02* mg/kg, the CXL was considered further. The CXL resulted in acute intake concerns (scenario 2); the CXL cannot be recommended for adoption.	2023
Cabbages, head	Head cabbages (0242020)	3	The CXL is higher than the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2008
Cauliflower	Cauliflower (0241020)	0.2	The CXL is lower than the current GB MRL of 0.3 mg/kg, an acute intake concern was identified for the current GB MRL (scenario 1) and for the lower CXL (scenario 2); the CXL cannot be recommended for adoption.	2006
Chickpea (dry)	Peas (0300030)	0.2	The CXL is the basis of the current GB MRL (EFSA, 2011), the CXL remains acceptable and does not	2006

			lead to consumer intake concerns – no further consideration required	
Cotton seed	Cotton seeds (0401090)	1	The CXL is the basis of the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2006
Cowpea (dry)	Beans (0300010)	0.1	The CXL is lower than the current GB MRL which is based on the CXL for chickpea.	2010
Cranberry	Cranberries (0154020)	1	The CXL is the basis of the current GB MRL (EFSA, 2011), the CXL remains acceptable and does not lead to consumer intake concerns – no further consideration required	2010
Edible offal (mammalian)	All mammalian species – liver, kidney and edible offals (Various)	0.05	The CXL is equivalent to the current GB MRL – no further consideration required	2010
Egg plant	Aubergines/ eggplants (0231030)	0.5	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2006
Eggs	Birds eggs (1030000)	0.02	The CXL is equivalent to the current GB MRL – no further consideration required	2010
Fruiting vegetables, cucurbits (group)	Cucurbits with edible peel (0232000)	0.5	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2010
Fruiting vegetables, cucurbits (group)	Cucurbits with inedible peel (0233000)	0.5	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2010
Grapes	Grapes (0151000)	2	The CXL is equivalent to the GB MRL, for which acute intake	2006

			concerns were identified. The CXL is not recommended for adoption.	
Lettuce, head	Lettuces (0251020)	7	The CXL is higher than the GB MRL, for which acute intake concerns were identified – no further consideration is made of the CXL	2006
Lettuce, leaf	Lettuces (0251020)	3	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2013
Maize cereals, subgroup of	Maize/corn (0500030)	0.015	The CXL is higher than the current GB MRL of 0.01* mg/kg. The CXL does not result in acute or chronic intake concerns and is recommended for adoption as a GB MRL.	2023
Mammalian fats (except milk)	All mammalian species – fat (Various)	2	The CXL is equivalent to the current GB MRL – no further consideration required	2023
Meat (from mammals other than marine mammals)	All mammalian species – muscle (fat soluble) (Various)	2	The CXL is equivalent to the current GB MRL – no further consideration required NB – the CXL for meat is based on the fat content given the active is fat soluble. MRLs for GB are set for the muscle; the equivalent MRL for muscle is 0.05 mg/kg. The GB MRL will be set at 0.05 mg/kg to reflect the residue in the muscle.	2023
Milks	Milk (1020000)	0.2	The CXL is higher than the proposed GB MRL of 0.01* mg/kg, the CXL was considered further. The CXL is not recommended for adoption as a GB MRL, see below.	2023

Mints	Basil and edible flowers (0256080)	15	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2010
Mung bean (dry)	Beans (0300010)	0.2	The CXL is the basis for current GB MRL (EFSA, 2011), the CXL remains acceptable and does not lead to consumer intake concerns – no further consideration required	2006
Peanut	Peanuts/gro undnuts (0401020)	0.02*	The CXL is equivalent to the current GB MRL, but is greater than the proposed GB MRL, which is based on a lower achievable LOQ – the CXL is recommended for adoption.	2006
Pear	Pear (0130020)	0.2	The CXL is lower than the current GB MRL of 0.5 mg/kg, an acute intake concern was identified for the current GB MRL (scenario 1) and for the lower CXL (scenario 2); the CXL cannot be recommended for adoption.	2006
Peppers (subgroup)	Sweet peppers/bell peppers (0231020)	0.3	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2006
Potato	Potatoes (0211000)	0.02	The CXL is the basis of the current GB MRL the CXL remains acceptable and does not lead to consumer intake concerns – no further consideration required.	2006
Poultry meat	Poultry – muscle (1016010)	0.01*	The CXL is equivalent to the current GB MRL – no further consideration required	2010
Poultry, edible offal of	Poultry – Liver (1016030)	0.01*	The CXL is equivalent to the current GB MRL – no further consideration required	2010
Poultry, edible offal of	Poultry – Kidney (1016040)	0.01*	The CXL is equivalent to the current GB MRL – no further consideration required	2010

Poultry, edible offal of	Poultry - edible offals (other than liver and kidney) (1016050)	0.01*	The CXL is equivalent to the current GB MRL – no further consideration required	2010
Soya bean (dry)	Soyabeans (0401070)	0.5	The CXL is equivalent to the current GB MRL – no further consideration required	2006
Stone fruits (group)	Stone fruits (0140000)	1	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2010
Sweet corn (corn-on-the-cob)	Sweetcorn (0234000)	0.02	The CXL is higher than the current GB MRL and is recommended for adoption as a GB MRL.	2006
Tea, green, black (black, fermented and dried)	Teas (0610000)	5	The CXL is equivalent to the current GB MRL – no further consideration required	2014
Tomato	Tomatoes (0231010)	0.5	The CXL is equivalent to the GB MRL, for which acute intake concerns were identified. The CXL is not recommended for adoption.	2006
Tree nuts	Tree nuts (0120000)	0.07	The CXL is higher than the current GB MRL of 0.02* mg/kg, the CXL was considered further. The CXL does not result in acute or chronic intake concerns and is recommended for adoption as a GB MRL.	2023

‡ GB MRLs not currently set on animal feed commodities or processed fractions.

The JMPR residue definition for risk assessment and enforcement in plant commodities, and enforcement in animal commodities is:

- the sum of indoxacarb and its R enantiomer

This is comparable to the proposed GB residue definition.

The JMPR residue definition for risk assessment in animal commodities is:

- sum of indoxacarb, its R enantiomer and IN-JT333 (methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl]amino] carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)- carboxylate), expressed as indoxacarb

For animal commodities, the JMPR RD-RA is more extensive than the GB residue definition and includes the metabolite 'IN-JT333'. The only CXL, for products of animal origin, which warrants further consideration is the CXL for milk. The proposed GB residue definition for risk assessment in milk includes the metabolite IN-MP819; no information is available on the occurrence of IN-MP819 in milk, or on the metabolites toxicological properties. As such, the CXL for milk is not recommended for adoption in GB.

The CXL database is available at the following link:

<http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

Assessment

1 Methods of Analysis

1.1 Methods for enforcement and monitoring of residues in food of plant origin

The current residue definition for enforcement is:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

No changes to this residue definition are proposed as a result of this review.

Analytical methods for the determination of indoxacarb in plant commodities (all crop groups) were considered in the EU renewal assessment. The LC-MS/MS methods were validated with an LOQ of 0.01 mg/kg. The extraction efficiency of the method for dry commodities was noted as a data gap. Acceptable extraction efficiency was demonstrated for grapes (high acid), tomatoes and lettuce (high water), potatoes (high starch), cotton seed (high oil), corn forage, corn fodder and corn kernels/cob (no group).

In addition, several monitoring methods have been evaluated by the JMPR. The JMPR assessed two single residue methods which were capable of determining indoxacarb in various plant commodities with an LOQ of 0.01* mg/kg (except for cranberry and mint tops – LOQ: 0.05 mg/kg) (JMPR, 2005). Additional validation data was evaluated by the JMPR in 2013 and 2022, in which data was provided to support the determination of indoxacarb in tea leaves, dry commodities and high oil commodities with an LOQ of 0.01 mg/kg.

Extraction efficiency was considered by the JMPR in 2005, for which it was noted that *'Extraction efficiency has been proven with various solvent mixtures on [14C]-indoxacarb incorporated into or incurred in crop and animal commodities. Extraction procedures used either ethyl acetate – water or acetonitrile – hexane.'* (JMPR, 2005). The additional method validation data considered by the JMPR in 2013 and 2022 (for dry commodities) utilised the same/similar extraction solvents. On this basis, HSE concludes that further data to address extraction efficiency is not necessary.

Enforcement of MRLs for products of plant origin at an LOQ of 0.01 mg/kg has been demonstrated.

It is noted that the LOQ MRL for many commodities in the GB MRL Register is currently 0.02* mg/kg – as a lower LOQ is achievable, the GB MRL Register will be updated to reflect this.

1.2 Methods for enforcement and monitoring of residues in food of animal origin

The current residue definition for enforcement is:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

No changes to this residue definition are proposed as a result of this review.

Analytical methods for the determination of indoxacarb in animal commodities were considered in the EU renewal assessment. The LC-MS/MS methods were validated with an LOQ of 0.01 mg/kg. The extraction efficiency of the method for animal commodities was not demonstrated in the renewal assessment.

In addition, several monitoring methods have been evaluated by the JMPR. The JMPR evaluated methods for animal commodities in 2005 and 2009. In 2005 it was concluded that sufficient methods were available for animal commodities with an LOQ of 0.01-0.03* mg/kg; additional methods for poultry matrices were validated with an LOQ of 0.01* mg/kg in 2009. As noted above for plant commodities, the JMPR considered extraction efficiency for animal commodities in 2005, the method considered by the JMPR in 2009 utilised the same extraction solvents for which the 2005 JMPR concluded extraction efficiency was demonstrated. Additional data is unlikely to affect the MRL calculated or the outcome of the consumer risk assessments, no further data are required at this time.

Enforcement of MRLs for products of animal origin at an LOQ of 0.01 mg/kg has been demonstrated.

2 Mammalian toxicology

New toxicological end points were established in the GB article 21 review of the approval of indoxacarb and these are summarised in Table 2.1.

Table 2.1 Overview of the toxicological reference values for indoxacarb

TRVs	Source	Year	Value	Study relied upon	Safety factor
ADI	GB	2022	0.005 mg/kg bw/d	Rat, developmental toxicity study	100
ARfD	GB	2022	0.005 mg/kg bw	Rat, developmental toxicity study	100

It is noted that the technical specification of indoxacarb was updated in the EU renewal assessment. The original technical specification was a mixture of the R- and S- isomers. The toxicological studies evaluated for the original approval were performed using either racemic indoxacarb or 75S:25R indoxacarb. The new specification defines indoxacarb as the almost pure S-isomer. It was concluded in the EU renewal assessment that both isomers should be considered as toxicologically equivalent, and the studies conducted using a mixture of isomers were considered appropriate. Additional toxicological studies, dosed with almost pure S-isomer, were evaluated for the EU renewal assessment.

2.1 Further toxicological studies

Metabolite IN-MK638 may be observed under certain processing conditions, see section 3.1.4. No QSAR analysis was available for this metabolite in the EU renewal assessment (RAR, 2017). QSAR analysis has been conducted in the current assessment by HSE to evaluate the genotoxic potential of IN-MK638. There were no structural alerts triggered in DEREK nexus for genotoxicity or SARAH nexus for mutagenicity. Therefore, metabolite IN-MK638 is unlikely to be genotoxic. HSE considers that the Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for chronic dietary risk assessment and that the value of 5 µg/kg bw is applicable for the acute dietary risk assessment of IN-MK638.

All other metabolites

QSAR genotoxicity analysis is available for a number of metabolites, as detailed in the EFSA conclusion and associated RAR (EFSA, 2018 & RAR, 2017).

QSAR genotoxicity analysis, from up to three models, covering bacterial mutagenicity, clastogenicity and aneugenicity demonstrated negative results for 5-OH-indoxacarb (free

and conjugated), IN-MN470, IN-MF014, IN-KT413, IN-MP819 and IN-TMG00. HSE concludes that the above metabolites are unlikely to be genotoxic

Regarding IN-JT333, a negative Ames test, gene mutation assay and chromosome aberration assay are available (EFSA, 2018). Aneugenicity has not been addressed; however, the available data supports the conclusion that the Cramer Class III TTC value of 1.5 µg/kg bw/d could be applied. HSE concludes that aneugenicity is a threshold effect, further data to address this data gap would not impact on this conclusion.

Overall, HSE considers that the Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for chronic dietary risk assessment and that the value of 5 µg/kg bw is applicable for the acute dietary risk assessment of the following metabolites: 5-OH-indoxacarb (free and conjugated), IN-MN470, IN-MF014, IN-KT413, IN-MP819, IN-TMG00, and IN-JT333. A combined exposure assessment is not required for these metabolites (or IN-MK638) as they have structural differences.

3 Residues in Plants

Indoxacarb does not meet the requirements outlined in the guidance document SANCO/11188/2013, rev 2 September 2015:

- Active substances approved as a basic substance
- Active substances listed Part 1 of the GB MRL Statutory Register
- Active substances with no identified hazards
- The consumer exposure associated with the use of the active substance as a PPP is negligible compared to other sources/natural background exposure
- The method of application of the PPP will lead to no consumer exposure

Therefore, HSE does not recommend that indoxacarb is included in Part 4 (active substances not subject to MRLs) of the GB MRL Statutory Register.

3.1 Primary crops

3.1.1 Nature of residues (Metabolism studies)

The metabolism of indoxacarb in fruit and fruiting vegetable crops (grapes and tomatoes), pulses and oilseeds (cotton) and leafy crops (lettuce) following foliar applications, was evaluated for the approval of the active substance (as the racemic mixture) (DAR, 2000). The same studies were evaluated by the JMPR in 2005.

The metabolism studies showed a similar pathway: indoxacarb (racemic mixture) was the main component in all studies; accounting for up to 84% TRR in mature cotton leaves, 95% TRR in grapes, 99% TRR in lettuce and up to 87% and 97% TRR in tomato fruit and leaves, respectively. In cotton (mature leaves) and tomato (fruits and leaves), the S/R isomeric ratio remained unchanged (1:1).

3.1.2.1 Residue definitions for enforcement and risk assessment

Based on the plant metabolism data, HSE recommends the following residue definition for enforcement and risk assessment:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

This applies to all crop categories and is the same as the current residue definition in the GB MRL Statutory Register.

As noted in section 2, the R- and S-isomers are considered toxicologically equivalent. The available information from the metabolism studies indicates the isomeric ratio remains unchanged. An assessment factor for potential differences in the toxicological profile of the isomers is not required.

3.1.2 Magnitude of residues (Residue trials)

No new residue field trials data were considered in support of the GB MRL review. The residue trials available from previous assessments are briefly summarised with a reference to the previous assessment and the residue trial data are presented in Table 3.1.2-1.

Only those MRLs which are proposed to be retained as GB MRLs based on scenario 3 of the risk assessment have been detailed; i.e. any MRL which is based on a previous GB/EU use which results in an acute exceedance has not been considered further. In such cases, if the CXL is lower, this has been considered for adoption – see section 7.

It is noted that for the MRLs which are proposed to be retained as GB MRLs (which are not based on CXLs) – no supporting GAP information is available as the uses have been withdrawn in the UK and EU.

To meet the UK's SPS/WTO obligations, the affected MRLs can be retained for a limited period (5 years). A supplementary data requirement footnote shall be added to all affected MRLs, data must be provided to support the retained MRLs – if no data is provided within 5 years, the MRLs shall fall to the LOQ (note no CXLs are available for the affected commodities).

The following footnote is required:

Supplementary information requirement with expiry date set

- HSE has identified the GAP information, supporting documentation, and residues trials data as unavailable. Further data may also be required including, but not limited to, analytical methods data and/or processing data. This information shall be provided by 31 January 2032. If no data is received, the MRL will default to 0.01* mg/kg on 31 January 2032. Full details of the supplementary information requirement is outlined in the MRL Decision document.

0152000 Strawberries

The critical GAP on strawberries, on which the current GB MRL is based, was authorised in Spain for use on protected strawberries at 2x37.5 g/ha, RTI – 10 days and a PHI of 3 days.

Eight trials which matched this GAP were available (EFSA, 2012), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.6 mg/kg.

0153030 Raspberries

The critical GAP on raspberries, on which the current GB MRL is based, was authorised in Spain for use on protected strawberries at 2x37.5 g/ha, RTI – 10 days and a PHI of 3 days.

Four trials which matched this GAP were available (EFSA, 2012), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.6 mg/kg.

- 0154030 Currants (black, red and white)**
- 0154040 Gooseberries (green, red and yellow)**
- 0154060 Mulberries (black and white)**
- 0154070 Azaroles/Mediterranean medlars**
- 0154080 Elderberries**
- 0154990 Others - Other small fruit and berries**

The critical GAP on small fruits and berries, on which the current GB MRLs are based, was authorised in Germany for use on outdoor small fruits and berries at 1x51 g/ha, and a PHI of 7 days.

Eight trials on currants (black, red and white) which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

The current MRLs for blueberries and rose hips lead to consumer intake concerns and will be lowered to the LOQ; the MRL for cranberries is the CXL (1 mg/kg) – this CXL is recommended to be retained as a GB MRL.

The derived MRL is 0.9 mg/kg (based on the OECD calculator); the current GB MRL was not calculated based on OECD methodology and is 0.8 mg/kg (EFSA, 2011).

0213080 Radishes

The critical GAP on radishes, on which the current GB MRL is based, was authorised in Germany for use on outdoor radishes at 2x25.5 g/ha, RTI of 7 days and a PHI of 3 days.

Four trials on radishes which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.4 mg/kg (based on the OECD calculator); the current GB MRL was not calculated based on OECD methodology and is 0.3 mg/kg (EFSA, 2011).

0242010 Brussels sprouts

The critical GAP on Brussels sprouts, on which the current GB MRL is based, was authorised in the UK for use on outdoor Brussels sprouts at 3x25 g/ha, RTI of 10 days and a PHI of 1 day.

Seven trials on Brussels sprouts which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.07 mg/kg (based on the OECD calculator); the current GB MRL was not calculated based on OECD methodology and is 0.06 mg/kg (EFSA, 2011).

0242020 Head cabbage

The critical GAP on head cabbage, on which the current GB MRL is based, was authorised in the NEU (all) and SEU (all) for use on outdoor head cabbage at 3x25 g/ha, RTI of 10 days and a PHI of 3 days.

Fourteen trials (7 NEU and 7 SEU) on head cabbage which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

It is noted that individually, the NEU and SEU GAPs both resulted in the same MRL proposal (0.2 mg/kg) during the Article 12 review (EFSA, 2011).

Seven trials is insufficient to support a major crop; however, on the basis that identical GAPs were available in both NEU and SEU, and that the trial residues are comparable (mean within 5 fold difference and comparable according to Mann-Whitney U-test) – fourteen combined trials are sufficient to support the current GB MRL.

The derived MRL is 0.15 mg/kg (based on the OECD calculator); the current GB MRL was not calculated based on OECD methodology and is 0.2 mg/kg (EFSA, 2011).

0251040 Cresses and other shoots and sprouts

0251050 Land cresses

0251070 Red mustards

0251990 Others – lettuces and other salad plants

0252020 Purslanes

0252990 Others – spinaches and similar leaves

The critical GAP on cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants, purslanes, and others – spinaches and similar leaves, on which the current GB MRLs are based, was authorised in the NEU (Belgium – **indoors**) at 3x25.5 g/ha, RTI of 7 days and a PHI of 14 days.

Eight trials on lettuce and four trials on lambs' lettuce were available, for a total of twelve trials (of which 6 were on open leaf lettuce) which matched this GAP (EFSA, 2013a), the residues are detailed in Table 3.1.2-1.

The derived MRL is 1 mg/kg.

0256000 Herbs and edible flowers

The critical GAP on **chervil, celery leaves, and parsley**, on which the current GB MRLs are based, was authorised in the SEU (Portugal - outdoors) at 6x37.5 g/ha, RTI of 10 days and a PHI of 3 days.

The critical GAP on **chives, sage, rosemary, thyme, laurel/bay leaves, tarragon**, on which the current GB MRLs are based, was authorised in the EU (**indoors**) at 2x25.5 g/ha, RTI of 10 days and a PHI of 14 days.

NB – the current GB MRL for basil is the CXL (15 mg/kg).

Four indoor trials on parsley were available to support the indoor EU GAP for **chives, sage, rosemary, thyme, laurel/bay leaves, tarragon** (EFSA, 2011).

Ten SEU trials on lettuce were available to support the SEU GAP for **chervil, celery leaves, and parsley** (EFSA, 2013a), the residues are detailed in Table 3.1.2-1.

For **chives, sage, rosemary, thyme, laurel/bay leaves, tarragon**, the derived MRL is 2 mg/kg.

For **chervil, celery leaves, and parsley**, the derived MRL (based on the OECD calculator) is 3 mg/kg; the current GB MRL was not calculated based on OECD methodology and is 2 mg/kg (EFSA, 2011).

0260010 Beans with pods

The critical GAP on beans with pods, on which the current GB MRL is based, was authorised in the EU (indoors) at 4x57 g/ha, RTI – unspecified and a PHI of 1 days. The dose was calculated based on plant height – with 25.5 g/ha per 1m of plant height (up to a max of 2m), with a minimum rate of 37.5 g/ha for crops below 1.5m.

Eight trials which matched this GAP were available (EFSA, 2013b), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.5 mg/kg.

0270050 Globe artichokes

The critical GAP on globe artichokes, on which the current GB MRL is based, was authorised in the SEU (all) at a rate of 2x38 g/ha, RTI – 7 days with a PHI of 14 days.

Four trials which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.15 mg/kg (based on the OECD calculator); the current GB MRL was not calculated based on OECD methodology and is 0.2 mg/kg (EFSA, 2011).

0401080 Mustard seeds

The critical GAP on mustard seed, on which the current GB MRL is based, was authorised in the UK at a rate of 1x25.5 g/ha at BBCH 59.

Ten trials which matched this GAP were available (EFSA, 2013b), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.05 mg/kg.

0900010 Sugar beet roots

The critical GAP on sugar beet, on which the current GB MRL is based, was authorised in the SEU (Italy) at a rate of 3x37.5 g/ha, RTI – unspecified with a PHI of 14 days.

Eight trials which matched this GAP were available (EFSA, 2011), the residues are detailed in Table 3.1.2-1.

The derived MRL is 0.1 mg/kg.

Table 3.1.2-1 Overview of the available residue trials data

RD-RA/RD-Enf: Indoxacarb (sum of indoxacarb and its R enantiomer)

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative of the critical GAP assessed for MRL purposes (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
Strawberries	SEU (Spain, indoors)	0.1, 0.11, 0.15, 0.3	Trials which support current GB MRL reported: EFSA 2012 Based on OECD calculator: 0.6/0.535 mg/kg	0.6	0.3	0.13
Raspberries	SEU (Spain, indoors)	0.08, 0.16, 2 x 0.19, 0.20, 0.21, 0.22, 0.27	Trials which support current GB MRL reported: EFSA 2012 Based on OECD calculator: 0.6/0.570 mg/kg	0.6	0.27	0.19
Other small fruits and berries (excluding blueberries, rose hips and cranberries)	NEU (Germany, outdoors)	0.04, 0.05, 0.08, 0.09, 0.13, 0.21, 0.33, 0.52	Trials which support current GB MRL reported: EFSA, 2011 Trials conducted on currants (black, red and white) Original MRL proposal was not based on the OECD calculator and was 0.8 Based on OECD calculator: 0.9/0.897 mg/kg	0.8 (current MRL) Or 0.9 (OECD MRL)	0.52	0.11
Radishes	NEU (Germany, outdoors)	3 x <0.02, 0.16	Trials which support current GB MRL reported: EFSA, 2011	0.3 (current MRL)	0.16	<0.02

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative of the critical GAP assessed for MRL purposes (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			Original MRL proposal was not based on the OECD calculator and was 0.3 Based on OECD calculator: 0.4/0.335 mg/kg	Or 0.4 (OECD MRL)		
Brussels sprouts	NEU (UK, outdoors)	0.01, 0.011, 0.014, 0.02, 0.022, 0.03, 0.04	Trials which support current GB MRL reported: EFSA, 2011 Original MRL proposal was not based on the OECD calculator and was 0.06 Based on OECD calculator: 0.07/0.065 mg/kg	0.06 (current MRL) Or 0.07 (OECD MRL)	0.04	0.02
Head cabbage	NEU (all, outdoors)	6 x <0.02, 0.09	Trials which support current GB MRL reported: EFSA, 2011 Original MRL proposal was not based on the OECD calculator and was 0.2 mg/kg Based on OECD calculator: 0.15/0.136 mg/kg	0.2 (current MRL) Or 0.15 (OECD MRL)	0.09	<0.02
	SEU (all, outdoors)	4 x <0.02, 0.02, 0.05, 0.07	Trials which support current GB MRL reported: EFSA, 2011	0.2 (current MRL)	0.07	<0.02

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative of the critical GAP assessed for MRL purposes (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			Original MRL proposal was not based on the OECD calculator and was 0.2 mg/kg Based on OECD calculator: 0.15/0.113 mg/kg	Or 0.15 (OECD MRL)		
	Combined	10 x <0.02, 0.02, 0.05, 0.07, 0.09	Trials which support current GB MRL reported: EFSA, 2011 Based on OECD calculator: 0.15/0.121 mg/kg	0.2 (current MRL) Or 0.15 (OECD MRL)	0.09	<0.02
cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants Purslanes, others – spinaches and similar leaves	NEU (Belgium – indoors)	0.12, 0.17, 0.19, 0.21, 0.22, 0.25, 0.29, 0.32, 0.49, 2 x 0.54, 0.55	Trials which support current GB MRL reported: EFSA, 2013a Trials conducted on lettuce and lambs lettuce Based on OECD calculator: 1.0/0.973 mg/kg	1.0	0.55	0.27
chervil, celery leaves, and parsley	SEU (Portugal – outdoors)	0.16, 0.19, 0.25, 0.39, 2 x 0.52, 0.55, 0.86, 0.89, 1.64	Trials which support current GB MRL reported: EFSA, 2011 Trials conducted on lettuce	2 (current MRL)	1.64	0.52

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative of the critical GAP assessed for MRL purposes (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			Original MRL proposal was not based on the OECD calculator and was 0.2 mg/kg Based on OECD calculator: 3.0/2.374 mg/kg	OR 3 (OECD MRL)		
chives, sage, rosemary, thyme, laurel/bay leaves, tarragon	EU (indoor)	0.19, 2 x 0.46, 0.98	Trials which support current GB MRL reported: EFSA, 2011 Trials conducted on parsley Based on OECD calculator: 2.0/1.844 mg/kg	2	0.98	0.46
Beans with pods	EU (indoor)	0.04; 0.06; 0.07; 0.09; 0.12; 0.13; 0.22; 0.24	Trials which support current GB MRL reported: EFSA, 2013b Based on OECD calculator: 0.5/0.42 mg/kg	0.5	0.24	0.11
Globe artichokes	SEU (all, outdoor)	0.02, 0.03, 0.04, 0.07	Trials which support current GB MRL reported: EFSA, 2011 Original MRL proposal was not based on the OECD calculator and was 0.2 mg/kg Based on OECD calculator: 1.0/0.973 mg/kg	0.2 (current MRL) Or 0.15 (OECD MRL)	0.07	0.035
Mustard seeds	NEU (UK, outdoor)	9 x <0.01, 0.034	Trials which support current GB MRL reported: EFSA, 2011	0.05	0.034	<0.01

Crop (trial GAP)	Region/ Indoor (a)	Residue levels (mg/kg) observed in the trials representative of the critical GAP assessed for MRL purposes (b)	Recommendations/ comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			Trials conducted on lettuce Original MRL proposal was not based on the OECD calculator and was 0.2 mg/kg Based on OECD calculator: 3.0/2.374 mg/kg			
Sugar beet	SEU (Italy, outdoor)	2 x <0.01, 0.013, 0.026, 0.031, 0.04, 0.06	Trials which support current GB MRL reported: EFSA, 2011 Based on OECD calculator: 0.1/0.101 mg/kg	0.1	0.06	0.03

3.1.3 Conversion factor for risk assessment for products of plant origin

As the residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are equivalent, conversion factors (CFs) for enforcement to risk assessment are not required.

3.1.4 Effect of industrial processing and/or household preparation

3.1.4.1 Nature of the residues in processed commodities

Hydrolysis of indoxacarb under representative conditions of pasteurisation, baking, brewing, boiling was evaluated for the approval of the active substance (DAR, 2000). Further data, including sterilisation, was evaluated for the EU renewal of indoxacarb.

A summary of the available hydrolysis data is presented below (DAR, 2000 and EFSA, 2018, respectively).

Table 3.1.4-1 Summary of hydrolysis data for indoxacarb

% applied radioactivity	Parent compound	IN-KT413	IN-MP819	IN-MK638	IN-P0036	IN-TMG00	Source
Pasteurisation	88-92 % †	-	-	-	-	-	DAR, 2000
20 min, 90°C, pH 4	109-115 %	-	-	-	-	-	EFSA, 2018
Baking, brewing and boiling	69-88 % †	14 %	-	-	-	-	DAR, 2000
60 min, 100°C, pH 5	79-86 %	1 %	-	-	-	-	EFSA, 2018
Sterilisation	43-47 %	29 %	10 %	10 %	16 %	12 %	EFSA, 2018
20 min, 120°C, pH 6							

† DAR study was conducted using racemic indoxacarb – the updated technical specification is for almost pure S-isomer.

The hydrolysis data demonstrates that indoxacarb is stable under standard pasteurisation conditions. Indoxacarb is not stable under conditions representative of sterilisation.

Data considered in the DAR was not conducted according to any prescribed guidelines (as none existed at the time); this study was also dosed with an outdated specification of indoxacarb. The DAR data suggests a degree of degradation may be observed under baking, brewing and boiling conditions – resulting in the formation of IN-KT413 (DAR, 2000). New data on representative baking, brewing and boiling conditions was considered for the renewal of indoxacarb – this data suggests IN-KT413 is unlikely to be formed under

these conditions. Due to the differing conclusions of the two studies, it is considered that it is possible for IN-KT413 to form under baking, brewing and boiling conditions. Degradation was more extensive under standard sterilisation conditions; a number of additional metabolites were identified: IN-KT413, IN-MP819, IN-MK638, IN-P0036 and IN-TMG00.

The toxicological profile of the above metabolites has not been fully elucidated. It is noted that *'all metabolites, except IN-MK638, are unlikely to be genotoxic whilst only IN-P0036 was considered as covered by the toxicity studies of indoxacarb'* (EFSA, 2018).

As noted in section 2.1, IN-MK638 can also be considered as unlikely to be genotoxic.

Based on the consideration of the available data, and the exposure to the metabolites (see below) HSE recommends the following residue definitions for processed commodities:

The residue definition for enforcement (RD-Enf) in processed commodities is proposed as:

- Indoxacarb (and its R- enantiomer)

The residue definition for risk assessment (RD-RA) in processed commodities is proposed as:

- Indoxacarb (and its R- enantiomer)

These definitions have been established on the basis of the combined exposure to the metabolites being below the TTC (see section 3.1.4.2). To establish further substantive MRLs, the consumer exposure assessments for the metabolites formed on processing may need to be updated; depending on the outcome of the combined exposures, additional information may be required. The further information required could include data on the toxicological profile of the metabolites and/or data to address their magnitude in processed fractions.

3.1.4.2 Magnitude of the residues in processed commodities

No new studies have been submitted within this evaluation. Trials analysing for the metabolites IN-KT413, IN-MK638, IN-P0036, IN-TMG00, were evaluated in the EU renewal assessment, IN-MP819 was not analysed for. These trials suggest that no residues of any metabolite above LOQ are expected in canned apples, peaches and green beans; however, the trials were not considered to be adequately supported by storage stability data, and as such were not considered robust (EFSA, 2018). It was also noted that the studies on peaches and apples investigated pasteurisation, rather than the worst case sterilisation process.

The available storage stability data has been re-considered in the current review. Samples of processed (canned) apples were stored for a maximum of 1 month; pears and green beans were stored for a maximum of 3 months. In each study/commodity, the stability of

each metabolite was tested by spiking processed samples with a mixed spiking solution (containing 0.1 mg/kg of IN-KT413, IN-MK638, IN-P0036, IN-TMG00 and parent indoxacarb). The spiked sample was stored frozen and re-analysed at regular intervals. The stability of all metabolites was acceptable for apple. For peaches and green beans, IN-P0036 degraded by approximately 50 % before analysis; however, all remaining metabolites were sufficiently stable for the duration of the study – including the potentially more prevalent metabolite IN-KT413.

It is noted that the use of mixed spiking solutions is not recommended in the OECD guidance document; this is due to the possibility that degradation could be masked by interconversion of molecules. In this case, the only metabolite for which a notable decline was observed was IN-KT413, the extent of the decline is unlikely to have impacted any other metabolites; therefore, this is considered a minor deviation in this case.

It is considered that the above studies are adequately supported by storage stability data; with the exception of IN-P0036 in peaches and green beans. The studies investigating processing of apples and peaches are not representative of sterilisation; however, they are considered sufficiently representative of typical industry practice for canning. The study investigating the canning of green beans is acceptable and is sufficiently representative of the worst case processing conditions. No residues of any metabolite were identified greater than LOQ (0.003 mg/kg) in any case (apples, peaches and green beans). The median processing factor derived in each study is presented in the table below, all other acceptable processing factors considered during the EU renewal assessment are also presented below.

Table 3.1.4-2 Processing factors for indoxacarb – parent only (*Studies analysing for parent, IN-KT413, IN-MK638, IN-P0036 and IN-TMG00*)

Commodity	Median pf (parent only)	No. of studies	Source
Apples – canned	0.7†	3	RAR, 2017
Peaches – canned	0.61†	3	
Green beans – canned	0.19†	3	

Table 3.1.4-3 Processing factors for indoxacarb – parent only (*studies analysing for parent only*)

Commodity	Median pf (parent only)	No. of studies	Source
Tomato puree	1.76	6	DAR, 2005
Tomato dry pomace	104	6	
Tomato wet pomace	13.5	6	

Catsup	3.5	6
Grape must	0.35	3
Grape wet pomace	1.53	3
Grape dry pomace	4.56	3
Grape lee	0.76	3
Grape raisin	2.7	3
Apple pomace	3.0	4
Peaches blanched	0.82	3

† Parent only, all metabolites were <LOQ (0.003 mg/kg).

Despite some minor deficiencies noted above, the available data is sufficient to conclude that residues of the aforementioned metabolites are unlikely to be observed in canned products.

The potential exclusion of the metabolites from the residue definitions for processed commodities has been considered on the basis of their exposures, as outlined below. As detailed in section 2.1, a combined exposure assessment is not required for the metabolites IN-KT413, IN-MP819, IN-MK638 or IN-TMG00.

As such, exposure to metabolite IN-KT413 (the largest individual component) has been assessed against the TTC (Threshold of toxicological concern) for CC III (Cramer Class III) compounds. The metabolite IN-P0036 has been considered separately as it is covered by the toxicological reference values for indoxacarb. The TTC assessment for IN-KT413 is detailed in appendix A.

In summary, the exposure estimates for IN-KT413, IN-MP819, IN-MK638 or IN-TMG00 in processed commodities are all below the Cramer Class III TTC value of 1.5 µg/kg bw/d for chronic dietary risk assessment and the threshold value of 5 µg/kg bw for acute dietary risk assessment.

The conclusion is only applicable to the uses considered in this application and the exposure estimates would need to be reconsidered for any additional or more critical uses.

In conclusion, the available information for processed commodities is sufficient to support the proposed/retained CXLs/MRLs detailed in table 8.1. Further information on the magnitude of residues on processing and/or data on the toxicological profile of the metabolites may be required to support further MRLs.

IN-P0036

According to hydrolysis data, the metabolite IN-P0036 may also be formed on processing. The toxicological reference values for indoxacarb can be applied to this metabolite.

The combined potential summed residue of parent indoxacarb and IN-P0036 in processed commodities is 63% of the residue of indoxacarb in the RAC (raw agricultural commodity), based on the hydrolysis data. The potential exposure to IN-P0036 via processed commodities is therefore covered by the consumer risk assessment conducted in section 7 (scenario 3). No further consideration is required at this time. However, further information to establish specific toxicological reference values for IN-P0036 and/or address the magnitude of residues in processed commodities of both indoxacarb and IN-P0036 may be required to establish additional substantive MRLs.

Conclusion

The dietary exposures for metabolites that may be formed on processing have been estimated. These dietary exposures are very conservative as it is assumed that all commodities that can be processed are consumed as the processed commodity only. In addition, the residue levels that occur have been estimated to occur at the maximum formation fraction from indoxacarb in the RAC.

Based on the dietary exposures for the metabolites, they do not need to be included in the residue definitions for processed commodities at this time

3.2 Rotational crops

No new data were submitted for the EU renewal assessment. With respect to the UK, all UK authorisations have been withdrawn and therefore no residues in crops grown in rotation in GB are expected.

With regards to the retention/adoption of CXLs, rotational crop residues do not need to be considered. With regards to retained uses, additional information may be required if/when the relevant supplementary information is provided. No further information is required at this time.

4 Residues in livestock

A consideration of residues in livestock has been made as residues may be present in feed items imported into GB. In addition, a number of CXLs have been established for animal commodities. HSE has calculated the dietary burden associated with the MRLs recommended for adoption and also compared this to the dietary burden associated with the CXLs.

4.1 Dietary burden

4.1.1 Indoxacarb

The dietary burden calculation has been undertaken using the OECD feeding tables (OECD guidance document on overview of residue chemistry studies Series 64/32) and the EFSA Animal Model 2017. Only the residues in feed items relevant to the MRLs recommended for adoption under scenario 3 (see section 7) have been considered in the dietary burden assessment.

The following assumptions have been made:

- The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.
- All produce eaten which may have been treated, has been treated and contains residues at the STMR/HR found in the trials considered to support the GAP.
- There is no loss of residue during transport, storage, preparation of feed prior to consumption.
- Default processing factors as set out in the EFSA Animal Model 2017 have been used unless other specific processing factors are available or residues <LOQ are expected.
- Only commodities for which no acute risk was identified in scenario 3 (section 7) have been included

Input values are summarised in Table 4.1-1 and the estimated animal intakes are summarised in Table 4.1-2.

Table 4.1-1 Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition:			Indoxacarb	(and its R-enantiomer)

Feed commodity		Median	dietary burden	Maximum	dietary burden
		Input (mg/kg)	Comment	Input (mg/kg)	Comment
Cabbage	heads	0.02	STMR (EFSA, 2011)	0.09	HR (EFSA, 2011)
Potato	Culls	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	HR (FAO, 2005; EFSA, 2011)
Bean	seed (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)	0.02	STMR (FAO, 2005; EFSA, 2011)
Corn, field (Maize)	grain	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)
Corn, pop	grain	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)
Pea (Field pea)	seed (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)	0.02	STMR (FAO, 2005; EFSA, 2011)
Soybean	seed	0.03	STMR (FAO, 2005; EFSA, 2011)	0.03	STMR (FAO, 2005; EFSA, 2011)
Beet, sugar	dried pulp	0.026	STMR (EFSA, 2011)	0.03	STMR (EFSA, 2011)
Beet, sugar	ensiled pulp	0.08	STMR (EFSA, 2011) * default pf (3)	0.08	STMR (EFSA, 2011) * default pf (3)
Beet, sugar	molasses	0.73	STMR (EFSA, 2011) * default pf (28)	0.73	STMR (EFSA, 2011) * default pf (28)
Canola (Rape seed)	meal	0.02	STMR (FAO, 2005; EFSA, 2011) * default pf (2)	0.01	STMR (FAO, 2005; EFSA, 2011) * default pf (2)
Coconut	meal	0.02	STMR-CXL (FAO, 2022) * default pf (1.5)	0.02	STMR-CXL (FAO, 2022) * default pf (1.5)

Feed commodity		Median	dietary burden	Maximum	dietary burden
		Input (mg/kg)	Comment	Input (mg/kg)	Comment
Corn, field	milled by-pdts	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)
Corn, field	hominy meal	0.06	STMR-CXL (FAO, 2022) * default pf (6)	0.06	STMR-CXL (FAO, 2022) * default pf (6)
Corn, field	gluten feed	0.03	STMR-CXL (FAO, 2022) * default pf (2.5)	0.03	STMR-CXL (FAO, 2022) * default pf (2.5)
Corn, field	gluten, meal	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)
Distiller's grain	dried	0.03	STMR-CXL (FAO, 2022) * default pf (3.3)	0.03	STMR-CXL (FAO, 2022) * default pf (3.3)
Peanut	meal	0.01	STMR (FAO, 2005; EFSA, 2011) x pf (1.0)	0.01	STMR (FAO, 2005; EFSA, 2011) x PF (1.0)
Potato	process waste	0.20	STMR (FAO, 2005; EFSA, 2011) * default pf (20)	0.20	STMR (FAO, 2005; EFSA, 2011) * default pf (20)
Potato	dried pulp	0.38	STMR (FAO, 2005; EFSA, 2011) * default pf (38)	0.38	STMR (FAO, 2005; EFSA, 2011) * default pf (38)
Rape	meal	0.02	STMR (FAO, 2005; EFSA, 2011) * default pf (2)	0.01	STMR (FAO, 2005; EFSA, 2011) * default pf (2)
Soybean	meal	0.04	STMR (FAO, 2005; EFSA, 2011) * default pf (1.3)	0.04	STMR (FAO, 2005; EFSA, 2011) * default pf (1.3)

Feed commodity		Median dietary burden		Maximum dietary burden	
		Input (mg/kg)	Comment	Input (mg/kg)	Comment
Soybean	hulls	0.35	STMR (FAO, 2005; EFSA, 2011) * default pf (13)	0.35	STMR (FAO, 2005; EFSA, 2011) * default pf (13)

Pf = processing factor

Table 4.1-2 Estimated animal intakes

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg /kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity^(a)	Previous assessment (Max. burden – EFSA 2011)	Previous assessment (Max. burden – JMPR 2005, 2009) †
Cattle (all diets)	0.021	0.025	Y	0.80	Potato process waste	6.85	41.0
Cattle (dairy only)	0.021	0.025	Y	0.64		6.85	33
Sheep (all diets)	0.023	0.025	Y	0.75		N/A	N/A
Sheep (ewe only)	0.023	0.025	Y	0.75		N/A	N/A
Swine (all diets)	0.009	0.010	Y	0.42		3.08	N/A
Poultry (all diets)	0.007	0.007	Y	0.11	Cabbage, heads leaves	1.04	0.705‡
Poultry (layer only)	0.006	0.007	Y	0.11		1.04	0.705‡

(a) Considering the maximum dietary animal burden

† The current GB MRLs are set on the basis of the CXLs recommended by the JMPR in 2005 and 2009.

‡ The JMPR DB was recalculated in 2022, with the inclusion of additional commodities, this was lower than the DB calculated in 2009 as the feed tables were updated in 2018, based on more recent data. The more recent DB, based on the updated model has been considered for poultry.

Based on the dietary burden calculations, consideration of the likely residues in products of animal origin is required as the trigger of 0.1 mg/kg DM and AR is exceeded for all animal groups.

The dietary burden calculated by the JMPR, and hence the basis of the CXLs, is significantly higher than the dietary burden resulting for GB reared livestock fed treated imported feed items. Hence, the CXLs are more critical to the consumer risk assessment.

4.1.2 Processing metabolites

In addition to the dietary burden calculation, which was undertaken with parent indoxacarb, it is necessary to consider the dietary burden for livestock considering the metabolites formed on processing (see section 3.1.4).

The metabolite IN-KT413 is the maximum observed metabolite (sterilisation conditions) at 29% AR (applied radioactivity), in line with section 3.1.4, a production factor of 0.3 was estimated and applied to all relevant (i.e. potentially processed) inputs as detailed in table 4.1-1.

The dietary burden calculation has been undertaken using the OECD feeding tables (OECD guidance document on overview of residue chemistry studies Series 64/32) and the EFSA Animal Model 2017. Only the residues in feed items relevant to the MRLs recommended for adoption under scenario 3 (see section 7) have been considered in the dietary burden assessment.

Furthermore, only the feed items which may have been subject to processing conditions have been included (i.e. byproducts).

The following assumptions have been made:

- The highest likely inclusion rate of all crops which may have been treated has been used with the proviso that the aggregate does not exceed 100% diet.
- All produce eaten which may have been treated, has been treated and contains residues at the STMR/HR found in the trials considered to support the GAP.
- There is no loss of residue during transport, storage, preparation of feed prior to consumption.
- Default processing factors as set out in the EFSA Animal Model 2017 have been used unless other specific processing factors are available or residues <LOQ are expected.
- Only commodities for which no acute risk was identified in scenario 3 (section 7) have been included

Input values are summarised in Table 4.1-3. The residue levels in all the processed animal feed items are < 0.05 mg/kg, and as such they are only minor residues in feed items. For completeness the estimated animal intakes are summarised in Table 4.1-4.

Table 4.1-3 Input values for the dietary burden calculation – IN-KT413

Feed commodity		Median dietary burden		Maximum dietary burden	
		Input (mg/kg)	Comment	Input (mg/kg)	Comment
Beet, sugar	dried pulp	0.0078	STMR (EFSA, 2011) * PrF	0.0078	STMR (EFSA, 2011) * PrF
Beet, sugar	ensiled pulp	0.0078	STMR (EFSA, 2011) * PrF * pf (1)	0.0078	STMR (EFSA, 2011) * PrF * pf (1)
Beet, sugar	molasses	0.0078	STMR (EFSA, 2011) * PrF * pf (1)	0.0078	STMR (EFSA, 2011) * PrF * pf (1)
Canola (Rape seed)	meal	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Coconut	meal	0.0039	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.0039	STMR-CXL (FAO, 2022) * PrF * pf (1)
Corn, field	milled by-pdts	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)
Corn, field	hominy meal	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)
Corn, field	gluten feed	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)
Corn, field	gluten, meal	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)
Distiller's grain	dried	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)	0.003	STMR-CXL (FAO, 2022) * PrF * pf (1)

Feed commodity		Median dietary burden		Maximum dietary burden	
		Input (mg/kg)	Comment	Input (mg/kg)	Comment
Peanut	meal	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Potato	process waste	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Potato	dried pulp	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Rape	meal	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.003	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Soybean	meal	0.0081	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.0081	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)
Soybean	hulls	0.0081	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)	0.0081	STMR (FAO, 2005; EFSA, 2011) * PrF * pf (1)

PrF = production factor (0.3), based on hydrolysis data, see section 3.1.4.

Pf = processing factor – all inputs are <0.01 mg/kg; as such, the default pfs have been set to 1 for all processed commodities.

Table 4.1-4 Estimated animal intakes – IN-KT413

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg /kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity ^(a)
Cattle (all diets)	0.001	0.001	N	0.02	Beet, sugar ensiled pulp

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	>0.1 mg /kg DM (Y/N)	Maximum burden (mg/kg DM)	Highest contributing commodity^(a)
Cattle (dairy only)	0.001	0.001	N	0.02	
Sheep (all diets)	<0.001	<0.001	N	0.01	Potato process waste
Sheep (ewe only)	<0.001	<0.001	N	0.01	
Swine (all diets)	<0.001	<0.001	N	0.01	
Poultry (all diets)	<0.001	<0.001	N	0.00	Soybean meal
Poultry (layer only)	<0.001	<0.001	N	0.00	

(a) Considering the maximum dietary animal burden

Based on the dietary burden calculations, consideration of the likely residues in products of animal origin is not required for IN-KT413 as the trigger of 0.1 mg/kg DM and AR is not exceeded for any animal groups.

The above conclusion also applies to the processing metabolites IN-MP819, IN-MK638, IN-P0036, and IN-TMG00 as these are all expected to occur in lower amounts than IN-KT413. An updated dietary burden for these metabolites formed on processing may be required as part of any application to set new MRLs; this may also trigger the need for additional data.

4.2 Nature of residues (Animal metabolism studies)

Metabolism was investigated in ruminants (lactating goats) and poultry (laying hens). A summary of the available livestock metabolism data from the approval of indoxacarb is presented below (DAR, 2000):

Table 4.2-1 Summary of animal metabolism data (DAR, 2000)

Species	Label position	Number of specimens	Application details		Sampling	
			Duration	Rate	Commodity	Time
Dairy cow	indanone-1- ¹⁴ C	2	5	0.408 mg/kg bw/d (10 mg/kg DM)	Milk (skim milk and cream)	Daily
	Trifluoromethoxy phenyl ring- ¹⁴ C	2			Urine and faeces	Daily
					Tissues	6 days
Laying hen	indanone-1- ¹⁴ C	2	5	0.705 mg/kg bw/d (10 mg/kg DM)	Egg (yolk, white)	Daily
	Trifluoromethoxy phenyl ring- ¹⁴ C	2			Excreta	Daily
					Tissues	6 days

The available animal metabolism studies have been considered in detail below. The residue definitions have been reconsidered.

4.2.1 Poultry

HSE has considered the residue levels that arise in products of poultry origin on the basis of a consideration to the calculated dietary burden for GB (calculated DB) and the dietary burden calculated by the JMPR for the CXLs (JMPR DB).

Eggs

Residues were determined separately in egg yolk and egg white; considering that MRLs are set for whole eggs, the results have been combined using a weighted average, assuming egg yolks make up 30% of the overall egg. Eggs were sampled after 72 hours, and 120 hours; the results for each label are described below, between 79-98% TRR was extracted in all cases.

Table 4.2.1-1 TRR and identified metabolites in eggs – indanone label (mg eq./kg)

Compound	72h			120h		
	Whites	Yolk	Whole egg	White	Yolk	Whole egg
TRR	0.033	0.114	0.057	0.098	0.318	0.164
extracted	0.03	0.09	0.048	0.09	0.25	0.138
IN-KG433	<0.01	0.02	0.006	<0.01	0.04	0.012
IN-KT319	<0.01	0.01	0.003	<0.01	0.02	0.006
IN-JU873	<0.01	0.01	0.003	<0.01	0.02	0.006
5-OH-JT333	<0.01	0.01	0.003	<0.01	0.04	0.012
Met. F	<0.01	0.01	0.003	<0.01	0.05	0.015
Indoxacarb	<0.01	0.01	0.003	<0.01	0.01	0.003
IN-JT333	<0.01	0.01	0.003	<0.01	0.02	0.006
IN-MK638	<0.01	0.01	0.003	0.01	<0.01	0.007
IN-KB687	<0.01	0.01	0.003	0.01	<0.01	0.007

Table 4.2.1-2 TRR and identified metabolites in eggs – trifluoromethoxy phenyl label (mg eq./kg)

Compound	72h			120h		
	Whites	Yolk	Whole egg	White	Yolk	Whole egg
TRR	0.021	0.138	0.056	0.051	0.329	0.134
extracted	0.02	0.11	0.047	0.05	0.31	0.128
IN-KG433	<0.01	0.02	0.006	<0.01	0.04	0.012
IN-KT319	<0.01	0.01	0.003	<0.01	0.02	0.006
IN-JU873	<0.01	0.01	0.003	<0.01	0.03	0.009
5-OH-JT333	<0.01	0.01	0.003	<0.01	0.04	0.012
Met. F	<0.01	0.01	0.003	<0.01	0.04	0.012
Indoxacarb	<0.01	0.01	0.003	<0.01	0.01	0.003
IN-JT333	<0.01	0.01	0.003	<0.01	0.02	0.006
IN-MK638	0.01	0.01	0.01	0.01	0.03	0.016
IN-KB687	0.01	0.01	0.01	0.01	0.03	0.016

Table 4.2.1-3 TRR and identified metabolites in tissues – indanone label (mg eq./kg)

Compound	Fat	Skin with fat	Liver	Thigh muscle	Breast muscle
TRR	0.457	0.213	0.105	0.04	0.02
extracted	0.450	0.210	0.05	0.04	0.02
IN-KG433	0.03	0.01	0.01	<0.01	<0.01
IN-KT319	0.02	0.01		<0.01	<0.01
IN-JU873	0.01	<0.01	0.02	<0.01	<0.01
5-OH-JT333	0.07	0.03		<0.01	<0.01
Met. F	0.22	0.06	0.01	0.01	<0.01
Indoxacarb	0.02	0.04	0.01	<0.01	<0.01
IN-JT333	0.08	0.04	<0.01	0.01	<0.01

† IN-KG433 and IN-KT319 co-eluted in liver sample

‡ IN-JU873 and 5-OH-JT333 co-eluted in liver sample

Table 4.2.1-4 TRR and identified metabolites in tissues – trifluoromethoxy phenyl label (mg eq./kg)

Compound	Fat	Skin with fat	Liver	Thigh muscle	Breast muscle
TRR	0.508	0.253	0.146	0.037	0.017
extracted	0.50	0.25	0.09	0.03	0.02
IN-KG433	0.03	0.02	0.01†	<0.01	<0.01
IN-KT319	0.03	0.02		<0.01	<0.01
IN-JU873	0.01	0.02	0.03‡	0.01	<0.01
5-OH-JT333	0.08	0.03		<0.01	<0.01
Met. F	0.19	0.04	0.01	<0.01	<0.01
Indoxacarb	0.03	0.02	0.01	<0.01	<0.01
IN-JT333	0.09	0.03	<0.01	<0.01	<0.01
IN-MK638	<0.01	0.01	0.01	0.01	<0.01
IN-KB687	0.01	<0.01	0.01	<0.01	<0.01

† IN-KG433 and IN-KT319 co-eluted in liver sample

‡ IN-JU873 and 5-OH-JT333 co-eluted in liver sample

Parent indoxacarb was a minor component in eggs (max. 0.003 mg/kg) and tissue samples (0.04 mg/kg – fat). A wide range of metabolites were identified in poultry commodities.

The calculated dietary burden, based on the retained MRLs/adopted CXLs considered acceptable in scenario 3; is 0.11 mg/kg DM. The maximum dietary burden calculated by the JMPR was 1.5 mg/kg DM (FAO, 2009); the JMPR feed tables were updated in 2018, and when the dietary burden was recalculated in 2022, the maximum dietary burden was

0.705 mg/kg DM. The 2022 JMPR DB included additional commodities, and as it is based on an updated diet, this value has been considered.

Considering the dose rate in the study (nominal 10 mg/kg DM); the study is overdosed by a factor of 91N (based on calculated dietary burden) and 14.2N (based on relevant JMPR DB). On this basis, all metabolites in eggs, skin with fat, liver and muscle (breast and thigh) are expected to be <0.01 mg/kg.

For fat, based on the worst case JMPR DB, metabolite 'F' may be present at up to 0.015 mg eq./kg. Based on the calculated DB, no residues are expected above 0.01 mg/kg.

The current GB MRLs and CXLs for indoxacarb in poultry tissue matrices are set at the LOQ (0.01* mg/kg).

For eggs, the current GB MRL is 0.02 mg/kg, which is equivalent to the CXL. As noted above, no metabolites are expected to exceed 0.01 mg/kg in eggs, as such the current GB MRL and CXL are sufficiently conservative.

Feeding study consideration

In addition, a feeding study was considered by the JMPR, and for the EU Article 12 review (Section 4.3), the lowest dose group was 1.75 mg/kg DM and is 2.5N compared to the maximum JMPR DB. Indoxacarb, IN-JT333, IN-KT319, IN-KG433, IN-JU873, and IN-KB687 were monitored in the feeding study.

Metabolite F was not analysed for.

When scaled to the worst case JMPR dietary burden, no residues are expected to exceed 0.01 mg/kg in eggs.

In tissues, when scaled to the worst case JMPR DB, no residues exceed 0.01 mg/kg in muscle, liver and skin. In fat, the metabolite IN-JT333 may be expected at up to 0.018 mg/kg. Based on the calculated DB, no residues are expected above 0.01 mg/kg.

4.2.1.1 Conclusion on residue definitions – poultry

HSE has considered the residue definitions for poultry on the basis of the calculated dietary burden for GB (calculated DB) and the dietary burden calculated by the JMPR for the CXLs (JMPR DB).

No measurable residues of any metabolite are expected in any poultry matrix, including eggs, based on the calculated DB. No further consideration is therefore required on the toxicity of the metabolites. The residue definition based on the calculated DB is proposed as parent indoxacarb (and its R enantiomer).

The further consideration of the residue definitions for poultry, including based on the JMPR DB is outlined below:

On considering the **residue definition for risk assessment and enforcement**, HSE has considered the relative levels and toxicological properties of parent indoxacarb, IN-JT333, 5-OH-JT333, IN-KG433, IN-KB687, IN-KT319, IN-JU873, IN-MK638 and 'metabolite F'.

No residues of **parent indoxacarb, 5-OH-JT333, IN-KG433, IN-KB687, IN-KT319, IN-JU873, and IN-MK638** are expected in poultry matrices when considering the GB dietary burden and the JMPR dietary burden.

IN-JT333 may be expected at up to 0.018 mg/kg in fat based on the calculated JMPR dietary burden (JMPR, 2009). As detailed in section 2, the CCIII TTC chronic and acute threshold values apply to IN-JT333. A TTC assessment has been conducted, see appendix A. Based on expected exposure from the current GB MRL, the CCIII TTC threshold values are not exceeded. On this basis, IN-JT333 does not need to be included in the RD-RA for fat.

Metabolite F may be present in poultry fat at up to 0.015 mg/kg; metabolite F has not been formally identified, and no toxicological data is available for metabolite F. In addition, metabolite F was not analysed for in the feeding study. On this basis, **metabolite F should be provisionally included in the RD-RA for fat.**

On the basis that residues of all metabolites are expected to be <LOQ in the majority of poultry matrices, and that IN-JT333 does not need to be considered, the **residue definition for enforcement is recommended as parent indoxacarb (and its R-enantiomer).**

Proposed residue definition for enforcement in poultry:

- Indoxacarb (and its R-enantiomer)

For risk assessment, only metabolite F is likely to be found in fat. Therefore, HSE recommends the following residue definitions for poultry as outlined below:

Proposed residue definition for risk assessment in poultry (excluding fat):

- Indoxacarb (and its R-enantiomer)

Proposed residue definitions for risk assessment in poultry fat:

- Indoxacarb (and its R-enantiomer)

- Metabolite F (provisional pending additional information to allow formal identification, as well as relevant toxicological information and/or feeding studies to elucidate its occurrence)

As noted the identity (and hence toxicity) of metabolite F is unknown. However, the MRL for poultry fat is set at the LOQ (0.01* mg/kg) and no changes to this MRL are proposed. Based on the calculated DB, maintaining the MRL at the LOQ will ensure there is no exposure to this metabolite.

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4.2.2 Ruminants/mammals

HSE has considered the residue levels and residue definitions for products of ruminant origin on the basis of a consideration to the calculated dietary burden for GB (calculated DB) and the dietary burden calculated by the JMPR for the CXLs (JMPR DB).

Milk

Table 4.2.2-1 TRR and identified metabolites in milk

Compound	Residue (mg eq./kg)	
	indanone label	trifluoromethoxy phenyl label
TRR	0.112	0.057
extracted	0.059	0.051
Indoxacarb	0.028	0.028
IN-JT333	ND	ND
IN-MP819	0.023	0.016
5-OH-JT333	ND	ND
5-OH-indoxacarb	ND	ND
IN-KG433	ND	ND
IN-MN470 & IN-MF014	ND	ND
OH-indoxacarb-glucuronide	ND	ND

Tissues

Table 4.2.2-2 TRR and identified metabolites in tissues – indanone label

Compound	Residue (mg eq./kg) – indanone label			
	Muscle	Liver	Kidney	Fat
TRR	0.04	0.537	0.365	1.1
extracted	0.032	0.294	0.257	1.07
Indoxacarb	0.01	0.038	0.153	0.89
IN-JT333	ND	<0.01	ND	0.06
IN-MP819	ND	<0.01	ND	ND
5-OH-JT333	ND	<0.01	ND	ND
5-OH-indoxacarb	<0.01	0.03	0.023	ND
IN-KG433	ND	ND	ND	ND
IN-KB687	ND	ND	ND	ND
IN-MN470 & IN-MF014	ND	ND	ND	ND
OH-indoxacarb-glucuronide	ND	0.024	ND	ND

Table 4.2.2-3 TRR and identified metabolites in tissues – trifluoromethoxy phenyl label

Compound	Residue (mg eq./kg) - trifluoromethoxy phenyl label			
	Muscle	Liver	Kidney	Fat
TRR	0.05	0.689	0.288	1.1
extracted	0.04	0.402	0.247	1.03
Indoxacarb	0.02	0.079	0.177	0.72
IN-JT333	ND	<0.01	ND	0.08
IN-MP819	ND	<0.01	ND	ND
5-OH-JT333	ND	<0.01	ND	ND
5-OH-indoxacarb	<0.01	0.063	0.037	ND
IN-KG433	ND	<0.01	ND	ND
IN-KB687	ND	0.022	ND	ND
IN-MN470 & IN-MF014	ND	0.060	ND	ND
OH-indoxacarb-glucuronide	ND	0.019	ND	ND

The calculated dietary burden, based on the retained MRLs/adopted CXLs considered acceptable in scenario 3 is 0.8 mg/kg DM. The maximum dietary burden calculated by the JMPR was 41 mg/kg DM (FAO, 2009); the JMPR feed tables were updated in 2018, and when the dietary burden was recalculated in 2022, the maximum dietary burden was 75 mg/kg DM. The current GB MRLs are based on the CXLs derived in 2009; the DB calculated in 2022 is not relevant.

Considering the dose rate in the study (nominal 10 mg/kg DM), the study is overdosed by a factor of 12.5N (based on calculated dietary burden) and is underdosed by a factor of 0.25N (based on relevant JMPR DB).

On this basis, all metabolites are expected to be <0.01 mg/kg, based on the calculated DB.

For ruminants, the parent compound (racemic mixture) was found to be the major component of the residue for muscle, kidney and fat – comprising between 30-100% of the identified residue in each tissue matrix. In milk, parent indoxacarb was again the major component – comprising at least 55% of the identified residue. On this basis, **parent indoxacarb is considered to be a suitable marker compound** in ruminant tissue and milk. Also on this basis, **parent indoxacarb is recommended for inclusion in the residue definition for risk assessment**.

On considering the **residue definition for risk assessment**, HSE has considered the relative levels and toxicological properties of IN-JT333, IN-MP819, 5-OH-JT333, 5-OH-indoxacarb, IN-KG433, IN-KB687, IN-MN470 & IN-MF014, and OH-indoxacarb-glucuronide.

Regarding milk, the only metabolite identified was **IN-MP819** – this was present at between 57-82% of the level of parent indoxacarb. IN-MP819 is to be assessed against CCIII TTC values; IN-MP819 is also formed on processing – a TTC assessment was undertaken in section 3.1.4.2. For the current GB MRL on milk (0.1 mg/kg), the chronic TTC value was exceeded. IN-MP819 should be provisionally included in the RD-RA, pending further toxicological information. IN-MP819 was not identified >0.01 mg eq./kg in any tissue matrix.

5-OH-indoxacarb was identified at 6-13% TRR in kidney, 6-9% TRR in liver, and up to 25% TRR in muscle. However, absolute levels in muscle were low (<0.01 mg eq./kg). In liver and kidney, 5-OH indoxacarb was present at between 15-20% of the level of parent indoxacarb in kidney and between 78-79% of the level of parent indoxacarb in liver. **OH-indoxacarb-glucuronide** (the glucuronide conjugate of 5-OH-indoxacarb) was identified at 2.8-4.5 %TRR in liver only. For the current GB MRLs, 5-OH indoxacarb (free and conjugated) is predicted to occur at <0.01 mg/kg in kidney, and at up to 0.012 mg/kg in liver. As detailed in section 2, HSE recommend that 5-OH-indoxacarb (free and conjugated) is assessed against TTC CCIII values. A TTC assessment has been conducted; see appendix A. 5-OH-indoxacarb (free and conjugated) does not exceed the TTC CCIII chronic or the acute threshold value, as such, this metabolite does not need to be included in the RD-RA.

IN-MN470 & IN-MF014 (co-eluted) were identified in liver (trifluoromethoxy phenyl label only) at 9% TRR. These metabolites were present at 76% of the level of parent indoxacarb in liver (one label only). As detailed in section 2, HSE recommend that IN-MN470 & IN-MF014 are assessed against TTC CCIII values. Given that a TTC assessment was conducted for 5-OH-indoxacarb, and that the levels of IN-MN470 & IN-MF014 are lower than the observed levels of 5-OH-indoxacarb, it can be concluded that IN-MN470 & IN-MF014 will not exceed the TTC CCIII chronic or the acute threshold value; as such, these metabolite does not need to be included in the RD-RA.

IN-JT333, was not detected at >0.01 mg eq./kg in any matrix except for fat. In fat, IN-JT333 was identified at 5-7% TRR, and was present at 7-11% of the level of parent indoxacarb. IN-JT333 was analysed for in the ruminant feeding study; based on the JMPR DB which supports the current GB MRLs, it is expected at a maximum of 0.046 mg/kg (JMPR, 2009). As detailed in section 2, HSE recommends the application of the CCIII TTC value and acute threshold value. Based on expected exposure from the current GB MRL, the CCIII TTC threshold values are not exceeded. On this basis, IN-JT333 does not need to be included in the RD-RA for fat.

IN-KB687 was identified in liver (trifluoromethoxy phenyl label only) at 3% TRR. IN-KB687 was present at 28% of the level of parent indoxacarb in liver. No genotoxicity information is available for these metabolites, based on the renewal review (EFSA, 2018). Based on the

current GB MRL for liver, IN-KB687 is expected to be <0.01 mg/kg. IN-KB867 is not recommended for inclusion in the RD-RA.

5-OH-JT333, and IN-KG433 were not detected at >0.01 mg eq./kg in any matrix, 5-OH-JT333, and IN-KG433 are not recommended for inclusion in the RD-RA.

4.2.2.1 Conclusion on residue definitions – ruminants/mammals

On the basis of the above, HSE recommends the following residue definitions:

Proposed residue definition for risk assessment in ruminant tissues, and enforcement definition in ruminant tissues and milk:

- Indoxacarb (and its R-enantiomer)

Proposed residue definition for risk assessment in milk:

1. Indoxacarb (and its R-enantiomer)
2. IN-MP819 (provisional – pending additional toxicological information; and/or feeding studies which elucidate its occurrence)

Milk

Based on the current GB MRL of 0.1 mg/kg, exposure to IN-MP819 exceeds the TTC CCIII chronic threshold value. In the absence of specific toxicological information, HSE recommends that the MRL for milk is set at 0.01* mg/kg and this will ensure residues of the metabolite will also be <0.01* mg/kg.

In order to set a substantive MRL for milk, additional toxicological data and feeding studies for the metabolite are required.

4.3 Magnitude of residues

Based on the retained MRLs (scenario 3), and considering the commodities which are relevant as imported feed items, the estimated livestock dietary burden is ≥0.1 mg/kg DM and the livestock metabolism studies indicate residues in products of animal origin may be at or above 0.01 mg/kg at a 1N dose. As such, consideration of feeding studies is required.

Livestock feeding studies were undertaken in lactating cows (ruminants) for the approval of the active substance (DAR, 2000) and in laying hens (poultry) by the JMPR (FAO, 2009) and for the Article 12 review (EFSA, 2011).

Laying hens were dosed with indoxacarb, at a rate of 1.75, 7, 21 and 70 mg/kg DM (which equates to of 0.11, 0.44, 1.33 and 4.42 mg/kg bw/day). The study duration was 28 days. Residues of indoxacarb, IN-JT333, IN-KT319, IN-KG433, IN-JU873, and IN-KB687 were analysed for.

Lactating cows were dosed with indoxacarb, at a rate of 7.5, 22.5 and 75 mg/kg DM (which equates to of 0.3, 0.9 and 3.0 mg/kg bw/day). The study duration was 28 days. Residues of indoxacarb, IN-JT333 were analysed for.

The feeding studies have not been used further within this section to estimate the residues as the current GB MRLs are based on the CXLs, and a consideration of these is outlined in Section 4.2: the MRLs for eggs, milk and mammalian liver are proposed to be lowered to the LOQ (0.01* mg/kg) – this is to avoid exposure to a number of metabolites.

Regarding the remaining animal commodity MRLs, the retention of the existing GB MRLs (which are based on the CXLs) is recommended on the basis of the following residue definition for risk assessment and enforcement:

- Indoxacarb (and its R-enantiomer)

It is noted that the current GB MRL for mammalian muscle (2 mg/kg) is set based on the CXL for meat – as indoxacarb is fat soluble, the CXL for meat was based on the residue levels in fat. As the GB MRL for muscle is set independently of residues in fat, it is appropriate to recalculate the GB MRL on a muscle only basis. This results in an MRL (CXL) of 0.05 mg/kg. The STMR/HR used in the consumer risk assessment (all scenarios) are already based on the 80/20 ratio for muscle/fat.

4.4 Conversion factor for risk assessment for products of animal origin

As the residue definitions for enforcement (RD-Enf) and risk assessment (RD-RA) are equivalent for poultry tissue, and ruminant tissue (excluding liver), conversion factors (CFs) for enforcement to risk assessment are not required.

For birds eggs, milks, and ruminant liver, the RD-Enf and RD-RA are not equivalent. However, as toxicological information is missing in each case, the MRL is to be set at the LOQ (0.01* mg/kg) for birds eggs, milks and all mammalian liver no conversion factors are required.

5 Residues in honey

As a result of the non-approval of indoxacarb, there are no GB uses. As such, the potential for indoxacarb residues in honey produced in GB does not need to be considered. No CXL exists for honey. The GB MRL for honey will be set at the limit of quantification applicable to honey which is 0.05* mg/kg.

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6 MRLs for commodities not covered in sections 3 and 4

Not applicable, see table 0.3.

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7 Consumer risk assessment

7.1 Dietary Exposure

Consumer intake calculations have been performed using the UK chronic and acute dietary exposure models (versions 1.2 and 1.1 respectively) and the EFSA PRIMo model. Model outputs for the UK acute and chronic models and for EFSA PRIMo revision 3.1 are presented in Appendix A.

Several different scenarios have been presented for the consumer risk assessments to find a combination of commodities which do not result in exposures that exceed the ADI and hence present a chronic risk to UK consumers:

- **Scenario 1:** Consumer risk assessments for the current GB MRLs
- **Scenario 2:** Consumer risk assessments for the current GB MRLs, excluding those which result in an acute risk. In addition, if a CXL exists for a commodity for which no acute risk was observed in scenario 1, this has been considered.

For the commodities for which an acute risk was identified in scenario 1, the input has been set at the LOQ (0.01* mg/kg), or if a lower CXL is available, the CXL has been used as an input.

- **Scenario 3:** Consumer risk assessments based on scenario 2, excluding any commodities which result in an acute risk.

For the acute assessments, the default LOQ MRL of 0.01* mg/kg does not lead to any exceedances of the ARfD; the default LOQ MRL meets the UK's appropriate level of protection for the acute risk assessment. Therefore, the acute risk assessments for each scenario have focused on the relevant commodities only. Further details of the approach HSE has taken to ensure the UK's appropriate level of protection is met is outlined in Appendix A.

UK NEDIs and NESTIs

The UK NEDIs and NESTIs for the active substance and commodities listed in the tables below have been calculated for ten consumer groups using the UK acute and chronic models (versions 1.2 and 1.1 respectively) as detailed in Regulatory Update 21/2005. The following assumptions have been made:

- For the NESTIs, upper range of normal (97.5th percentile) consumption of each individual crop which may have been treated.

- For the NEDIs, the 'Rees-Day' approach is taken which sums the two highest 97.5th percentile intakes and the mean intakes for all remaining commodities.
- All produce eaten which may have been treated has been treated and contains residues at the levels given in the tables below.
- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

PRIMo

The PRIMo IEDIs and IESTIs for the active substance and commodities listed in the tables below have been calculated using PRIMo revision 3.1 – Pesticide Residues Intake Model.

The following assumptions have been made:

- All produce eaten which may have been treated, has been treated and contains residues at the levels as given in the tables below.
- There is no loss of residue during transport or storage, or processing of foods prior to consumption.

7.1.1 Scenario 1: Consumer risk assessment for the current GB MRLs

The consumer risk assessment of the current MRLs (GB MRL Statutory Register) with the supporting input values has been presented below. The STMRs which support the current GB MRLs are taken from previous assessments (presented in EFSA 2016b) and, for the remaining commodities, the existing MRLs established in the GB MRL Statutory Register have been used.

The input values for the UK risk assessments are given in Table 7.1-1.

Table 7.1-1 Input values for the UK consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Apples	0.21	STMR (FAO, 2005; EFSA, 2011)	0.26	HR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Pears	0.21	STMR (FAO, 2005; EFSA, 2011)	0.26	HR (FAO, 2005; EFSA, 2011)
Stone fruits (apricots, peaches, plums, cherries)	0.17	STMR (FAO, 2009)	0.64	HR (FAO, 2009)
Table and wine grapes	0.32	STMR (FAO, 2005)	1.5	HR (FAO, 2005)
Strawberries	0.19	STMR (EFSA, 2012)	0.27	HR (EFSA, 2012)
Blackberries ¹	0.255	STMR (EFSA, 2011)	0.52	HR (EFSA, 2011)
Raspberries ¹	0.26	STMR (EFSA, 2011)	0.3	HR (EFSA, 2012)
Gooseberries, currants (black, red and white) ¹	0.11	STMR (EFSA, 2011)	0.52	HR (EFSA, 2011)
Cranberries ¹	0.15	Current STMR (FAO 2009)	0.69	Current HR (FAO 2009)
Bananas	0.044	STMR (EFSA, 2011)	0.092	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	HR (FAO, 2005; EFSA, 2011)
Radishes	0.02	STMR (EFSA, 2011)	0.16	HR (EFSA, 2011)
Tomatoes	0.11	STMR (FAO, 2005; EFSA, 2011)	0.3	HR (FAO, 2005; EFSA, 2011)
Peppers	0.06	STMR (FAO, 2005; EFSA, 2011)	0.21	HR (FAO, 2005; EFSA, 2011)
Aubergines	0.11	STMR (FAO, 2005; EFSA, 2011)	0.3	HR (FAO, 2005; EFSA, 2011)
Cucurbits with edible and inedible peel	0.06	STMR (FAO, 2005; EFSA, 2011)	0.39	HR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	HR (FAO, 2005; EFSA, 2011)
Flowering brassica	0.08	STMR (EFSA, 2011)	0.21	HR (EFSA, 2011)
Brussels sprouts	0.02	STMR (EFSA, 2011)	0.04	HR (EFSA, 2011)
Head cabbage	0.02	STMR (EFSA, 2011)	0.09	HR (EFSA, 2011)
Chinese cabbage	0.49	STMR (EFSA, 2011)	1.54	HR (EFSA, 2011)
Kale ⁴	0.05	STMR (EFSA, 2011)	0.13	HR (EFSA, 2011)
Lambs lettuce ⁵	8.6	STMR (EFSA, 2012)	15	HR (EFSA, 2012)
Lettuce	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Roman rocket/rucola (covered by lettuce)	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomers)	commodities:
Baby leaf crops (including brassica) (covered by lettuce)	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Escaroles/broad leaved endives, cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants (input as chicory)	0.27	STMR (EFSA, 2013)	0.55	HR (EFSA, 2013)
Spinach	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Purslanes, Chards/beet leaves, others – spinaches and similar leaves (covered by spinach)	0.27	STMR (EFSA, 2013)	0.55	HR (EFSA, 2013)
Herbs and edible flowers (except basil) (input as parsley) ²	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Basil ²	3.5	STMR (FAO, 2005; EFSA, 2011)	6.8	HR (FAO, 2005; EFSA, 2011)
Beans with pods	0.11	STMR (EFSA, 2013b)	0.24	STMR (EFSA, 2013b)
Cardoons, fennel, rhubarb (covered by fennel and rhubarb)	0.97	STMR (EFSA, 2012)	1.53	HR (EFSA, 2012)
Celeries	0.849	STMR (EFSA, 2011)	0.931	HR (EFSA, 2011)
Globe artichokes	0.035	STMR (EFSA, 2011)	0.070	HR (EFSA, 2011)
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)	0.13	HR (FAO, 2005; EFSA, 2011)
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	STMR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Rapeseeds ³	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	STMR (FAO, 2005; EFSA, 2011)
Soyabeans ³	0.027	STMR (FAO, 2005; EFSA, 2011)	0.027	STMR (FAO, 2005; EFSA, 2011)
Cotton seed ³	0.36	STMR (FAO, 2005; EFSA, 2011)	0.36	STMR (FAO, 2005; EFSA, 2011)
Mustard seed ³	0.01	STMR (EFSA, 2013b)	0.01	STMR (EFSA, 2013b)
Maize/ corn	0.01	STMR (EFSA, 2011)	0.01	STMR (EFSA, 2011)
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	0.41	STMR (FAO, 2013; EFSA, 2014)
Sugar beet roots	0.026	STMR (EFSA, 2011)	0.060	STMR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Mammalian muscle	0.08	STMR (FAO, 2009; EFSA, 2011)	0.25	HR (FAO, 2009; EFSA, 2011)
Mammalian fat	0.38	STMR (FAO, 2009; EFSA, 2011)	1.07	HR (FAO, 2009; EFSA, 2011)
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2009; EFSA, 2011)	0.03	HR (FAO, 2009; EFSA, 2011)
Milk	0.037	STMR (FAO, 2009; EFSA, 2011)	0.037	STMR (FAO, 2009; EFSA, 2011)
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	0.05	STMR-CXL x (FAO, 2009)
Poultry liver	0.01	STMR-CXL x (FAO, 2009)	0.01	STMR-CXL x (FAO, 2009)
Birds eggs	0.01	STMR-CXL x (FAO, 2009)	0.02	STMR-CXL x (FAO, 2009)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
All other commodities	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk only for the uses	assessment undertaken commodities relevant to under assessment

Assessments using surrogate crops been conducted separately for the acute risk assessment, in order to assess the risk associated with the crops used for the surrogate assessment – for the chronic risk assessment, the worst case input was used, this applies to footnotes 1, 2, 3, 4 and 5.

¹ There is no UK consumption data for cranberries, blueberries or rose hips. The following surrogate commodity have been used: cranberries – blackcurrants; blueberries & rose hips – blackberries and raspberries.

² There is no UK consumption data for basil, parsley has been used as a surrogate commodity.

³ There is no UK consumption data for specific oilseeds; the input is for oilseeds only.

⁴ There is no UK consumption data for kale, head cabbage has been used as a surrogate commodity.

⁵ There is no UK consumption data for lamb's lettuce, lettuce has been used as a surrogate commodity.

The input values for the PRIMo risk assessments are given in Table 7.1-2.

Table 7.1-2 Input values for the PRIMo consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Apples	0.21	STMR (FAO, 2005; EFSA, 2011)	0.26	HR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Pears	0.21	STMR (FAO, 2005; EFSA, 2011)	0.26	HR (FAO, 2005; EFSA, 2011)
Stone fruits	0.17	STMR (FAO, 2009)	0.64	HR (FAO, 2009)
Table and wine grapes	0.32	STMR (FAO, 2005)	1.5	HR (FAO, 2005)
Strawberries	0.19	STMR (EFSA, 2012)	0.27	HR (EFSA, 2012)
Blackberries	0.255	STMR (EFSA, 2011)	0.52	HR (EFSA, 2011)
Raspberries	0.26	STMR (EFSA, 2011)	0.3	HR (EFSA, 2012)
Other small fruits and berries (except cranberries)	0.11	STMR (EFSA, 2011)	0.52	HR (EFSA, 2011)
Cranberries ³	0.15	Current STMR (FAO 2009)	0.69	Current HR (FAO 2009)
Bananas	0.044	STMR (EFSA, 2011)	0.092	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	HR (FAO, 2005; EFSA, 2011)
Radishes	0.02	STMR (EFSA, 2011)	0.16	HR (EFSA, 2011)
Tomatoes	0.11	STMR (FAO, 2005; EFSA, 2011)	0.3	HR (FAO, 2005; EFSA, 2011)
Peppers	0.06	STMR (FAO, 2005; EFSA, 2011)	0.21	HR (FAO, 2005; EFSA, 2011)
Aubergines	0.11	STMR (FAO, 2005; EFSA, 2011)	0.3	HR (FAO, 2005; EFSA, 2011)
Cucurbits with edible and inedible peel	0.06	STMR (FAO, 2005; EFSA, 2011)	0.39	HR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	HR (FAO, 2005; EFSA, 2011)
Flowering brassica	0.08	STMR (EFSA, 2011)	0.21	HR (EFSA, 2011)
Brussels sprouts	0.02	STMR (EFSA, 2011)	0.04	HR (EFSA, 2011)
Head cabbage	0.02	STMR (EFSA, 2011)	0.09	HR (EFSA, 2011)
Chinese cabbage	0.49	STMR (EFSA, 2011)	1.54	HR (EFSA, 2011)
Kale, other leafy brassica vegetables	0.05	STMR (EFSA, 2011)	0.13	HR (EFSA, 2011)
Lambs lettuce	8.6	STMR (EFSA, 2012)	15	HR (EFSA, 2012)
Lettuce	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Roman rocket/rucola	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomers)	commodities:
Baby leaf crops (including brassica)	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Escaroles/broad leaved endives, cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants	0.27	STMR (EFSA, 2013)	0.55	HR (EFSA, 2013)
Spinach	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)
Purslanes, Chards/beet leaves, others – spinaches and similar leaves	0.27	STMR (EFSA, 2013)	0.55	HR (EFSA, 2013)
Chives, sage, rosemary, thyme, laurel/bay leaves, tarragon	0.46	STMR (EFSA, 2011)	0.98	HR (EFSA, 2011)
Chervil, celery leaves, parsley	0.52	STMR (EFSA, 2011)	1.64	HR (EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Basil	3.5	STMR (FAO, 2005; EFSA, 2011)	6.8	HR (FAO, 2005; EFSA, 2011)
Beans with pods	0.11	STMR (EFSA, 2013b)	0.24	STMR (EFSA, 2013b)
Cardoons, fennel, rhubarb	0.97	STMR (EFSA, 2012)	1.53	HR (EFSA, 2012)
Celeries	0.849	STMR (EFSA, 2011)	0.931	HR (EFSA, 2011)
Globe artichokes	0.035	STMR (EFSA, 2011)	0.070	HR (EFSA, 2011)
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)	0.13	HR (FAO, 2005; EFSA, 2011)
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	STMR (FAO, 2005; EFSA, 2011)
Rapeseeds	0.01	STMR (FAO, 2005; EFSA, 2011)	0.01	STMR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment	Acute risk assessment		
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Soyabeans	0.027	STMR (FAO, 2005; EFSA, 2011)	0.027	STMR (FAO, 2005; EFSA, 2011)
Cotton seed	0.36	STMR (FAO, 2005; EFSA, 2011)	0.36	STMR (FAO, 2005; EFSA, 2011)
Mustard seed	0.01	STMR (EFSA, 2013b)	0.01	STMR (EFSA, 2013b)
Maize/ corn	0.01	STMR (EFSA, 2011)	0.01	STMR (EFSA, 2011)
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	0.41	STMR (FAO, 2013; EFSA, 2014)
Sugar beet roots	0.026	STMR (EFSA, 2011)	0.060	STMR (EFSA, 2011)
Mammalian muscle	0.08	STMR (FAO, 2005; EFSA, 2011)	0.25	HR (FAO, 2005; EFSA, 2011)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum	residue of indoxacarb	definition and its R	plant/animal enantiomers)	commodities:
Mammalian fat	0.38	STMR (FAO, 2005; EFSA, 2011)	1.07	HR (FAO, 2005; EFSA, 2011)
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2005; EFSA, 2011)	0.03	HR (FAO, 2005; EFSA, 2011)
Milk	0.037	STMR (FAO, 2005; EFSA, 2011)	0.037	STMR (FAO, 2005; EFSA, 2011)
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	0.05	STMR-CXL x (FAO, 2009)
Poultry liver	0.01	STMR-CXL x (FAO, 2009)	0.01	STMR-CXL x (FAO, 2009)
Birds eggs	0.01	STMR-CXL x (FAO, 2009)	0.02	STMR-CXL x (FAO, 2009)
All other commodities	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk only for the uses	assessment undertaken commodities relevant to under assessment

Model outputs for the UK acute and chronic models (versions 1.2 and 1.1 respectively) are presented in Appendix B.

Conclusions

The highest UK NEDI was 273 % of the ADI (toddler). The highest PRIMo IEDI was 163% of the ADI (NL toddler). Therefore, a chronic intake concern has been identified from exposure to indoxacarb from all dietary sources.

The highest UK NESTI was 2324.5 % of the ARfD (infant/head cabbage). The highest IESTI was 2188% of the ARfD (child/table grapes). The MRLs which result in acute intake concerns are detailed in the table below:

Table 7.1-3 Acute exposure output – scenario 1 assessment

Model	Commodities	which result	in an acute	exceedance
	Commodity	Exceedance (%)	Commodity	Exceedance (%)
UK acute model, version 1.2	Lamb's lettuce ¹	5341.5	Cauliflower	243.3
	Table grapes	1831.0	Cucumber	230.2
	Rhubarb	1138.3	Spinach	186.1
	Chinese cabbage	779.7	Marrow	166.0
	Wine grapes	711.6	basil ¹	162.9
	Peaches	704.5	Celery	154.2
	Melons	648.4	Bananas	153.8
	Lettuce	584	Chicory	152.1
	Roman rocket ¹	584	Aubergines	150.0
	Baby leaf crops ¹	584	Gourd	114.7
	Fennel	570.3	kale ¹	111.9
	Apples	509.4	Blackberries	111.5
	Pears	441.4	blueberries ¹	111.5
	Plums	378.4	rosehips ¹	111.5
	Courgette	362.6	Broccoli	103.7
	Apricots	299.3	Oilseeds (cotton seed) ¹	103.3
	Tomatoes	289.7		
PRIMo rev 3.1	Table grapes	2188	Courgettes	362
	Lettuces	1249	Tomatoes	348
	Peaches	1216	Cardoons	318 (adult)
	Melons	1183	Wine grapes	278

Rhubarbs	1138	Sweet peppers/bell peppers	249
Chinese cabbages/ pe-tsai	990	Cauliflowers	243
Watermelons	954	Pumpkins	208
Lamb's lettuce/corn salads	843	Chards/beet leaves	208 (adult)
Spinaches	741	Gherkins	179 (pickled – child)
Pears	720	Bananas	178
Celeries	696	Broccoli	174
Florence fennels	570 (adult)	Aubergines/egg plants	162 (adult)
Apples	560	Cherries (sweet)	156
Plums	539	Spinaches	131 (adult)
Cucumbers	511	Kales	114
Apricots	447	Blackberries	111
Escaroles/broad-leaved endives	441		

¹ based on surrogate consumption data – see table 7.1-1

HSE concludes that harmful effects on human health cannot be excluded for residues of indoxacarb occurring in all commodities listed in table 7.1-3. Consequently, the required level of protection has not been met. The remaining commodities have been considered further in scenario 2, including any CXLs for which fall back values exist.

7.1.2 Scenario 2 – MRLs that did not result in an acute intake concern in scenario 1, 'fallback CXLs', and additional CXLs, for commodities which did not result in acute exceedances in scenario 1.

Consumer risk assessments for the current GB MRLs, excluding those which result in an acute risk.

For the commodities for which an acute risk was identified in scenario 1, the input has been set at the LOQ (0.01* mg/kg), or if a lower CXL is available, the CXL has been used as an input. Additionally, if no acute risk was identified in scenario 1, and a higher CXL is available, the CXL has been considered further in this case.

In addition, based on the TTC assessment conducted for the metabolite IN-MP819, the current MRL for milk results in a chronic intake concern – see 4.2.2 and appendix A. In the absence of specific toxicological information on this metabolite, the MRL for milk shall be lowered to the LOQ (0.01* mg/kg).

The following CXLs have been included in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beans with pods, beetroot, cauliflower, maize/corn, pear, tree nuts.**

For the remaining commodities, the existing MRLs established in the GB MRL Statutory Register have been used.

Table 7.1-4 Input values for the UK consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Tree nuts	0.013	STMR-CXL (FAO, 2022)	0.046	HR-CXL (FAO, 2022)
Apples	0.01	LOQ	0.01	LOQ
Pears	0.051	STMR - 'fallback CXL' (FAO, 2005)	0.11	HR - 'fallback CXL' (FAO, 2005)
Stone fruits (apricots, peaches, plums, cherries)	0.01	LOQ	0.01	LOQ
Table and wine grapes	0.01	LOQ	0.01	LOQ
Strawberries	0.19	STMR (EFSA, 2012)	See scenario 1	
Blackberries ¹	0.01	LOQ	0.01	LOQ
Raspberries ¹	0.26	STMR (EFSA, 2011)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Gooseberries, Currants (black, red and white) ¹	0.58	STMR-CXL (FAO, 2022)	1.04	HR-CXL (FAO, 2022)
Cranberries ¹	0.15	Current STMR (FAO 2009)	See scenario 1	
Bananas	0.01	LOQ	0.01	LOQ
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Radishes	0.02	STMR (EFSA, 2011)		
Beetroot	0.18	STMR-CXL (FAO, 2022)	0.22	HR-CXL (FAO, 2022)
Tomatoes	0.01	LOQ	0.01	LOQ
Peppers	0.01	LOQ	0.01	LOQ
Aubergines	0.01	LOQ	0.01	LOQ
Cucurbits with edible and inedible peel (all gone)	0.01	LOQ	0.01	LOQ
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Broccoli	0.055	STMR - 'fallback CXL' (FAO, 2005)	0.14	HR -'fallback CXL' (FAO, 2005)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Cauliflower	0.02	STMR - 'fallback CXL' (FAO, 2005)	0.14	HR -'fallback CXL' (FAO, 2005)
Brussels sprouts	0.02	STMR (EFSA, 2011)	See scenario 1	
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbage	0.01	LOQ	0.01	LOQ
Kale ⁴	0.01	LOQ	0.01	LOQ
Lambs lettuce ⁵	0.01	LOQ	0.01	LOQ
Lettuce	0.01	LOQ	0.01	LOQ
Roman rocket/rucola (covered by lettuce)	0.01	LOQ	0.01	LOQ
Baby leaf crops (including brassica) (covered by lettuce)	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants (input as chicory)	0.27	STMR (EFSA, 2013)	See scenario 1	
Escaroles/broad leaved endives (input as chicory)	0.01	LOQ	0.01	LOQ
Spinach	0.01	LOQ	0.01	LOQ
Purslanes, others – spinaches and similar leaves (covered by spinach)	0.27	STMR (EFSA, 2013)	See scenario 1	
Chards/beet leaves (covered by spinach)	0.01	LOQ	0.01	LOQ
Herbs and edible flowers (except basil) (input as parsley) ²	0.52	STMR (EFSA, 2011)	See scenario 1	
Basil ²	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Beans with pods	0.16	STMR-CXL (FAO, 2022)	0.59	HR-CXL (FAO, 2022)
Cardoons, fennel, rhubarb (covered by fennel and rhubarb)	0.01	LOQ	0.01	LOQ
Celeries	0.01	LOQ	0.01	LOQ
Globe artichokes	0.035	STMR (EFSA, 2011)	See scenario 1	
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)		
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)		
Rapeseeds ³	0.01	STMR (FAO, 2005; EFSA, 2011)		
Soyabeans ³	0.027	STMR (FAO, 2005; EFSA, 2011)		
Cotton seed ³	0.01	LOQ	0.01	LOQ
Mustard seed ³	0.01	STMR (EFSA, 2013b)	See scenario 1	
Maize/ corn	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of	definition indoxacarb and	plant/animal its R enantiomer)
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	See scenario 1	
Sugar beet roots	0.026	STMR (EFSA, 2011)		
Mammalian muscle	0.01	STMR (FAO, 2005; EFSA, 2011)		
Mammalian fat	0.38	STMR (FAO, 2005; EFSA, 2011)		
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2005; EFSA, 2011)		
Milk	0.01	LOQ	0.01	LOQ
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	See scenario 1	
Poultry liver	0.01	STMR-CXL x (FAO, 2009)		
Birds eggs	0.01	STMR-CXL x (FAO, 2009)		
All other commodities ‡	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk undertaken only commodities uses under	assessment for the relevant to the assessment

Assessments using surrogate crops been conducted separately for the acute risk assessment, in order to assess the risk associated with the crops used for the surrogate assessment – for the chronic risk assessment, the worst case input was used, this applies to footnotes 1, 2, 3, 4 and 5.

¹ There is no UK consumption data for cranberries, blueberries or rose hips. The following surrogate commodity have been used: cranberries – blackcurrants; blueberries & rose hips – blackberries and raspberries.

² There is no UK consumption data for basil, parsley has been used as a surrogate commodity.

³ There is no UK consumption data for specific oilseeds; the input is for oilseeds only.

⁴ There is no UK consumption data for kale, head cabbage has been used as a surrogate commodity.

⁵ There is no UK consumption data for lamb's lettuce, lettuce has been used as a surrogate commodity.

The input values for the PRIMo risk assessments are given in Table 7.1-5.

Table 7.1-5 Input values for the PRIMo consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: enantiomer)	assessment residue indoxacarb	(sum of	definition indoxacarb	plant/animal and its R
Tree nuts	0.013	STMR-CXL (FAO, 2022)	0.046	HR-CXL (FAO, 2022)
Apples	0.01	LOQ	0.01	LOQ
Pears	0.051	STMR - 'fallback CXL' (FAO, 2005)	0.11	HR - 'fallback CXL' (FAO, 2005)
Stone fruits	0.01	LOQ	0.01	LOQ
Table and wine grapes	0.01	LOQ	0.01	LOQ
Strawberries	0.19	STMR (EFSA, 2012)	See scenario 1	
Blackberries	0.01	LOQ	0.01	LOQ
Raspberries	0.26	STMR (EFSA, 2011)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: enantiomer)	assessment indoxacarb	residue (sum of	definition indoxacarb	plant/animal and its R
Gooseberries, Currants (black, red and white)	0.58	STMR-CXL (FAO, 2022)	1.04	HR-CXL (FAO, 2022)
Blueberries, rose hips	0.01	LOQ	0.01	LOQ
Cranberries	0.15	Current STMR (FAO 2009)	See scenario 1	
All other small fruit and berries	0.11	STMR (EFSA, 2011)		
Bananas	0.01	LOQ	0.01	LOQ
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Radishes	0.02	STMR (EFSA, 2011)		
Beetroot	0.18	STMR-CXL (FAO, 2022)	0.22	HR-CXL (FAO, 2022)
Tomatoes	0.01	LOQ	0.01	LOQ
Peppers	0.01	LOQ	0.01	LOQ
Aubergines	0.01	LOQ	0.01	LOQ
Cucurbits with edible and inedible peel (all gone)	0.01	LOQ	0.01	LOQ
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: (enantiomers)	assessment indoxacarb	residue (sum of	definition indoxacarb	plant/animal and its R
Broccoli	0.055	STMR - 'fallback CXL' (FAO, 2005)	0.14	HR -'fallback CXL' (FAO, 2005)
Cauliflower	0.02	STMR - 'fallback CXL' (FAO, 2005)	0.14	HR -'fallback CXL' (FAO, 2005)
Others – flowering brassica	0.01	LOQ	0.01	LOQ
Brussels sprouts	0.02	STMR (EFSA, 2011)	See scenario 1	
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbage	0.01	LOQ	0.01	LOQ
Kale, other leafy brassica vegetables	0.01	LOQ	0.01	LOQ
Lambs lettuce	0.01	LOQ	0.01	LOQ
Lettuce	0.01	LOQ	0.01	LOQ
Roman rocket/rucola	0.01	LOQ	0.01	LOQ
Baby leaf crops (including brassica)	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: enantiomer)	assessment indoxacarb	residue (sum of	definition indoxacarb	plant/animal and its R
Cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants	0.27	STMR (EFSA, 2013)	See scenario 1	
Escaroles/broad leaved endives	0.01	LOQ	0.01	LOQ
Spinach	0.01	LOQ	0.01	LOQ
Chards/beet leaves	0.01	LOQ	0.01	LOQ
Purslanes, others – spinaches and similar leaves (covered by spinach)	0.27	STMR (EFSA, 2013)	See scenario 1	
Chives, sage, rosemary, thyme, laurel/bay leaves, tarragon	0.46	STMR (EFSA, 2011)		
Chervil, celery leaves, parsley	0.52	STMR (EFSA, 2011)		
Basil	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: enantiomer)	assessment	residue	definition	indoxacarb plant/animal and its R
Beans with pods	0.16	STMR-CXL (FAO, 2022)	0.59	HR-CXL (FAO, 2022)
Cardoons, fennel, rhubarb	0.01	LOQ	0.01	LOQ
Celeries	0.01	LOQ	0.01	LOQ
Globe artichokes	0.035	STMR (EFSA, 2011)	See scenario 1	
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)		
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)		
Rapeseeds	0.01	STMR (FAO, 2005; EFSA, 2011)		
Soyabeans	0.027	STMR (FAO, 2005; EFSA, 2011)		
Cotton seed	0.01	LOQ	0.01	LOQ
Mustard seed	0.01	STMR (EFSA, 2013b)	See scenario 1	
Maize/ corn	0.01	STMR-CXL (FAO, 2022)	0.01	STMR-CXL (FAO, 2022)
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities: assessment residue indoxacarb (sum of enantiomers)			definition indoxacarb	plant/animal and its R
Sugar beet roots	0.026	STMR (EFSA, 2011)		
Mammalian muscle	0.08	STMR (FAO, 2005; EFSA, 2011)		
Mammalian fat	0.38	STMR (FAO, 2005; EFSA, 2011)		
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2005; EFSA, 2011)		
Milk	0.01	LOQ	0.01	LOQ
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	See scenario 1	
Poultry liver	0.01	STMR-CXL x (FAO, 2009)		
Birds eggs	0.01	STMR-CXL x (FAO, 2009)		
All other commodities ‡	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk assessment undertaken only for the commodities relevant to the uses under assessment	

Model outputs for the UK acute and chronic models (versions 1.2 and 1.1 respectively) are presented in Appendix B.

Conclusions

The highest UK NEDI was 65% of the ADI (toddler). The highest PRIMo IEDI was 44% of the ADI (NL toddler).

The highest UK NESTI was 187% of the ARfD (infant/pears). The highest IESTI was 251% of the ARfD (child/beetroots). The MRLs which result in acute intake concerns are detailed in the table below:

Table 7.1-6 Acute exposure output – scenario 2

Model	Commodities which result in an acute exceedance	
UK acute model, version 1.2	Commodity	Exceedance (%)
	Pears	187
	Cauliflower	162
	Blackcurrants	105
PRIMo rev 3.1	Pears	305
	Beetroots	251
	Currants (red, black and white)	164
	Cauliflowers	162
	Beans (with pods)	135
	Gooseberries (green, red and yellow)	122
	Broccoli	116

HSE concludes that harmful effects on human health cannot be excluded for residues of indoxacarb occurring in all commodities listed in table 7.1-6. Consequently, the required level of protection has not been met..

7.1.3 Scenario 3 – Additional refinements based on scenario 2, excluding the CXLs which result in acute intake concerns

The following additional CXLs were considered in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beans with pods, beetroot, cauliflower, maize/corn, pear, tree nuts.**

The following CXLs resulted in acute intake concerns in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beetroot, beans with pods, cauliflower, pear.**

Scenario 3 was undertaken with all inputs considered in scenario 2, excluding the aforementioned CXLs which resulted in acute intake concerns.

Table 7.1-7 Input values for the UK consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment	residue	definition	plant/animals
	indoxacarb	(sum of indoxacarb	and its R	enantiomers)
Tree nuts	0.013	STMR-CXL (FAO, 2022)	See scenario 2	
Apples	0.01	LOQ		
Pears	0.01	LOQ	0.01	LOQ
Stone fruits (apricots, peaches, plums, cherries)	0.01	LOQ	See scenario 2	
Table and wine grapes	0.01	LOQ		
Strawberries	0.19	STMR (EFSA, 2012)	See scenario 1	
Blackberries ¹	0.01	LOQ	See scenario 2	
Raspberries ¹	0.26	STMR (EFSA, 2011)	See scenario 1	
Gooseberries, Currants (black, red and white) ¹	0.11	STMR (EFSA, 2011)		
Cranberries ¹	0.15	Current STMR (FAO 2009)		
Bananas	0.01	LOQ	See scenario 2	
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Radishes	0.02	STMR (EFSA, 2011)		
Beetroot	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of indoxacarb	definition and its R	plant/animals enantiomer)
Tomatoes	0.01	LOQ	See scenario 2	
Peppers	0.01	LOQ		
Aubergines	0.01	LOQ		
Cucurbits with edible and inedible peel	0.01	LOQ		
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Broccoli	0.01	LOQ	0.01	LOQ
Cauliflower	0.01	LOQ	0.01	LOQ
Brussels sprouts	0.02	STMR (EFSA, 2011)	See scenario 1	
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbage	0.01	LOQ	See scenario 2	
Kale ⁴	0.01	LOQ		
Lambs lettuce ⁵	0.01	LOQ		
Lettuce	0.01	LOQ		
Roman rocket/rucola (covered by lettuce)	0.01	LOQ	See scenario 1	
Baby leaf crops (including brassica) (covered by lettuce)	0.01	LOQ		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of indoxacarb	definition and its R	plant/animals enantiomer)
Cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants (input as chicory)	0.27	STMR (EFSA, 2013)		
Escaroles/broad leaved endives (input as chicory)	0.01	LOQ	See scenario 2	
Spinach	0.01	LOQ		
Purslanes, others – spinaches and similar leaves (covered by spinach)	0.27	STMR (EFSA, 2013)	See scenario 1	
Chards/beet leaves (covered by spinach)	0.01	LOQ	See scenario 2	
Herbs and edible flowers (except basil) (input as parsley) ²	0.52	STMR (EFSA, 2011)	See scenario 1	
Basil ²	0.01	LOQ	See scenario 2	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of indoxacarb	definition and its R	plant/animals enantiomer)
Beans with pods	0.11	STMR (EFSA, 2013b)	See scenario 1	
Cardoons, fennel, rhubarb (covered by fennel and rhubarb)	0.01	LOQ	See scenario 2	
Celeries	0.01	LOQ		
Globe artichokes	0.035	STMR (EFSA, 2011)	See scenario 1	
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)		
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)		
Rapeseeds ³	0.01	STMR (FAO, 2005; EFSA, 2011)		
Soyabeans ³	0.027	STMR (FAO, 2005; EFSA, 2011)		
Cotton seed ³	0.01	LOQ	See scenario 2	
Mustard seed ³	0.01	STMR (EFSA, 2013b)	See scenario 1	
Maize/ corn	0.01	STMR-CXL (FAO, 2022)	See scenario 2	
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	See scenario 1	
Sugar beet roots	0.026	STMR (EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk commodities:	assessment indoxacarb	residue (sum of indoxacarb	definition and its R	plant/animals enantiomer)
Mammalian muscle	0.08	STMR (FAO, 2005; EFSA, 2011)		
Mammalian fat	0.38	STMR (FAO, 2005; EFSA, 2011)		
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2005; EFSA, 2011)		
Milk	0.01	LOQ	0.01	LOQ
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	See scenario 1	
Poultry liver	0.01	STMR-CXL x (FAO, 2009)		
Birds eggs	0.01	STMR-CXL x (FAO, 2009)		
All other commodities ‡	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk assessment undertaken only for the commodities relevant to the uses under assessment	

Assessments using surrogate crops been conducted separately for the acute risk assessment, in order to assess the risk associated with the crops used for the surrogate assessment – for the chronic risk assessment, the worst case input was used, this applies to footnotes 1, 2, 3, 4 and 5.

¹ There is no UK consumption data for cranberries, blueberries or rose hips. The following surrogate commodity have been used: cranberries – blackcurrants; blueberries & rose hips – blackberries and raspberries.

² There is no UK consumption data for basil, parsley has been used as a surrogate commodity.

³ There is no UK consumption data for specific oilseeds; the input is for oilseeds only.

⁴ There is no UK consumption data for kale, head cabbage has been used as a surrogate commodity.

⁵ There is no UK consumption data for lamb's lettuce, lettuce has been used as a surrogate commodity.

The input values for the PRIMo risk assessments are given in Table 7.1-8.

Table 7.1-8 Input values for the PRIMo consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Tree nuts	0.013	STMR-CXL (FAO, 2022)	See scenario 2	
Apples	0.01	LOQ	See scenario 2	
Pears	0.01	LOQ	See scenario 2	
Stone fruits	0.01	LOQ	See scenario 2	
Table and wine grapes	0.01	LOQ	See scenario 2	
Strawberries	0.19	STMR (EFSA, 2012)	See scenario 1	
Blackberries	0.01	LOQ	See scenario 2	
Raspberries	0.26	STMR (EFSA, 2011)	See scenario 1	
Gooseberries, Currants (black, red and white)	0.11	STMR (EFSA, 2011)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Blueberries, rose hips	0.01	LOQ	See scenario 2	
Cranberries	0.15	Current STMR (FAO 2009)	See scenario 1	
All other small fruit and berries	0.11	STMR (EFSA, 2011)		
Bananas	0.01	LOQ	See scenario 2	
Potatoes	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Radishes	0.02	STMR (EFSA, 2011)		
Beetroot	0.01	LOQ	0.01	LOQ
Tomatoes	0.01	LOQ	See scenario 2	
Peppers	0.01	LOQ		
Aubergines	0.01	LOQ		
Cucurbits with edible and inedible peel	0.01	LOQ		
Sweet corn	0.01	STMR (FAO, 2005; EFSA, 2011)	See scenario 1	
Broccoli	0.01	LOQ	0.01	LOQ
Cauliflower	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Others – flowering brassica	0.01	LOQ	See scenario 2	
Brussels sprouts	0.02	STMR (EFSA, 2011)	See scenario 1	
Head cabbage	0.02	STMR (EFSA, 2011)		
Chinese cabbage	0.01	LOQ	See scenario 2	
Kale, other leafy brassica vegetables	0.01	LOQ		
Lambs lettuce	0.01	LOQ		
Lettuce	0.01	LOQ		
Roman rocket/rucola	0.01	LOQ	See scenario 1	
Baby leaf crops (including brassica)	0.01	LOQ		
Cresses and other shoots and sprouts, land cresses, red mustards, others – lettuces and other salad plants	0.27	STMR (EFSA, 2013)		
Escaroles/broad leaved endives	0.01	LOQ	See scenario 2	
Spinach	0.01	LOQ		
Chards/beet leaves	0.01	LOQ		
Purslanes, others – spinaches and similar leaves	0.27	STMR (EFSA, 2013)	See scenario 1	

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Chives, sage, rosemary, thyme, laurel/bay leaves, tarragon	0.46	STMR (EFSA, 2011)		
Chervil, celery leaves, parsley	0.52	STMR (EFSA, 2011)		
Basil	0.01	LOQ	See scenario 2	
Beans with pods	0.11	STMR (EFSA, 2013b)	See scenario 1	
Cardoons, fennel, rhubarb	0.01	LOQ	See scenario 2	
Celeries	0.01	LOQ		
Globe artichokes	0.035	STMR (EFSA, 2011)	See scenario 1	
Beans (dry), peas (dry)	0.02	STMR (FAO, 2005; EFSA, 2011)		
Peanuts/ groundnuts	0.01	STMR (FAO, 2005; EFSA, 2011)		
Rapeseeds	0.01	STMR (FAO, 2005; EFSA, 2011)		

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Soyabeans	0.027	STMR (FAO, 2005; EFSA, 2011)		
Cotton seed	0.01	LOQ	See scenario 2	
Mustard seed	0.01	STMR (EFSA, 2013b)	See scenario 1	
Maize/ corn	0.01	STMR-CXL (FAO, 2022)	See scenario 2	
Teas	0.41	STMR (FAO, 2013; EFSA, 2014)	See scenario 1	
Sugar beet roots	0.026	STMR (EFSA, 2011)		
Mammalian muscle	0.08	STMR (FAO, 2005; EFSA, 2011)		
Mammalian fat	0.38	STMR (FAO, 2005; EFSA, 2011)		
Mammalian liver, kidney and other edible offals	0.014	STMR (FAO, 2005; EFSA, 2011)		
Milk	0.01	LOQ	0.01	LOQ

Commodity	Chronic risk assessment		Acute risk assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment indoxacarb (sum of	residue indoxacarb	definition and its R	plant/animal enantiomer)	commodities:
Poultry meat and fat	0.025	STMR-CXL x (FAO, 2009)	See scenario 1	
Poultry liver	0.01	STMR-CXL x (FAO, 2009)		
Birds eggs	0.01	STMR-CXL x (FAO, 2009)		
All other commodities ‡	MRL	Supported LOQ (0.01 mg/kg) (see section 1)	Acute risk assessment undertaken only for the commodities relevant to the uses under assessment	

Model outputs for the UK acute and chronic models (versions 1.2 and 1.1 respectively) are presented in Appendix B.

Conclusions

Chronic exposure

The highest UK NEDI was 56% of the ADI (toddler). The highest PRIMo IEDI was 35% of the ADI (NL toddler). Therefore, on the basis of the lowered MRLs for a number of commodities, and the adoption of several CXLs, no health effects due to chronic exposure are expected from the consumption of commodities treated with indoxacarb.

Acute exposure

The highest UK NESTI was 17% of the ARfD (infant/pears). The highest IESTI was 28% of the ARfD (child/pears). Therefore, on the basis of the lowered MRLs for a number of

commodities, and the adoption of several CXLs, no health effects due to acute exposure are expected from the consumption of commodities treated with indoxacarb.

Overall

The MRLs/commodities considered at scenario 3 will not result in consumer exposures exceeding the toxicological reference values and therefore the MRLs detailed in table 8.1 are unlikely to have harmful effects on human health.

7.2 Other routes of exposure

Not applicable.

8 The draft conclusion of the competent authority

Sufficiently validated analytical methods for the determination of indoxacarb in plant commodities, in line with the enforcement residue definition for products of plant origin, are available to support the crop groups considered in the MRL review; an LOQ of 0.01* mg/kg is achievable for all commodity types, this change will be reflected in the GB MRL Statutory Register.

Sufficiently validated analytical methods for the determination of indoxacarb in animal commodities, in line with the enforcement residue definition for products of animal origin, are available for all POAO.

Toxicological reference values were established in the GB review of the approval of indoxacarb: an ADI of 0.005 mg/kg bw/day and an ARfD of 0.005 mg/kg bw.

The metabolism of indoxacarb in primary crops was investigated in fruit and fruiting vegetables (grapes and tomatoes), pulses and oilseeds (cotton) and leafy crops (lettuce) following foliar applications for the approval of the active substance (DAR, 2000). The available information is sufficient to cover the crops considered in this MRL review.

The residue definition for enforcement and risk assessment (RD-Enf and RD-RA) in plants is recommended as:

- Indoxacarb (sum of indoxacarb and its R enantiomer)

Hydrolysis of indoxacarb under representative conditions of pasteurisation, baking, brewing, boiling and sterilisation was evaluated for the approval of the active substance. The hydrolysis data demonstrate that indoxacarb is stable under standard pasteurisation conditions; however, a number of metabolites (IN-KT413, IN-MP819, IN-MK638, IN-P0036 and IN-TMG00) are formed under standard sterilisation conditions. It is possible that the metabolite 'IN-KT413' may also form under standard baking, brewing and boiling conditions.

IN-P0036 is covered by the toxicological reference values established for indoxacarb; potential exposure to this metabolite is covered by the full consumer risk assessment conducted in section 7.

The genotoxic potential of IN-KT413, IN-MP819, and IN-TMG00 were considered for the EU renewal of the active substance, these compounds were considered unlikely to be genotoxic. As noted, the renewal assessment including all relevant studies were made

available to HSE. The genotoxic potential of IN-MK638 has been considered in the framework of the current evaluation. All metabolites are considered unlikely to be genotoxic as a result of QSAR/read across data.

The Cramer Class III TTC value of 1.5 µg/kg bw/d and the acute threshold value of 5 µg/kg bw are considered applicable for IN-KT413, IN-MP819, IN-MK638, IN-TMG00. The potential exposure to the above metabolites through consumption of processed commodities was assessed. A worst case assessment was conducted, assuming that all exposure to indoxacarb is via the consumption of processed commodities. The estimated chronic and estimated acute exposures are lower than the thresholds and therefore no harmful effects on human health are expected.

In addition, a number of metabolites were considered for inclusion in the RD-RA for animal commodities. HSE has reviewed the data submitted for the renewal of the active substance: 5-OH-indoxacarb (free and conjugated), IN-JT333, IN-MN470, and IN-MF014. HSE agrees with the EFSA conclusion (EFSA, 2018) and has concluded that sufficient information is available to conclude that these metabolites are unlikely to be genotoxic, HSE recommends that the TTC Cramer Class III and acute threshold values apply to these metabolites.

Residues in rotational crops were considered for the approval of the active substance. The metabolism studies demonstrated that residues in rotational crops are expected to be <0.01 mg/kg for all crops at PBIs of 90 and 125 days and specific residue definitions for rotational crops are not required. There were some deficiencies noted in the studies, relating to poor metabolite identification, and the lack of consideration of soil plateau concentrations in light of the potential persistence of indoxacarb and several soil metabolites. Nonetheless, the available information is sufficient to conclude that the proposed MRLs are unlikely to be affected by possible uptake from soil residues.

A dietary burden was calculated based on the MRLs which are recommended for plant commodities, and which may be imported as feed items. The maximum livestock dietary burden exceeded the trigger value for further assessment (0.1 mg/kg DM and AR) for poultry and mammalian species. Metabolism of indoxacarb in ruminants was considered for the approval of the active substance and, for poultry, during the Article 12 review (DAR, 2000 and EFSA, 2011). The approval assessment concluded that the metabolic pathways in rodents and ruminants are comparable; the findings in ruminants can therefore be extrapolated to pigs.

The residue definition for risk assessment for poultry was tentative, and two supplementary requirements were included in the GB MRL Statutory register for poultry commodities:

Supplementary requirement 1

- *Further information on the nature and occurrence of the metabolite F that was encountered in poultry*

Supplementary requirement 2

- *Storage stability data for eggs*

Additional data was provided for the EU renewal of the active substance demonstrating acceptable storage stability in eggs. No further information was made available for metabolite 'F'.

Supplementary requirement 2 is considered addressed, and HSE recommends the footnotes is deleted from the GB Statutory Register. Supplementary requirement 1 is addressed for all poultry matrices except for poultry fat.

HSE has reconsidered the residue definitions for animal commodities in view of the expected occurrence of the compounds based on the metabolism and feeding studies, and the available toxicological information.

As such, HSE recommends the following residue definitions for poultry as outlined below:

Proposed residue definition for risk assessment in poultry (excluding fat):

- Indoxacarb (and its R-enantiomer)

Proposed residue definitions for risk assessment in poultry fat:

- Indoxacarb (and its R-enantiomer)
- Metabolite F (provisional pending additional information to allow formal identification, as well as relevant toxicological information and/or feeding studies to elucidate its occurrence)

Proposed residue definition for enforcement in poultry:

- Indoxacarb (and its R-enantiomer)

All GB MRLs are currently set at the LOQ (0.01* mg/kg) for poultry; on the basis of the calculated DB, this is considered sufficiently protective. Further information on metabolite F is required if a higher MRL is requested in future.

On the basis that the current MRLs are set at the LOQ, HSE recommends that supplementary requirement 1 is also deleted from the GB Statutory Register.

For mammals, based on the available metabolism data, feeding studies, and calculated DB, as well as the relative toxicity of the observed metabolites, HSE recommends the following residue definitions for mammals as outlined below:

Proposed residue definition for risk assessment in ruminant tissues, and enforcement definition in ruminant tissues and milk:

- Indoxacarb (and its R-enantiomer)

Proposed residue definition for risk assessment in milk:

1. Indoxacarb (and its R-enantiomer)
2. IN-MP819 (provisional – pending additional toxicological information; and/or feeding studies which elucidate its occurrence)

Based on the current GB MRL, exposure to IN-MP819 exceeds the TTC CCIII chronic threshold value. In the absence of specific toxicological information, HSE recommends that the MRL for milk is set at 0.01* mg/kg and this will ensure residues of the metabolite will also be <0.01* mg/kg.

In order to set a substantive MRL for milk, additional toxicological data and feeding studies for the metabolite are required.

The above residue definitions may require further consideration with regards to possible metabolites if the dietary burden increases in future. At present, the above residue definitions are suitable for risk assessment and enforcement in animal commodities imported into GB. Should the above residue definitions require further consideration in future, further toxicological data may be required on a number of metabolites.

The consumer risk assessments have been undertaken for three different scenarios. Based on the outcome of the refined consumer risk assessments in scenario 3, HSE recommends that a number of MRLs are retained, and that several CXLs are adopted. All other MRLs should be set at the LOQ.

For the retained MRLs and CXLs: The highest UK NEDI was 56% of the ADI (toddler). The highest PRIMo IEDI was 35% of the ADI (NL toddler).

The highest UK NESTI was 17% of the ARfD (infant/pears). The highest IESTI was 28% of the ARfD (child/pears). Therefore, on the basis of the lowered MRLs for a number of commodities, and the adoption of several CXLs, no health effects due to chronic or acute exposure are expected from the consumption of commodities treated with indoxacarb.

A number of the current MRLs for plant commodities have a footnote relating to missing information. No information has been provided for these commodities; however, an acute

risk was identified for all affected commodities, as such, HSE recommends that the footnotes are deleted from the GB Statutory Register when the MRLs are set at the LOQ.

The MRLs proposed by HSE are outlined in Table 8.1.

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Table 8.1 MRLs proposed by HSE for indoxacarb**Enforcement residue definition for products of plant origin: Indoxacarb (and its R-enantiomer)**

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0100000	FRUITS, FRESH or FROZEN; TREE NUTS			
0110000	Citrus fruits			
0110010	Grapefruits	0.02*	0.01 *	2
0110020	Oranges	0.02*	0.01 *	2
0110030	Lemons	0.02*	0.01 *	2
0110040	Limes	0.02*	0.01 *	2
0110050	Mandarins	0.02*	0.01 *	2
0110990	Others - Citrus Fruit	0.02*	0.01 *	2
0120000	Tree Nuts			
0120010	Almonds	0.02*	0.07	2,4
0120020	Brazil nuts	0.02*	0.07	2,4
0120030	Cashew nuts	0.02*	0.07	2,4
0120040	Chestnuts	0.02*	0.07	2,4
0120050	Coconuts	0.02*	0.07	2,4
0120060	Hazelnuts/cobnuts	0.02*	0.07	2,4
0120070	Macadamias	0.02*	0.07	2,4
0120080	Pecans	0.02*	0.07	2,4
0120090	Pine nut kernels	0.02*	0.07	2,4
0120100	Pistachios	0.02*	0.07	2,4
0120110	Walnuts	0.02*	0.07	2,4
0120990	Others - Tree nuts	0.02*	0.07	2,4
0130000	Pome fruits			
0130010	Apples	0.5	0.01 *	2
0130020	Pears	0.5	0.01 *	2
0130030	Quinces	0.02*	0.01 *	2
0130040	Medlars	0.02*	0.01 *	2
0130050	Loquats/Japanese medlars	0.02*	0.01 *	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0130990	Others - Pome fruit	0.02*	0.01 *	2
0140000	Stone fruits			
0140010	Apricots	1	0.01 *	2
0140020	Cherries (sweet)	1	0.01 *	2
0140030	Peaches	1	0.01 *	2
0140040	Plums	1	0.01 *	2
0140990	Others - Stone fruit	1	0.01 *	2
0150000	Berries and small fruits			
0151000	Grapes			
0151010	Table grapes	2	0.01 *	2
0151020	Wine grapes	2	0.01 *	2
0152000	Strawberries			
0152000	Strawberries	0.6	0.6	2,3
0153000	Cane fruits			
0153010	Blackberries	0.5	0.01*	2
0153020	Dewberries	0.02*	0.01*	2
0153030	Raspberries (red and yellow)	0.6	0.6	2,3
0153990	Others - Cane fruit	0.02*	0.01*	2
0154000	Other small fruits and berries			
0154010	Blueberries	0.8	0.01*	2
0154020	Cranberries	1	1	2,4
0154030	Currants (black, red and white)	0.8	0.8	2,3
0154040	Gooseberries (green, red and yellow)	0.8	0.8	2,3
0154050	Rose hips	0.8	0.01*	2
0154060	Mulberries (black and white)	0.8	0.8	2,3
0154070	Azaroles/Mediterranean medlars	0.8	0.8	2,3
0154080	Elderberries	0.8	0.8	2,3
0154990	Others - Other small fruit and berries	0.8	0.8	2,3
0160000	Miscellaneous fruits with			
0161000	Edible peel			
0161010	Dates	0.02*	0.01*	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0161020	Figs	0.02*	0.01*	2
0161030	Table olives	0.02*	0.01*	2
0161040	Kumquats	0.02*	0.01*	2
0161050	Carambolas	0.02*	0.01*	2
0161060	Kaki/Japanese persimmons	0.02*	0.01*	2
0161070	Jambuls/jambolans	0.02*	0.01*	2
0161990	Others - Edible peel	0.02*	0.01*	2
0162000	Inedible peel, small			
0162010	Kiwi fruits (green, red, yellow)	0.02*	0.01*	2
0162020	Litchis/lychees	0.02*	0.01*	2
0162030	Passionfruits/maracujas	0.02*	0.01*	2
0162040	Prickly pears/cactus fruits	0.02*	0.01*	2
0162050	Star apples/cainitos	0.02*	0.01*	2
0162060	American persimmons/Virginia kaki	0.02*	0.01*	2
0162990	Others - Inedible peel, small	0.02*	0.01*	2
0163000	Inedible peel, large			
0163010	Avocados	0.02*	0.01*	2
0163020	Bananas	0.2	0.01*	2
0163030	Mangoes	0.02*	0.01*	2
0163040	Papayas	0.02*	0.01*	2
0163050	Granate apples/pomegranates	0.02*	0.01*	2
0163060	Cherimoyas	0.02*	0.01*	2
0163070	Guavas	0.02*	0.01*	2
0163080	Pineapples	0.02*	0.01*	2
0163090	Breadfruits	0.02*	0.01*	2
0163100	Durians	0.02*	0.01*	2
0163110	Soursops/guanabanas	0.02*	0.01*	2
0163990	Others - Inedible peel, large	0.02*	0.01*	2
0200000	VEGETABLES, FRESH or FROZEN			
0210000	Root and tuber vegetables			
0211000	Potatoes	0.02*	0.02	2,4

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0212000	Tropical root and tuber vegetables			
0212010	Cassava roots/manioc	0.02*	0.01*	2
0212020	Sweet potatoes	0.02*	0.01*	2
0212030	Yams	0.02*	0.01*	2
0212040	Arrowroots	0.02*	0.01*	2
0212990	Others - Tropical root and tuber vegetables	0.02*	0.01*	2
0213000	Other root and tuber vegetables except sugar beets			
0213010	Beetroots	0.02*	0.01*	2
0213020	Carrots	0.02*	0.01*	2
0213030	Celeriacs/turnip rooted celeries	0.02*	0.01*	2
0213040	Horseradishes	0.02*	0.01*	2
0213050	Jerusalem artichokes	0.02*	0.01*	2
0213060	Parsnips	0.02*	0.01*	2
0213070	Parsley roots/Hamburg roots parsley	0.02*	0.01*	2
0213080	Radishes	0.3	0.3	2,3
0213090	Salsifies	0.02*	0.01*	2
0213100	Swedes/rutabagas	0.02*	0.01*	2
0213110	Turnips	0.02*	0.01*	2
0213990	Others - Other root and tuber vegetables except sugar beet	0.02*	0.01*	2
0220000	Bulb vegetables			
0220010	Garlic	0.02*	0.01*	2
0220020	Onions	0.02*	0.01*	2
0220030	Shallots	0.02*	0.01*	2
0220040	Spring onions/green onions and Welsh onions	0.02*	0.01*	2
0220990	Others - bulb vegetables	0.02*	0.01*	2
0230000	Fruiting vegetables			

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0231000	Solanaceae and Malvaceae			
0231010	Tomatoes	0.5	0.01*	2
0231020	Sweet peppers/bell peppers	0.3	0.01*	2
0231030	Aubergines/eggplants	0.5	0.01*	2
0231040	Okra/lady's fingers	0.02*	0.01*	2
0231990	Others - Solanacea	0.02*	0.01*	2
0232000	Cucurbits with edible peel			
0232010	Cucumbers	0.5	0.01*	2
0232020	Gherkins	0.5	0.01*	2
0232030	Courgettes	0.5	0.01*	2
0232990	Others - Cucurbits-edible peel	0.5	0.01*	2
0233000	Cucurbits with inedible peel			
0233010	Melons	0.5	0.01*	2
0233020	Pumpkins	0.5	0.01*	2
0233030	Watermelons	0.5	0.01*	2
0233990	Others - Cucurbits - inedible peel	0.5	0.01*	2
0234000	Sweet corn	0.02*	0.02	2,4
0239000	Other fruiting vegetables	0.02*	0.01*	2
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)			
0241000	Flowering brassica			
0241010	Broccoli	0.3	0.01*	2
0241020	Cauliflowers	0.3	0.01*	2
0241990	Others - Flowering Brassicas	0.3	0.01*	2
0242000	Head brassica			
0242010	Brussels sprouts	0.06	0.06	2,3
0242020	Head cabbages	0.2	0.2	2,3
0242990	Others - Head Brassicas	0.02*	0.01*	2
0243000	Leafy brassica			
0243010	Chinese cabbages/pe-tsai	3	0.01*	2
0243020	Kales	0.4	0.01 *	1,2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0243990	Others - Leafy Brassicas	0.4	0.01*	2
0244000	Kohlrabies	0.02*	0.01*	2
0250000	Leaf vegetables, herbs and edible flowers			
0251000	Lettuces and salad plants			
0251010	Lamb's lettuces/corn salads	30	0.01*	2
0251020	Lettuces	3	0.01*	2
0251030	Escaroles/broad-leaved endives	1	0.01*	2
0251040	Cresses and other sprouts and shoots	1	1	2,3
0251050	Land cresses	1	1	2,3
0251060	Roman rocket/rucola	2	0.01*	
0251070	Red mustards	1	1	2,3
0251080	Baby leaf crops (including brassica species)	2	0.01*	
0251990	Others - Lettuce and other salad plants including brassica	1	1	2,3
0252000	Spinaches and similar leaves			
0252010	Spinaches	2	0.01*	
0252020	Purslanes	1	1	2,3
0252030	Chards/beet leaves	1	0.01*	
0252990	Others - Spinach and similar (leaves)	1	1	2,3
0253000	Grape leaves and similar species	0.02*	0.01*	2
0254000	Watercresses	0.02*	0.01*	2
0255000	Witloofs/Belgian endives	0.02*	0.01*	2
0256000	Herbs and edible flowers			
0256010	Chervil	2	2	2,3
0256020	Chives	2	2	2,3
0256030	Celery leaves	2	2	2,3
0256040	Parsley	2	2	2,3
0256050	Sage	2	2	2,3
0256060	Rosemary	2	2	2,3
0256070	Thyme	2	2	2,3

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0256080	Basil and edible flowers	15	0.02*	2
0256090	Laurel/bay leaves	2	2	2,3
0256100	Tarragon	2	2	2,3
0256990	Others - Herbs	2	2	2,3
0260000	Legume vegetables			
0260010	Beans (with pods)	0.5	0.5	2,3
0260020	Beans (without pods)	0.02*	0.01*	2
0260030	Peas (with pods)	0.02*	0.01*	2
0260040	Peas (without pods)	0.02*	0.01*	2
0260050	Lentils	0.02*	0.01*	2
0260990	Others - Legume vegetables (fresh)	0.02*	0.01*	2
0270000	Stem vegetables			
0270010	Asparagus	0.02*	0.01*	2
0270020	Cardoons	3	0.01*	2
0270030	Celeries	2	0.01*	2
0270040	Florence fennels	3	0.01*	2
0270050	Globe artichokes	0.2	0.2	2,3
0270060	Leeks	0.02*	0.01*	2
0270070	Rhubarbs	3	0.01*	2
0270080	Bamboo shoots	0.02*	0.01*	2
0270090	Palm hearts	0.02*	0.01*	2
0270990	Others - Stem vegetables (fresh)	0.02*	0.01*	2
0280000	Fungi, mosses and lichens			
0280010	Cultivated fungi	0.02*	0.01*	2
0280020	Wild fungi	0.02*	0.01*	2
0280990	Mosses and lichens	0.02*	0.01*	2
0290000	Algae and prokaryotes organisms	0.02*	0.01*	2
0300000	PULSES, DRY			
0300010	Beans	0.2	0.2	2,4
0300020	Lentils	0.01*	0.01*	2
0300030	Peas	0.2	0.2	2,4

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0300040	Lupins/lupini beans	0.01*	0.01*	2
0300990	Others - pulses	0.01*	0.01*	2
0400000	OILSEEDS AND OIL FRUITS			
0401000	Oilseeds			
0401010	Linseeds	0.02*	0.01*	2
0401020	Peanuts/groundnuts	0.02*	0.02*	2,4
0401030	Poppy seeds	0.02*	0.01*	2
0401040	Sesame seeds	0.02*	0.01*	2
0401050	Sunflower seeds	0.02*	0.01*	2
0401060	Rapeseeds/canola seeds	0.05	0.05	2,4
0401070	Soyabeans	0.5	0.5	2,4
0401080	Mustard seeds	0.05	0.05	2,3
0401090	Cotton seeds	1	0.01*	2
0401100	Pumpkin seeds	0.02*	0.01*	2
0401110	Safflower seeds	0.02*	0.01*	2
0401120	Borage seeds	0.02*	0.01*	2
0401130	Gold of pleasure seeds	0.02*	0.01*	2
0401140	Hemp seeds	0.02*	0.01*	2
0401150	Castor beans	0.02*	0.01*	2
0401990	Others - Oilseeds	0.02*	0.01*	2
0402000	Oil fruits			
0402010	Olives for oil production	0.02*	0.01*	2
0402020	Oil palms kernels	0.02*	0.01*	2
0402030	Oil palms fruits	0.02*	0.01*	2
0402040	Kapok	0.02*	0.01*	2
0402990	Others - Oilfruits	0.02*	0.01*	2
0500000	CEREALS			
0500010	Barley	0.01*	0.01*	2
0500020	Buckwheat and other pseudocereals	0.01*	0.01*	2
0500030	Maize/corn	0.01*	0.015	2,4
0500040	Common millet/proso millet	0.01*	0.01*	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0500050	Oat	0.01*	0.01*	2
0500060	Rice	0.01*	0.01*	2
0500070	Rye	0.01*	0.01*	2
0500080	Sorghum	0.01*	0.01*	2
0500090	Wheat	0.01*	0.01*	2
0500990	Others - cereals	0.01*	0.01*	2
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS			
0610000	Teas	5	5	2,4
0620000	Coffee beans	0.05*	0.05*	2
0630000	Herbal infusions from Dried product			
0631000	Flowers			
0631010	Chamomile	0.05*	0.05*	2
0631020	Hibiscus/roselle	0.05*	0.05*	2
0631030	Rose	0.05*	0.05*	2
0631040	Jasmine	0.05*	0.05*	2
0631050	Lime/linden	0.05*	0.05*	2
0631990	Others - Flowers	0.05*	0.05*	2
0632000	Leaves and herbs			
0632010	Strawberry	0.05*	0.05*	2
0632020	Rooibos	0.05*	0.05*	2
0632030	Mate	0.05*	0.05*	2
0632990	Others - Herbal infusions (leaves and herbs)	0.05*	0.05*	2
0633000	Roots			
0633010	Valerian	0.05*	0.05*	2
0633020	Ginseng	0.05*	0.05*	2
0633990	Others - Roots	0.05*	0.05*	2
0639000	Other herbal Infusions - Parts of the plant other than flowers, leaves and herbs, and roots	0.05*	0.05*	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0639000	Any other parts of the plant	0.05*	0.05*	2
0640000	Cocoa beans	0.05*	0.05*	2
0650000	Carobs/Saint John's breads	0.05*	0.05*	2
0700000	Hops	0.05*	0.05*	2
0800000	SPICES			
0810000	Seed spices			
0810010	Anise/aniseed	0.05*	0.05*	2
0810020	Black caraway/black cumin	0.05*	0.05*	2
0810030	Celery seed	0.05*	0.05*	2
0810040	Coriander seed	0.05*	0.05*	2
0810050	Cumin seed	0.05*	0.05*	2
0810060	Dill seed	0.05*	0.05*	2
0810070	Fennel seed	0.05*	0.05*	2
0810080	Fenugreek	0.05*	0.05*	2
0810090	Nutmeg	0.05*	0.05*	2
0810990	Others - Seeds	0.05*	0.05*	2
0820000	Fruit spices			
0820010	Allspice/pimento	0.05*	0.05*	2
0820020	Sichuan pepper	0.05*	0.05*	2
0820030	Caraway	0.05*	0.05*	2
0820040	Cardamom	0.05*	0.05*	2
0820050	Juniper berry	0.05*	0.05*	2
0820060	Peppercorn (black, green and white)	0.05*	0.05*	2
0820070	Vanilla	0.05*	0.05*	2
0820080	Tamarind	0.05*	0.05*	2
0820990	Others - Fruit spices	0.05*	0.05*	2
0830000	Bark spices			
0830010	Cinnamon	0.05*	0.05*	2
0830990	Others - Bark	0.05*	0.05*	2
0840000	Root and rhizome spices			
0840010	Liquorice	0.05*	0.05*	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
0840020	Ginger	0.05*	0.05*	2,5
0840030	Turmeric/curcuma	0.05*	0.05*	2
0840040	Horseradish	0.02*	0.02*	2,6
0840990	Others - Roots or rhizome	0.05*	0.05*	2
0850000	Bud spices			
0850010	Cloves	0.05*	0.05*	2
0850020	Capers	0.05*	0.05*	2
0850990	Others - Buds	0.05*	0.05*	2
0860000	Flower pistil spices			
0860010	Saffron	0.05*	0.05*	2
0860990	Others - Flower pistil spices	0.05*	0.05*	2
0870000	Aril spices			
0870010	Mace	0.05*	0.05*	2
0870990	Others - Aril spices	0.05*	0.05*	2
0900000	SUGAR PLANTS			
0900010	Sugar beet roots	0.1	0.1	2,3
0900020	Sugar canes	0.02*	0.01*	2
0900030	Chicory roots	0.02*	0.01*	2
0900990	Others - Sugar plants	0.02*	0.01*	2
1000000	PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS			
1010000	Products of animal origin – terrestrial animals			
1011000	Swine			
1011010	Muscle - swine	2	0.05	2,4
1011020	Fat - swine	2	2	2,4
1011030	Liver - swine	0.05	0.05	2,4
1011040	Kidney - swine	0.05	0.05	2,4
1011050	Edible offals (other than liver and kidney) - swine	0.05	0.05	2,4
1011990	Others - swine	0.05	0.05	2,4

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
1012000	Bovine			
1012010	Muscle - bovine	2	0.05	2,4
1012020	Fat - bovine	2	2	2,4
1012030	Liver - bovine	0.05	0.05	2,4
1012040	Kidney - bovine	0.05	0.05	2,4
1012050	Edible offals (other than liver and kidney) - bovine	0.05	0.05	2,4
1012990	Others - bovine	0.05	0.05	2,4
1013000	Sheep			
1013010	Muscle - sheep	2	0.05	2,4
1013020	Fat - sheep	2	2	2,4
1013030	Liver - sheep	0.05	0.05	2,4
1013040	Kidney - sheep	0.05	0.05	2,4
1013050	Edible offals (other than liver and kidney) - sheep	0.05	0.05	2,4
1013990	Others - sheep	0.05	0.05	2,4
1014000	Goat			
1014010	Muscle - goat	2	0.05	2,4
1014020	Fat - goat	2	2	2,4
1014030	Liver - goat	0.05	0.05	2,4
1014040	Kidney - goat	0.05	0.05	2,4
1014050	Edible offals (other than liver and kidney) - goat	0.05	0.05	2,4
1014990	Others - goat	0.05	0.05	2,4
1015000	Equine			
1015010	Muscle - equine	2	0.05	2,4
1015020	Fat - equine	2	2	2,4
1015030	Liver - equine	0.05	0.05	2,4
1015040	Kidney - equine	0.05	0.05	2,4
1015050	Edible offals (other than liver and kidney) - equine	0.05	0.05	2,4

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
1015990	Others - equine	0.05	0.05	2,4
1016000	Poultry			
1016010	Muscle - poultry	0.01*	0.01*	2,4
1016020	Fat - poultry	0.01*	0.01*	2,4
1016030	Liver - poultry	0.01*	0.01*	2,4
1016040	Kidney - poultry	0.01*	0.01*	2,4
1016050	Edible offals (other than liver and kidney) - poultry	0.01*	0.01*	2,4
1016990	Others - poultry	0.01*	0.01*	2,4
1017000	Other farmed terrestrial animals			
1017010	Muscle - other farmed terrestrial animals	2	0.05	2,4
1017020	Fat - other farmed terrestrial animals	2	2	2,4
1017030	Liver - other farmed terrestrial animals	0.05	0.05	2,4
1017040	Kidney - other farmed terrestrial animals	0.05	0.05	2,4
1017050	Edible offals (other than liver and kidney) - other farmed terrestrial animals	0.05	0.05	2,4
1017990	Others - Other farm animals	0.05	0.05	2,4
1020000	Milk			
1020010	Cattle - milk	0.1	0.01*	2
1020020	Sheep - milk	0.1	0.01*	2
1020030	Goat - milk	0.1	0.01*	2
1020040	Horse - milk	0.1	0.01*	2
1020990	Others - Milk and cream	0.1	0.01*	2
1030000	Birds eggs			
1030010	Chicken - eggs	0.02	0.02	2,4
1030020	Duck - eggs	0.02	0.02	2,4
1030030	Geese - eggs	0.02	0.02	2,4
1030040	Quail - eggs	0.02	0.02	2,4
1030990	Others - Birds' eggs	0.02	0.02	2,4
1040000	Honey and other apiculture products	0.05*	0.05*	2
1050000	Amphibians and reptiles	0.01*	0.01*	2

GB Code No	Commodity to which the MRL applies	Current MRL in force (mg/kg)	Proposed MRL (mg/kg)	Footnote
1060000	Terrestrial invertebrate animals	0.01*	0.01*	2
1070000	Wild terrestrial vertebrate animals	0.01*	0.01*	2

Footnotes

Part 1 of the GB MRL Statutory Register should be consulted for the full list of products of plant and animal origin to which the maximum residue levels of pesticides ('MRLs') apply. The following should be noted:

Transitional provision

1) MRLs shall apply to radish leaves as from 1 January 2025

Fat Soluble

2) Fat soluble

Supplementary information with submission date set

3) HSE has identified that there is missing data for this MRL. Supplementary information to support the continued validity of this MRL should be provided within 5 years of the date of enforcement of the new MRLs. If no date is provided to support this MRL or an alternative MRL, HSE would recommend that the MRL is lowered to the LOQ of 0.05* mg/kg

This data is currently necessary to meet existing regulatory requirements. Potential changes to the regulatory regime may impact its relevance and applicability. Consequently, any data generated now may not align with future requirements.

MRL clarification

4) This MRL is a CXL adopted by GB in 2026

Ginger

5) The applicable maximum residue level for ginger (*Zingiber officinale*) in the spice group (code 0840020) is the one set for ginger roots (*Zingiber officinale*) in the Part 1B of the Statutory Register (code 0213040-006, equal to the one of horseradish (*Armoracia rusticana*) code 0213040), taking into account changes in the levels by processing (drying), according to Art. 20 (1) of Assimilated Regulation 396/2005.

Horseradish

6) The applicable maximum residue level for horseradish (*Armoracia rusticana*) in the spice group (code 0840040) is the one set for horseradish (*Armoracia rusticana*) in the Vegetables category, root and tuber vegetables group (code 0213040), taking into account changes in the levels by processing (drying) according to Art. 20 (1) of Assimilated Regulation 396/2005

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GB, 2023. Art 21 review of the approval of indoxacarb.

Appendix A – Consumer risk assessments

Approach to the risk assessments

Scenario 1

The consumer risk assessments under scenario 1 cover the current MRLs in the GB MRL Statutory Register.

The NEDIs and IEDIs were estimated using the STMRs supporting the current GB MRLs. Where the MRL is set at the LOQ of 0.01* mg/kg a value of 0.01 mg/kg was used in the assessment.

The NEDIs ranged from 91% - 273% of the ADI. The highest IEDI was 163% of the ADI.

HSE concludes that harmful effects on human health cannot be excluded.

Acute risk assessments were also undertaken; a number of exceedances of the ARfD were observed. The affected crops are detailed below. For the crops not detailed below, no health effects are expected as a result of acute exposure.

Table A-1 Acute exposure output – scenario 1 assessment

Model	Commodities	which result	in an acute	exceedance
UK acute model, version 1.2	Commodity	Exceedance (%)	Commodity	Exceedance (%)
	Lamb's lettuce ¹	5341.5	Cauliflower	243.3
	Table grapes	1831.0	Cucumber	230.2
	Rhubarb	1138.3	Spinach	186.1
	Chinese cabbage	779.7	Marrow	166.0
	Wine grapes	711.6	basil ¹	162.9
	Peaches	704.5	Celery	154.2
	Melons	648.4	Bananas	153.8
	Lettuce	584	Chicory	152.1
	Roman rocket ¹	584	Aubergines	150.0
	Baby leaf crops ¹	584	Gourd	114.7
	Fennel	570.3	kale ¹	111.9
	Apples	509.4	Blackberries	111.5

PRIMo rev 3.1	Pears	441.4	blueberries ¹	111.5
	Plums	378.4	rosehips ¹	111.5
	Courgette	362.6	Broccoli	103.7
	Apricots	299.3	Oilseeds (cotton seed) ¹	103.3
	Tomatoes	289.7		
	Table grapes	2188	Courgettes	362
	Lettuces	1249	Tomatoes	348
	Peaches	1216	Cardoons	318 (adult)
	Melons	1183	Wine grapes	278
	Rhubarbs	1138	Sweet peppers/bell peppers	249
	Chinese cabbages/ pe- tsai	990	Cauliflowers	243
	Watermelons	954	Pumpkins	208
	Lamb's lettuce/corn salads	843	Chards/beet leaves	208 (adult)
	Spinaches	741	Gherkins	179 (pickled – child)
	Pears	720	Bananas	178
	Celeries	696	Broccoli	174
	Florence fennels	570 (adult)	Aubergines/egg plants	162 (adult)
	Apples	560	Cherries (sweet)	156
	Plums	539	Spinaches	131 (adult)
	Cucumbers	511	Kales	114
	Apricots	447	Blackberries	111
	Escaroles/broad- leaved endives	441		

¹ based on surrogate consumption data – see table 7.1-1

Scenario 2

Consumer risk assessments for the current GB MRLs, excluding those which result in an acute risk.

For the commodities for which an acute risk was identified in scenario 1, the input has been set at the LOQ (0.01* mg/kg), or if a lower CXL is available, the CXL has been used as an input. Additionally, if no acute risk was identified in scenario 1, and a higher CXL is available, the CXL has been considered further in this case.

The following CXLs have been included in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beans with pods, beetroot, cauliflower, maize/corn, pear, tree nuts.**

In addition, based on the TTC assessment conducted for the metabolite IN-MP819, the current MRL for milk results in a chronic intake concern – appendix A. In the absence of specific toxicological information on this metabolite, the MRL for milk shall be lowered to the LOQ (0.01* mg/kg).

For the remaining commodities, the existing MRLs established in the GB MRL Statutory Register have been used.

The NEDIs ranged from 18% - 65% of the ADI. The highest IEDI was 44 % of the ADI.

Acute risk assessments were also undertaken; a number of exceedances of the ARfD were observed. The affected crops are detailed below. For the crops not detailed below, no health effects are expected as a result of acute exposure.

Table A-2 Acute exposure output – scenario 2 assessment

Model	Commodities which result in an acute exceedance	
UK acute model, version 1.2	Commodity	Exceedance (%)
	Pears	187
	Cauliflower	162
	Blackcurrants	105
PRIMo rev 3.1	Pears	305
	Beetroots	251
	Currants (red, black and white)	164
	Cauliflowers	162
	Beans (with pods)	135
	Gooseberries (green, red and yellow)	122

	Broccoli	116
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Scenario 3

The following additional CXLs were considered in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beans with pods, beetroot, cauliflower, maize/corn, pear, tree nuts.**

The following CXLs resulted in acute intake concerns in scenario 2: **broccoli, currants (black, red and white), gooseberries (green, red and yellow), beans with pods, beetroot, cauliflower, pear.**

Scenario 3 was undertaken with all inputs considered in scenario 2, excluding the CXLs which resulted in acute intake concerns.

In addition, in section 4, the MRL for milk is recommended to be lowered to the LOQ due to uncertainties and a lack of toxicity data for the metabolite IN-MP819, which based on the metabolism data, may be expected at similar levels to parent indoxacarb.

The NEDIs ranged from 15% - 56% of the ADI. The highest IEDI was 35% of the ADI. The NESTIs and IESTIs were all below the ARfD.

Based on the chronic and acute risk assessments from scenario 3 no health effects are expected.

TTC Assessments

Processed commodities

As outlined in Section 3.1.4.2, the exclusion of metabolites from the residue definitions for processing was considered on the basis of their dietary exposure.

TTC consideration - IN-KT413, IN-MP819, IN-MK638 and IN-TMG00

As detailed in section 2.1, a combined exposure assessment is not required for the metabolites IN-KT413, IN-MP819, IN-MK638 or IN-TMG00.

As such, exposure to metabolite IN-KT413 (the largest individual component) has been assessed against the TTC (Threshold of toxicological concern) for CC III (Cramer Class III) compounds. The metabolite IN-P0036 has been considered separately as it is covered by the toxicological reference values for indoxacarb.

Of the CXLs/MRLs considered acceptable for consumer risk at scenario 3 (section 7), cranberries, cotton seeds, teas and meat fat have an STMR/HR >0.1 mg/kg. Nevertheless, all CXLs/MRLs (>LOQ only) considered at scenario 3 have been considered further.

The consumer risk associated with the processing metabolite IN-KT413 has been considered below.

Introduction

In section 2, HSE concluded that the Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment of IN-KT413, IN-MP819 and IN-TMG00 (RAR, 2017); the value of 5 µg/kg bw is applicable for the acute dietary risk assessment.

The genotoxic potential of IN-MK638 is discussed in section 2.1. HSE concluded that the Cramer Class III TTC value of 1.5 µg/kg bw/d was also applicable for this metabolite, the acute value of 5 µg/kg bw is therefore applicable for the acute dietary risk assessment.

Estimation of residue levels

There are insufficient Pf to estimate the residue levels of the metabolites in processed commodities. The available data demonstrates that the metabolites are not expected to be found in canned apples, peaches and green beans. The processing study for green beans involved a sterilization step and hence the data indicate that the metabolites may not be found in processed foods, even under worst case processing conditions. However, there are uncertainties and therefore, the potential levels of the metabolites in processed food must be considered further.

HSE has estimated the levels of the metabolites on the basis of the standard hydrolysis study. This approach is uncertain, particularly given the standard hydrolysis study does not involve the treatment of any plant material and is conducted in buffered water solutions. However, given that the data available on the magnitude of residues on processing indicates the metabolites are likely to be low and the approach has considered the worst case formation fraction to cover the sum of the metabolites, the approach is appropriate provided the exposures are below the TTC values. It should be further noted that in these assessments, the formation fraction for the metabolites have also been applied to products of animal origin; typically the nature and magnitude of residues in products of animal origin is not considered, and this approach therefore represents a very conservative estimate of the overall dietary exposure to the metabolites.

As an estimate of the potential formation fraction, the hydrolysis data for representative sterilisation conditions has been used as a worst case assumption. Considering the sterilisation data from section 3.1.4.1, the metabolite IN-KT413 is expected to occur in the highest proportion (29%); IN-MP819, IN-MK638 and IN-TMG00 do not individually exceed 12% of the identified residue following sterilization. It is unlikely that the only route of dietary exposure will be processed (specifically sterilised) commodities. Additionally, as a first step, the combined exposure from each of the metabolites has been considered. Any commodity, for which the GB MRL is proposed to be set at LOQ has not been considered.

Taking into account the estimated production factor, STMR-P and HR-P values have been derived in the table below for IN-KT413. The STMR-P and HR-P values are obtained by applying the production factor to the STMR and HR in the RAC.

Table A-3 Estimation of metabolite levels in processed commodities based on worst case production factor from hydrolysis data

Commodity	Estimated production factor	STMR RAC (mg/kg)	STMR-P (mg/kg)	HR RAC (mg/kg)	HR-P (mg/kg)
Tree nuts	0.3	0.013	0.004	0.046	0.014
Strawberries	0.3	0.19	0.057	0.27	0.081
Raspberries	0.3	0.26	0.078	0.3	0.09
Cranberries	0.3	0.15	0.045	0.69	0.207
Currants, gooseberries, mulberries, azeroles/ mediterranean medlars, elderberries, others (small	0.3	0.11	0.033	0.52	0.156

fruits and berries)					
Potatoes	0.3	0.01	0.003	0.01	0.003
Sweetcorn	0.3	0.01	0.003	0.012	0.0035
Cresses and other sprouts and shoots, land cresses, red mustards, purslanes	N/A				
Herbs and edible flowers (except basil)	N/A				
Head cabbage	0.3	0.02	0.006	0.09	0.027
Beans with pods	0.3	0.11	0.033	0.24	0.072
Beans (dry)	0.3	0.02	0.006	0.02	0.006
Peas (dry)	0.3	0.02	0.006	0.02	0.006
Peanuts	0.3	0.01	0.003	0.01	0.003
Rapeseeds/ canola seeds	0.3	0.01	0.003	0.01	0.003
Soyabeans	0.3	0.027	0.008	0.027	0.008
Mustard seeds	0.3	0.01	0.003	0.01	0.003
Maize/corn	0.3	0.01	0.003	0.01	0.003
Teas	0.3	0.41	0.123	0.41	0.123
Sugar beet roots	0.3	0.026	0.0078	0.06	0.018
Mammalian muscle	0.3	0.08	0.024	0.25	0.075
Mammalian fat	0.3	0.38	0.198	1.07	0.57
Mammalian edible offals	0.3	0.014	0.009	0.03	0.018
Milk	0.3	0.01	0.003	0.01	0.003
Eggs	0.3	0.01	0.003	0.02	0.006

N/A - not routinely consumed processed beyond 'simple' processes, such as washing

Dietary exposure estimates for IN-KT413, IN-MP819, IN-MK638 and IN-TMG00

Exposure to IN-KT413 has been estimated on the basis of the STMR-P and HR-P values derived above and the consumption data in the UK model and the EFSA PRIMo model.

For the chronic exposure assessment using UK consumption data, the chronic assessment uses the 97.5th percentile consumption level of 'consumers only' for the two commodities which give the highest intakes, and for the remaining commodities, the mean consumption of the total population group is used.

The chronic exposure to IN-KT413, IN-MP819, IN-MK638 and IN-TMG00 is 0.64 µg/kg bw/day (toddler) using UK consumption data and 0.35 µg/kg bw/day (NL child) using PRIMo consumption data.

The acute exposure to IN-KT413, IN-MP819, IN-MK638 and IN-TMG00 is 1.16 µg/kg bw (infant /head cabbage) using UK consumption data and 1.3 µg/kg bw (infant/strawberries) using PRIMo consumption data.

Conclusion on exposure to IN-KT413, IN-MP819, IN-MK638 and IN-TMG00

The Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment. As a first step, the exposure to the largest single metabolite (IN-KT413) has been considered.

The estimated chronic and the estimated acute exposures for the metabolites, are lower than the TTC values.

As the exposure estimates are all below the Cramer Class III TTC value of 1.5 µg/kg bw/d for chronic dietary risk assessment and the threshold value of 5 µg/kg bw for acute dietary risk assessment, no chronic or acute health effects are expected from the consumption of processed commodities containing the metabolites IN-KT413.

As IN-MP819, IN-MK638 and IN-TMG00 are expected to occur at lower levels than IN-KT413, the above conclusion also applies to these metabolites.

Furthermore, the conclusion is only applicable to the uses considered in this application and the exposure estimates would need to be reconsidered for any additional or more critical uses.

In conclusion, the available information for processed commodities is sufficient to support the proposed retained CXLs/MRLs detailed in table 8.1. Further information on the magnitude of residues on processing and/or data on the toxicological profile of the metabolites may be required to support further MRLs.

Products of animal origin

As outlined in section 4.2.2, a number of metabolites found in products of animal origin have been excluded from the residue definitions on the basis of their exposures. The details of these assessments are outlined below.

IN-MP819

The potential exposure to IN-MP819 via processed commodities was estimated above.

IN-MP819 is expected to occur in milk at similar levels to parent indoxacarb. The worst case ratio of Indoxacarb:IN-MP819 in milk was 1:0.82. The STMR for the current GB MRL in milk is 0.037 mg eq./kg, this is based on the CXL derived by the JMPR in 2005 (0.1 mg/kg); since then, the CXL has been raised to 0.2 mg/kg (JMPR, 2022).

Considering the relative molecular weights; IN-MP819 (STMR) is estimated as:
 $0.82 \times 0.037 \times \text{MWconversion} (527/470) = 0.034 \text{ mg/kg}$.

The chronic exposure to IN-MP819 (milk only) is 3.32 µg/kg bw/day (infant) using UK consumption data and 2.03 µg/kg bw/day (NL child) using PRIMo consumption data.

The acute exposure to IN-MP819 (milk only) is 4.22 µg/kg bw (infant /milk) using UK consumption data and 4.22 µg/kg bw (infant/milk) using PRIMo consumption data.

On the basis that the current GB MRL for milk results in a chronic exposure exceedance of the CCIII TTC value, further consideration is required.

The current GB MRL for milk is based on a revoked CXL. The calculated MRL for milk, based on the calculated GB dietary burden is 0.01^* mg/kg .

As detailed in section 4.2.2.1, in the absence of specific toxicological information, HSE recommends that the MRL for milk is set at 0.01^* mg/kg and this will ensure residues of the metabolite (IN-MP819) will also be $<0.01^* \text{ mg/kg}$.

In order to set a substantive MRL for milk, additional toxicological data and feeding studies for the metabolite are required.

5-OH-indoxacarb

5-OH indoxacarb (free and conjugated) is expected to be present in ruminant matrices at >0.01 mg/kg.

The current GB MRLs for ruminant tissues are based on the CXLs, the STMR/HR which support the current MRL (CXLs) are detailed below (JMPR, 2009):

Table A-4 STMR/HR which support the current GB MRLs

Matrix	STMR	HR
Mammalian muscle†	0.08	0.25
Mammalian fat	0.38	1.07
Mammalian liver, kidney and edible offals	0.014	0.03

† Calculated based on 80:20 muscle:fat.

It is noted that these STMR/HR values are based on the sum of indoxacarb (and its R enantiomer) and IN-JT333. From the ruminant feeding study, IN-JT333 was identified in fat and milk (including skim milk and cream), the metabolite was <LOQ in all other matrices.

In fat, IN-JT333 was identified at between 4.2-6.7% of the level of parent indoxacarb (and its R enantiomer). In milk, skim milk and cream IN-JT333 was identified at up to 5%, 12%, and 3.4%, of the level of parent indoxacarb (and its R enantiomer), respectively.

As such, the contribution of IN-JT333 is expected to be insignificant to parent indoxacarb (and its R enantiomer).

For the purposes of estimating the level of 5-OH indoxacarb (free and conjugated) in ruminant matrices, the contribution of IN-JT333 to the above STMR/HRs is considered insignificant.

Based on the metabolism study 5-OH indoxacarb (free and conjugated) was identified at between 104-142% of the level of parent indoxacarb in liver; and at between 15-20% of the level of parent indoxacarb in kidney.

Based on table A-4; the following STMR/HRs are derived:

Table A-5 STMR/HR input for 5-OH-indoxacarb TTC assessment

Matrix	STMR	HR
Mammalian kidney	0.003	0.006

Mammalian liver	0.020	0.043
Mammalian other edible offals	0.020	0.043

The chronic exposure to 5-OH-indoxacarb (free and conjugated) is 0.09 µg/kg bw/day (toddler) using UK consumption data and 0.01 µg/kg bw/day (IE adult) using PRIMo consumption data.

The acute exposure to 5-OH-indoxacarb (free and conjugated) is 0.35 µg/kg bw (infant /liver) using UK consumption data and 0.35 µg/kg bw (infant/bovine liver) using PRIMo consumption data.

Conclusion on exposure to 5-OH-indoxacarb (free and conjugated)

The Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment.

The calculated chronic and acute exposures for the combination of metabolites, are lower than the TTC values set for Cramer Class III substances.

As the exposure estimates are below the Cramer Class III TTC value of 1.5 µg/kg bw/d for chronic dietary risk assessment and the threshold value of 5 µg/kg bw for acute dietary risk assessment, no chronic or acute health effects are expected from the consumption of animal commodities containing the metabolite 5-OH-indoxacarb (free and conjugated).

IN-JT333

IN-JT333 is expected to be present in ruminant fat and poultry fat at >0.01 mg/kg.

The current GB MRLs for ruminant tissues are based on the CXLs, the STMR/HR which support the current MRL (CXLs) are detailed in table A.1. The STMR for poultry fat, based on the CXL, is 0.01 mg/kg.

In poultry fat, based on the current MRL and on the feeding study considered by the JMPR, and during the Article 12 review, the metabolite IN-JT333 may be expected at up to 0.018 mg/kg in fat (section 4.2.1).

In ruminant fat, IN-JT333 was identified at 5-7% TRR, and was present at 7-11% of the level of parent indoxacarb based on the metabolism study. Based on the feeding study, IN-JT333 was identified at between 4.2-6.7% of the level of parent indoxacarb (and its R enantiomer).

Based on the values in table A.1 and the maximum ratio observed in the feeding study, the following STMR and HR are derived: STMR: 0.0266 mg/kg; HR: 0.075 mg/kg.

The chronic exposure to IN-JT333 is 0.02 µg/kg bw/day (toddler) using UK consumption data and 0.01 µg/kg bw/day (GEMS/Food G15) using PRIMo consumption data.

The acute exposure to IN-JT333 is 0.16 µg/kg bw (infant /meat fat) using UK consumption data and 0.16 µg/kg bw (infant/bovine fat) using PRIMo consumption data.

Conclusion on exposure to IN-JT333

The Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a value of 5 µg/kg bw is applicable for the acute dietary risk assessment.

The calculated chronic and acute exposures for the combination of metabolites, are lower than the TTC values set for Cramer Class III substances.

As the exposure estimates are below the Cramer Class III TTC value of 1.5 µg/kg bw/d for chronic dietary risk assessment and the threshold value of 5 µg/kg bw for acute dietary risk assessment, no chronic or acute health effects are expected from the consumption of animal commodities containing the metabolite IN-JT333.

IN-MN470 & IN-MF014

IN-MN470 & IN-MF014 were identified in ruminant liver only; these metabolites were present at 76% of the level of parent indoxacarb in liver (one label only). IN-MN470 & IN-MF014 were identified at 73% of the level of 5-OH-indoxacarb (free and conjugated) in ruminant liver.

Estimated levels of IN-MN470 & IN-MF014 are as follows: STMR: 0.015 mg/kg; HR: 0.031 mg/kg.

Given that the levels are lower than those observed for 5-OH-indoxacarb (free and conjugated); and that exposure to 5-OH-indoxacarb (free and conjugated) were below the CCIII TTC and threshold values; IN-MN470 & IN-MF014 will also be below these values.

Appendix B – UK models and Pesticide Residues Intake Model (PRIMo)

Scenario 1

Table B.1 Chronic risk assessment undertaken using UK model version 1.1

Active substance: indoxacarb ADI: 0.005 ^{mg/kg} bw/day Source: GB Art 21, 2023

TOTAL INTAKE based on 97.5th percentile										
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00956	0.00838	0.01363	0.01052	0.00968	0.00584	0.00582	0.01050	0.00741	0.00454
% of ADI	191%	168%	273%	210%	194%	117%	116%	210%	148%	91%

STMR		P		COMMODITY INTAKES								
Commodity	(mg/kg)			(mg/kg bw/day)								
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

The review of the existing MRLs for indoxacarb – proposed MRLs

Chestnuts	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.01		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.01		0.00000	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Apples	0.21		0.00056	0.00177	0.00312	0.00198	0.00158	0.00086	0.00075	0.00070	0.00046	0.00022
Pears	0.21		0.00029	0.00054	0.00137	0.00076	0.00046	0.00039	0.00030	0.00039	0.00048	0.00025
Apricots	0.17		0.00006	0.00023	0.00017	0.00011	0.00007	0.00006	0.00004	0.00013	0.00007	0.00006
Peaches	0.17		0.00023	0.00023	0.00053	0.00027	0.00020	0.00013	0.00008	0.00016	0.00016	0.00007
Plums	0.17		0.00016	0.00008	0.00037	0.00023	0.00013	0.00005	0.00004	0.00012	0.00011	0.00004
Cherries	0.17		0.00008	0.00024	0.00018	0.00026	0.00009	0.00012	0.00010	0.00009	0.00006	0.00001
Table grapes	0.32		0.00042	0.00053	0.00150	0.00069	0.00083	0.00035	0.00020	0.00065	0.00042	0.00015
Wine grapes	0.32		0.00315	0.00039	0.00028	0.00029	0.00010	0.00032	0.00113	0.00311	0.00213	0.00047
Strawberries	0.19		0.00011	0.00036	0.00038	0.00026	0.00017	0.00013	0.00010	0.00018	0.00019	0.00010
Blackberries	0.255		0.00003	L/C	0.00050	0.00002	0.00008	0.00006	0.00002	0.00008	0.00007	0.00001
Loganberries	0.02		0.00000	0.00001	0.00002	0.00000	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000
Raspberries	0.26		0.00011	L/C	0.00062	0.00017	0.00026	0.00007	0.00002	0.00010	0.00022	0.00010
Gooseberries	0.26		0.00006	0.00013	0.00017	0.00006	0.00006	0.00006	0.00005	0.00019	0.00021	0.00006
Blackcurrants	0.15		0.00009	0.00018	0.00027	0.00027	0.00021	0.00015	0.00017	0.00005	0.00008	0.00004
Red currants	0.11		0.00001	L/C	0.00009	L/C	0.00001	0.00001	0.00000	0.00000	0.00004	L/C
White currants	0.11		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.044		0.00009	0.00031	0.00029	0.00020	0.00015	0.00009	0.00006	0.00009	0.00007	0.00008
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000

The review of the existing MRLs for indoxacarb – proposed MRLs

Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C
Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.01		0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.02		0.00001	L/C	0.00002	L/C	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Salsify	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.11		0.00015	0.00020	0.00029	0.00021	0.00020	0.00012	0.00015	0.00019	0.00016	0.00015
Peppers	0.06		0.00002	L/C	0.00005	0.00002	0.00004	0.00002	0.00002	0.00004	0.00003	0.00001
Aubergines	0.11		0.00003	L/C	0.00017	0.00008	0.00003	0.00006	0.00004	0.00007	0.00004	L/C
Marrows	0.06		0.00003	L/C	0.00009	0.00002	0.00004	0.00004	0.00002	0.00003	0.00008	0.00004

The review of the existing MRLs for indoxacarb – proposed MRLs

Cucumbers	0.06		0.00002	0.00001	0.00015	0.00009	0.00006	0.00003	0.00003	0.00003	0.00003	0.00001
Gourd	0.06		0.00003	L/C	L/C	L/C	L/C	0.00002	L/C	0.00001	L/C	L/C
Courgettes	0.06		0.00003	0.00009	0.00014	0.00008	0.00005	0.00003	0.00002	0.00003	0.00003	0.00003
Melons	0.06		0.00015	0.00018	0.00031	0.00021	0.00018	0.00013	0.00017	0.00015	0.00018	0.00006
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.08		0.00005	0.00009	0.00014	0.00010	0.00008	0.00006	0.00005	0.00005	0.00008	0.00003
Cauliflower	0.08		0.00007	0.00025	0.00017	0.00013	0.00007	0.00006	0.00007	0.00010	0.00009	0.00005
Brussels sprouts	0.02		0.00001	0.00005	0.00004	0.00003	0.00001	0.00002	0.00001	0.00002	0.00002	0.00001
Head cabbage	0.05		0.00003	0.00009	0.00009	0.00006	0.00004	0.00004	0.00003	0.00004	0.00006	0.00004
Chinese cabbage	0.49		0.00024	L/C	L/C	L/C	L/C	L/C	L/C	0.00025	0.00017	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	8.6		0.00533	0.00306	0.00735	0.00592	0.00623	0.00348	0.00380	0.00606	0.00460	0.00236
Spinach	0.52		0.00027	0.00052	0.00081	0.00045	0.00046	0.00033	0.00018	0.00035	0.00029	0.00018
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.27		0.00002	L/C	L/C	L/C	L/C	L/C	L/C	0.00002	L/C	L/C
Parsley	3.5		0.00059	L/C	0.00039	L/C	0.00056	0.00015	0.00005	0.00060	0.00063	0.00128
Beans with pods	0.11		0.00006	0.00013	0.00021	0.00014	0.00007	0.00004	0.00008	0.00004	0.00008	0.00003
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

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Fennel	0.97		0.00037	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.035		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.97		0.00039	0.00070	0.00107	0.00023	0.00049	0.00013	0.00016	0.00034	0.00065	0.00040
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.02		0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002
Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.36		0.00114	0.00227	0.00261	0.00257	0.00201	0.00145	0.00127	0.00168	0.00115	0.00139
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Tea (dried leaves)	0.41		0.00009	0.00029	0.00011	0.00007	0.00005	0.00005	0.00006	0.00009	0.00009	0.00009
Hops (dried 0.25% of beer)	0.01		0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.06		0.00010	0.00010	0.00018	0.00017	0.00011	0.00009	0.00009	0.00010	0.00010	0.00005
Meat fat	0.38		0.00007	0.00016	0.00027	0.00016	0.00011	0.00010	0.00009	0.00004	0.00008	0.00006
Meat excl. poultry & offal	0.08		0.00015	0.00033	0.00033	0.00028	0.00024	0.00016	0.00017	0.00003	0.00014	0.00014
All types of kidney	0.014		0.00000	0.00001	0.00002	0.00000	0.00000	0.00000	0.00000	L/C	0.00001	0.00000
All types of Liver	0.02		0.00001	0.00004	0.00005	0.00001	0.00001	0.00001	0.00001	L/C	0.00001	0.00001
Other types of offal	0.02		0.00001	0.00003	0.00004	0.00002	0.00002	0.00002	0.00001	0.00000	0.00002	0.00001

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Eggs	0.02		0.00002	0.00009	0.00007	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00003
Milk	0.037		0.00030	0.00361	0.00206	0.00109	0.00067	0.00044	0.00034	0.00036	0.00032	0.00043
Sugar beet	0.026		0.00036	0.00087	0.00145	0.00088	0.00082	0.00052	0.00050	0.00031	0.00028	0.00039

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.2 Chronic risk assessment undertaken using PRIMo revision 3.1

Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
		No of diets exceeding the ADI :			4				Exposure resulting from	
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor or to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor or to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
163.4%	NL toddler	8.17	45.3%	Apples	44.2%	Milk: Cattle	18.2%	Pears	3.0%	160.3%
139.0%	DE child	6.95	52.4%	Apples	34.8%	Sweet peppers/bell peppers	14.6%	Milk: Cattle	2.9%	136.1%
108.7%	GEMS/Food G15	5.44	67.2%	Sweet peppers/bell peppers	6.4%	Wine grapes	5.2%	Milk: Cattle	2.4%	106.3%
102.0%	GEMS/Food G06	5.10	57.9%	Sweet peppers/bell peppers	7.9%	Tomatoes	6.7%	Table grapes	3.2%	98.8%
92.6%	RO general	4.63	50.0%	Sweet peppers/bell peppers	10.8%	Wine grapes	8.6%	Milk: Cattle	1.6%	91.0%
89.3%	GEMS/Food G08	4.46	34.0%	Sweet peppers/bell peppers	12.3%	Lamb's lettuce/corn salads	6.7%	Wine grapes	2.7%	86.6%
85.2%	NL child	4.26	24.3%	Apples	18.1%	Milk: Cattle	6.6%	Table grapes	2.2%	83.0%
84.1%	GEMS/Food G11	4.20	20.1%	Sweet peppers/bell peppers	14.6%	Lamb's lettuce/corn salads	6.5%	Apples	2.8%	81.2%
67.5%	DK child	3.37	26.7%	Sweet peppers/bell peppers	9.8%	Apples	9.3%	Milk: Cattle	2.6%	64.9%
64.3%	GEMS/Food G07	3.22	14.4%	Sweet peppers/bell peppers	9.5%	Wine grapes	4.8%	Milk: Cattle	2.7%	61.7%
63.7%	IE adult	3.18	16.4%	Sweet peppers/bell peppers	8.0%	Wine grapes	4.7%	Rhubarbs	2.9%	60.8%
63.2%	GEMS/Food G10	3.16	23.7%	Sweet peppers/bell peppers	4.1%	Milk: Cattle	3.4%	Lettuces	2.5%	60.7%
62.8%	DE women 14-50 yr	3.14	16.5%	Sweet peppers/bell peppers	10.8%	Apples	9.2%	Milk: Cattle	1.5%	61.3%
62.2%	SE general	3.11	22.6%	Sweet peppers/bell peppers	9.2%	Milk: Cattle	7.0%	Bovine: Muscle/meat	1.6%	60.6%
59.5%	DE general	2.97	15.1%	Sweet peppers/bell peppers	10.2%	Apples	9.1%	Milk: Cattle	1.4%	58.1%
58.6%	FR child 3 15 yr	2.93	16.9%	Milk: Cattle	7.0%	Apples	5.3%	Sweet peppers/bell peppers	2.5%	56.1%
58.5%	FR toddler 2 3 yr	2.93	21.7%	Milk: Cattle	13.3%	Apples	2.3%	Sweet peppers/bell peppers	1.8%	56.7%

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55.1%	PT general	2.76	23.2%	Sweet peppers/bell peppers	15.9%	Wine grapes	4.4%	Apples	1.6%	53.5%
51.6%	ES child	2.58	13.8%	Sweet peppers/bell peppers	9.2%	Milk: Cattle	4.8%	Apples	1.9%	49.7%
48.9%	UK infant	2.44	28.6%	Milk: Cattle	6.6%	Apples	2.0%	Bovine: Muscle/meat	1.5%	47.4%
47.6%	ES adult	2.38	18.6%	Sweet peppers/bell peppers	5.6%	Lettuces	3.7%	Milk: Cattle	1.2%	46.4%
42.3%	FR adult	2.12	14.9%	Wine grapes	4.2%	Sweet peppers/bell peppers	3.3%	Milk: Cattle	1.0%	41.3%
42.2%	UK toddler	2.11	15.3%	Milk: Cattle	7.2%	Apples	2.5%	Sweet peppers/bell peppers	1.7%	40.5%
40.0%	NL general	2.00	6.4%	Sweet peppers/bell peppers	6.3%	Milk: Cattle	6.1%	Apples	1.3%	38.7%
38.4%	DK adult	1.92	11.9%	Sweet peppers/bell peppers	6.1%	Wine grapes	4.0%	Apples	0.6%	37.8%
33.6%	FR infant	1.68	12.4%	Milk: Cattle	7.0%	Apples	2.8%	Spinaches	0.7%	32.9%
31.1%	IT adult	1.55	8.4%	Sweet peppers/bell peppers	3.9%	Lettuces	3.3%	Apples	1.3%	29.8%
30.0%	IT toddler	1.50	7.3%	Sweet peppers/bell peppers	3.7%	Apples	3.1%	Tomatoes	2.0%	28.0%
29.5%	FI 3 yr	1.47	11.9%	Sweet peppers/bell peppers	4.0%	Apples	1.5%	Table grapes	1.2%	28.3%
28.9%	UK vegetarian	1.44	9.7%	Sweet peppers/bell peppers	5.2%	Wine grapes	2.5%	Apples	0.9%	27.9%
26.6%	PL general	1.33	9.3%	Sweet peppers/bell peppers	8.6%	Apples	2.0%	Table grapes	0.3%	26.3%
25.7%	FI 6 yr	1.29	12.1%	Sweet peppers/bell peppers	2.4%	Apples	1.1%	Table grapes	1.0%	24.7%
24.4%	UK adult	1.22	6.9%	Wine grapes	5.2%	Sweet peppers/bell peppers	2.2%	Milk: Cattle	0.7%	23.7%
22.0%	LT adult	1.10	7.8%	Apples	2.9%	Milk: Cattle	2.4%	Sweet peppers/bell peppers	0.7%	21.3%
17.8%	FI adult	0.89	5.5%	Sweet peppers/bell peppers	2.4%	Apples	2.0%	Wine grapes	1.7%	16.1%
9.7%	IE child	0.48	2.7%	Milk: Cattle	1.7%	Sweet peppers/bell peppers	1.4%	Apples	0.4%	9.3%

Conclusion:

The estimated TMDI/NEDI/IEDI was in the range of 0 % to 163.4 % of the ADI.
For 4 diet(s) the ADI is exceeded.

Table B.3A Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apples	0.26		0.00389	77.8	0.02547	509.4	0.01873	374.6	0.01449	289.9	0.01069	213.8
Pears	0.26		0.00459	91.8	0.01883	376.6	0.02207	441.4	0.01564	312.8	0.01039	207.8
Apricots	0.64		0.00448	89.6	0.01236	247.2	0.01332	266.3	0.01497	299.3	0.00994	198.8
Peaches	0.64		0.00785	157.0	0.02204	440.8	0.03523	704.5	0.02457	491.3	0.01643	328.6
Plums	0.64		0.00467	93.4	0.01385	277.0	0.01892	378.4	0.01416	283.2	0.00902	180.4
Cherries	0.64		0.00121	24.2	0.00177	35.3	0.00284	56.8	0.00347	69.4	0.00239	47.7
Oilseeds	0.36		0.00216	43.1	0.00420	83.9	0.00485	97.1	0.00516	103.3	0.00393	78.6
Potatoes	0.01		0.00024	4.8	0.00154	30.8	0.00106	21.3	0.00080	16.0	0.00055	11.0
Wine grapes	1.50		0.03558	711.6	0.01166	233.1	0.00704	140.9	0.00949	189.8	0.00279	55.7
Table grapes	1.50		0.02959	591.7	0.04310	862.1	0.09155	1831.0	0.07562	1512.4	0.06959	1391.7
Strawberries	0.27		0.00071	14.2	0.00121	24.2	0.00132	26.4	0.00187	37.4	0.00131	26.1
Blackberries	0.52		0.00040	8.0	0.00084	16.7	0.00557	111.5	0.00022	4.5	0.00121	24.1
Raspberries	0.30		0.00056	11.1	0.00123	24.7	0.00121	24.2	0.00078	15.5	0.00146	29.3
Gooseberries	0.52		0.00051	10.2	0.00169	33.7	0.00110	21.9	0.00088	17.7	0.00057	11.5
Blackcurrants	0.52		0.00082	16.4	0.00126	25.1	0.00187	37.4	0.00263	52.6	0.00175	35.1
Red currants	0.52		0.00021	4.3	0.00000	0.0	0.00105	21.0	0.00014	2.8	0.00010	2.0
White currants	0.52		0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Bananas	0.09		0.00113	22.5	0.00769	153.8	0.00516	103.1	0.00393	78.6	0.00272	54.4
Radishes	0.16		0.00017	3.3	0.00000	0.0	0.00050	10.0	0.00020	4.1	0.00014	2.9
Tomatoes	0.30		0.00313	62.6	0.01448	289.7	0.01242	248.5	0.00933	186.6	0.00664	132.8
Peppers	0.21		0.00277	55.4	0.00000	0.0	0.00343	68.5	0.00245	49.0	0.00345	69.0
Aubergines	0.30		0.00293	58.6	0.00000	0.0	0.00644	128.9	0.00750	150.0	0.00281	56.2
Marrows	0.39		0.00508	101.5	0.00000	0.0	0.00830	166.0	0.00424	84.8	0.00555	111.1
Cucumbers	0.39		0.00276	55.3	0.00291	58.3	0.01151	230.2	0.00917	183.4	0.00690	138.1
Gourd	0.39		0.00573	114.7	0.00000	0.0	0.00000	0.0	0.00495	98.9	0.00000	0.0
Courgettes	0.39		0.00431	86.3	0.01236	247.3	0.01813	362.6	0.01560	312.0	0.01008	201.6

The review of the existing MRLs for indoxacarb – proposed MRLs

Melons	0.39	0.01441	288.2	0.02847	569.3	0.02804	560.8	0.03242	648.4	0.02852	570.5
Sweet corn	0.01	0.00018	3.6	0.00030	6.0	0.00043	8.7	0.00035	7.0	0.00042	8.4
Broccoli	0.21	0.00270	54.0	0.00432	86.4	0.00440	87.9	0.00518	103.7	0.00471	94.2
Cauliflower	0.21	0.00324	64.8	0.01217	243.3	0.00696	139.2	0.00730	146.1	0.00411	82.2
Brussels sprouts	0.04	0.00010	2.0	0.00029	5.8	0.00019	3.7	0.00028	5.6	0.00015	3.0
Head cabbage	0.09	0.00109	21.8	0.00387	77.5	0.00229	45.8	0.00289	57.9	0.00158	31.7
Chinese cabbage	1.54	0.02379	475.8	0.00000	0.0	0.01641	328.2	0.00000	0.0	0.03424	684.8
Cress	0.55	0.00009	1.9	0.00000	0.0	0.00016	3.2	0.00016	3.2	0.00009	1.8
Lettuce	1.64	0.01618	323.7	0.02074	414.7	0.01979	395.9	0.02920	584.0	0.02205	441.0
Spinach	1.64	0.00415	82.9	0.00863	172.7	0.00650	130.1	0.00930	186.1	0.00531	106.1
Chicory	0.55	0.00203	40.5	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00536	107.2
Parsley	1.64	0.00107	21.4	0.00000	0.0	0.00051	10.2	0.00048	9.6	0.00179	35.9
Beans with pods	0.24	0.00055	11.0	0.00120	24.1	0.00120	24.0	0.00090	18.0	0.00049	9.7
Celery	0.93	0.00541	108.2	0.00626	125.2	0.00552	110.4	0.00490	98.1	0.00390	78.0
Fennel	1.53	0.02196	439.1	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Globe artichokes	0.07	0.00060	12.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00029	5.7
Rhubarb	1.53	0.01196	239.2	0.05195	1039.0	0.05692	1138.3	0.01802	360.5	0.02606	521.3
Beans	0.13	0.00072	14.4	0.00238	47.5	0.00161	32.3	0.00151	30.2	0.00107	21.4
dried Peas	0.13	0.00039	7.8	0.00000	0.0	0.00055	10.9	0.00042	8.4	0.00043	8.6
Tea (dried leaves)	0.41	0.00012	2.4	0.00038	7.5	0.00016	3.2	0.00010	2.1	0.00008	1.7
Maize	0.01	0.00000	0.1	0.00007	1.3	0.00004	0.8	0.00002	0.3	0.00001	0.2
Poultry	0.06	0.00033	6.6	0.00041	8.3	0.00052	10.4	0.00057	11.3	0.00042	8.5
Meat fat	1.07	0.00072	14.3	0.00223	44.5	0.00199	39.8	0.00215	42.9	0.00146	29.3
Meat excl.poultry & offal	0.25	0.00123	24.6	0.00295	59.0	0.00254	50.8	0.00227	45.4	0.00194	38.8
All types of kidney	0.03	0.00005	1.0	0.00007	1.5	0.00011	2.3	0.00007	1.5	0.00005	1.0
All types of liver	0.03	0.00008	1.6	0.00024	4.8	0.00020	4.0	0.00005	1.1	0.00008	1.5
Other types of offal	0.03	0.00009	1.8	0.00022	4.4	0.00021	4.3	0.00017	3.4	0.00016	3.3
Eggs	0.02	0.00006	1.1	0.00025	5.0	0.00016	3.1	0.00013	2.7	0.00010	2.0
Milk	0.04	0.00048	9.6	0.00460	91.9	0.00271	54.3	0.00172	34.5	0.00110	22.1
Sugar Beet	0.06	0.00156	31.1	0.00334	66.7	0.00467	93.3	0.00383	76.6	0.00314	62.8

The review of the existing MRLs for indoxacarb – proposed MRLs

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Apples	0.26		0.00671	134.1	0.00550	110.0	0.00460	92.0	0.00346	69.2	0.00344	68.8
Pears	0.26		0.00683	136.6	0.00523	104.6	0.00515	103.0	0.00480	96.0	0.00473	94.5
Apricots	0.64		0.00349	69.8	0.00482	96.4	0.00484	96.7	0.00448	89.7	0.00499	99.7
Peaches	0.64		0.01185	237.0	0.00863	172.6	0.00814	162.8	0.00744	148.9	0.00733	146.6
Plums	0.64		0.00557	111.3	0.00417	83.4	0.00506	101.2	0.00405	81.0	0.00344	68.8
Cherries	0.64		0.00319	63.8	0.00176	35.3	0.00154	30.8	0.00089	17.8	0.00016	3.2
Oilseeds	0.36		0.00293	58.6	0.00253	50.5	0.00346	69.2	0.00171	34.1	0.00197	39.5
Potatoes	0.01		0.00039	7.8	0.00029	5.8	0.00030	6.0	0.00024	4.8	0.00026	5.2
Wine grapes	1.50		0.01058	211.7	0.02842	568.5	0.03207	641.4	0.01964	392.8	0.00502	100.4
Table grapes	1.50		0.05434	1086.9	0.02713	542.6	0.04583	916.6	0.01691	338.1	0.01208	241.6
Strawberries	0.27		0.00081	16.1	0.00063	12.5	0.00092	18.3	0.00071	14.2	0.00032	6.3
Blackberries	0.52		0.00086	17.2	0.00035	7.0	0.00111	22.3	0.00040	8.1	0.00008	1.5
Raspberries	0.30		0.00055	11.0	0.00009	1.8	0.00051	10.2	0.00066	13.2	0.00044	8.8
Gooseberries	0.52		0.00085	17.1	0.00067	13.4	0.00115	22.9	0.00095	18.9	0.00049	9.8
Blackcurrants	0.52		0.00111	22.2	0.00155	30.9	0.00041	8.3	0.00067	13.4	0.00033	6.5
Red currants	0.52		0.00040	8.0	0.00016	3.2	0.00012	2.4	0.00047	9.4	0.00021	4.2
White currants	0.52		0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Bananas	0.09		0.00159	31.9	0.00136	27.1	0.00131	26.2	0.00104	20.8	0.00117	23.4
Radishes	0.16		0.00013	2.6	0.00011	2.3	0.00019	3.9	0.00016	3.1	0.00004	0.8
Tomatoes	0.30		0.00424	84.7	0.00358	71.6	0.00408	81.6	0.00301	60.2	0.00355	70.9
Peppers	0.21		0.00221	44.1	0.00209	41.7	0.00343	68.6	0.00201	40.2	0.00110	21.9
Aubergines	0.30		0.00373	74.6	0.00240	48.0	0.00532	106.3	0.00201	40.2	0.00000	0.0
Marrows	0.39		0.00677	135.4	0.00298	59.7	0.00716	143.2	0.00621	124.2	0.00239	47.9
Cucumbers	0.39		0.00376	75.2	0.00356	71.3	0.00337	67.5	0.00252	50.4	0.00110	22.0
Gourd	0.39		0.00317	63.5	0.00173	34.6	0.00231	46.2	0.00275	55.1	0.00000	0.0
Courgettes	0.39		0.00448	89.5	0.00377	75.5	0.00523	104.7	0.00441	88.2	0.00490	97.9
Melons	0.39		0.01893	378.5	0.01528	305.6	0.01168	233.6	0.01028	205.6	0.00771	154.2
Sweet corn	0.01		0.00018	3.7	0.00024	4.9	0.00022	4.4	0.00014	2.9	0.00010	1.9

The review of the existing MRLs for indoxacarb – proposed MRLs

Broccoli	0.21		0.00327	65.4	0.00293	58.7	0.00351	70.1	0.00268	53.5	0.00145	29.0
Cauliflower	0.21		0.00350	70.0	0.00321	64.3	0.00487	97.4	0.00318	63.7	0.00213	42.5
Brussels sprouts	0.04		0.00012	2.3	0.00012	2.5	0.00016	3.1	0.00010	1.9	0.00007	1.4
Head cabbage	0.09		0.00150	30.0	0.00108	21.5	0.00153	30.6	0.00119	23.8	0.00089	17.8
Chinese cabbage	1.54		0.00316	63.2	0.03898	779.7	0.01356	271.3	0.00578	115.5	0.00000	0.0
Cress	0.55		0.00008	1.5	0.00007	1.4	0.00021	4.2	0.00013	2.7	0.00009	1.8
Lettuce	1.64		0.01367	273.3	0.01316	263.2	0.01802	360.5	0.01156	231.2	0.00647	129.4
Spinach	1.64		0.00503	100.6	0.00267	53.4	0.00587	117.5	0.00350	70.0	0.00231	46.3
Chicory	0.55		0.00000	0.0	0.00760	152.1	0.00115	23.1	0.00000	0.0	0.00000	0.0
Parsley	1.64		0.00047	9.5	0.00016	3.3	0.00196	39.3	0.00071	14.3	0.00069	13.7
Beans with pods	0.24		0.00047	9.4	0.00066	13.2	0.00067	13.3	0.00052	10.4	0.00026	5.2
Celery	0.93		0.00525	104.9	0.00390	77.9	0.00771	154.2	0.00590	118.0	0.00196	39.3
Fennel	1.53		0.00000	0.0	0.00000	0.0	0.02852	570.3	0.01593	318.6	0.00000	0.0
Globe artichokes	0.07		0.00000	0.0	0.00000	0.0	0.00044	8.8	0.00000	0.0	0.00000	0.0
Rhubarb	1.53		0.00944	188.8	0.01217	243.4	0.01420	283.9	0.01219	243.8	0.01343	268.7
Beans	0.13		0.00097	19.5	0.00086	17.1	0.00082	16.4	0.00042	8.4	0.00039	7.7
dried Peas	0.13		0.00085	17.1	0.00029	5.9	0.00043	8.6	0.00034	6.8	0.00018	3.6
Tea (dried leaves)	0.41		0.00009	1.9	0.00010	2.0	0.00013	2.5	0.00010	2.1	0.00010	2.1
Maize	0.01		0.00001	0.1	0.00001	0.2	0.00002	0.4	0.00000	0.1	0.00000	0.0
Poultry	0.06		0.00035	7.1	0.00032	6.5	0.00070	14.1	0.00028	5.5	0.00015	3.0
Meat fat	1.07		0.00107	21.4	0.00102	20.4	0.00053	10.7	0.00052	10.4	0.00048	9.6
Meat excl.poultry & offal	0.25		0.00143	28.7	0.00142	28.5	0.00067	13.4	0.00092	18.5	0.00079	15.9
All types of kidney	0.03		0.00004	0.8	0.00006	1.3	0.00000	0.0	0.00005	1.0	0.00004	0.8
All types of liver	0.03		0.00013	2.5	0.00006	1.2	0.00000	0.0	0.00007	1.4	0.00006	1.1
Other types of offal	0.03		0.00014	2.7	0.00007	1.4	0.00003	0.6	0.00007	1.5	0.00007	1.5
Eggs	0.02		0.00008	1.5	0.00006	1.2	0.00008	1.5	0.00004	0.8	0.00005	0.9
Milk	0.04		0.00076	15.3	0.00065	13.0	0.00055	11.0	0.00041	8.2	0.00053	10.6
Sugar Beet	0.06		0.00234	46.9	0.00216	43.1	0.00125	25.0	0.00084	16.7	0.00113	22.7

Table B.3B Acute risk assessment undertaken using UK model UK model 1.2 – surrogate commodities

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Oilseeds	0.03		0.00016	3.2	0.00031	6.3	0.00036	7.3	0.00039	7.7	0.00029	5.9
Blackberries	0.52		0.00040	8.0	0.00084	16.7	0.00557	111.5	0.00022	4.5	0.00121	24.1
Raspberries	0.52		0.00096	19.3	0.00214	42.8	0.00210	42.0	0.00135	26.9	0.00254	50.8
Blackcurrants	0.69		0.00109	21.8	0.00167	33.3	0.00248	49.7	0.00349	69.7	0.00233	46.5
Head cabbage	0.13		0.00158	31.5	0.00560	111.9	0.00331	66.2	0.00418	83.6	0.00229	45.7
Lettuce	15.00		0.14803	2960.5	0.18966	3793.1	0.18103	3620.7	0.26707	5341.5	0.20170	4034.0
Parsley	6.80		0.00445	88.9	0.00000	0.0	0.00211	42.2	0.00199	39.8	0.00744	148.8

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Oilseeds	0.03		0.00022	4.4	0.00019	3.8	0.00026	5.2	0.00013	2.6	0.00015	3.0
Blackberries	0.52		0.00086	17.2	0.00035	7.0	0.00111	22.3	0.00040	8.1	0.00008	1.5
Raspberries	0.52		0.00095	19.1	0.00016	3.1	0.00088	17.7	0.00115	22.9	0.00076	15.3
Blackcurrants	0.69		0.00147	29.4	0.00205	41.0	0.00055	11.0	0.00089	17.8	0.00043	8.7
Head cabbage	0.13		0.00217	43.4	0.00155	31.1	0.00221	44.2	0.00172	34.4	0.00128	25.6
Lettuce	15.00		0.12500	2500.0	0.12038	2407.5	0.16484	3296.9	0.10572	2114.4	0.05917	1183.4
Parsley	6.80		0.00197	39.4	0.00068	13.6	0.00815	162.9	0.00296	59.2	0.00285	57.0

Table B.4 Acute assessment undertaken PRIMo revision 3.1

Unprocessed commodities	Results for children				Results for adults			
	No. of commodities for which ARfD/ADI is exceeded (IESTI):				No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	30				25			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	2187.50%	Table grapes	0 / 1.5	109.38	1017.40%	Table grapes	0 / 1.5	50.87
	1248.72%	Lettuces	0 / 1.64	62.44	779.66%	Chinese cabbages/pe-tsai	0 / 1.54	38.98
	1216.38%	Peaches	0 / 0.64	60.82	711.56%	Wine grapes	0 / 1.5	35.58
	1183.15%	Melons	0 / 0.39	59.16	570.34%	Florence fennels	0 / 1.53	28.52
	1138.32%	Rhubarbs	0 / 1.53	56.92	563.91%	Lamb's lettuce/corn salads	0 / 15	28.20
	989.75%	Chinese cabbages/pe-tsai	0 / 1.54	49.49	398.29%	Lettuces	0 / 1.64	19.91
	953.73%	Watermelons	0 / 0.39	47.69	317.60%	Cardoons	0 / 1.53	15.88
	842.70%	Lamb's lettuce/corn salads	0 / 15	42.13	316.69%	Watermelons	0 / 0.39	15.83
	741.32%	Spinaches	0 / 1.64	37.07	305.64%	Melons	0 / 0.39	15.28
	720.15%	Pears	0 / 0.26	36.01	297.92%	Celeries	0 / 0.93	14.90
	696.68%	Celeries	0 / 0.93	34.83	283.93%	Rhubarbs	0 / 1.53	14.20
	560.47%	Apples	0 / 0.26	28.02	239.74%	Peaches	0 / 0.64	11.99
	539.29%	Plums	0 / 0.64	26.96	228.02%	Plums	0 / 0.64	11.40
	511.29%	Cucumbers	0 / 0.39	25.56	221.79%	Escaroles/broad-leaved endives	0 / 0.55	11.09
	496.94%	Florence fennels	0 / 1.53	24.85	216.81%	Cucumbers	0 / 0.39	10.84
	447.69%	Apricots	0 / 0.64	22.38	207.88%	Chards/beet leaves	0 / 0.55	10.39
	441.85%	Escaroles/broad-leaved endives	0 / 0.55	22.09	181.62%	Courgettes	0 / 0.39	9.08
	362.62%	Courgettes	0 / 0.39	18.13	162.49%	Aubergines/egg plants	0 / 0.3	8.12
	348.88%	Tomatoes	0 / 0.3	17.44	158.82%	Pears	0 / 0.26	7.94
	278.34%	Wine grapes	0 / 1.5	13.92	145.98%	Apples	0 / 0.26	7.30

The review of the existing MRLs for indoxacarb – proposed MRLs

249.90%	Sweet peppers/bell peppers	0 / 0.21	12.50	139.22%	Apricots	0 / 0.64	6.96
243.31%	Cauliflowers	0 / 0.21	12.17	131.20%	Spinaches	0 / 1.64	6.56
208.26%	Pumpkins	0 / 0.39	10.41	128.00%	Cherries (sweet)	0 / 0.64	6.40
178.59%	Bananas	0 / 0.09	8.93	114.66%	Pumpkins	0 / 0.39	5.73
174.72%	Broccoli	0 / 0.21	8.74	100.12%	Broccoli	0 / 0.21	5.01
171.64%	Chards/beet leaves	0 / 0.55	8.58	97.38%	Cauliflowers	0 / 0.21	4.87
156.51%	Cherries (sweet)	0 / 0.64	7.83	95.14%	Tomatoes	0 / 0.3	4.76
150.00%	Aubergines/egg plants	0 / 0.3	7.50	94.83%	Blueberries	0 / 0.52	4.74
114.40%	Kales	0 / 0.13	5.72	85.28%	Blackberries	0 / 0.52	4.26
111.46%	Blackberries	0 / 0.52	5.57	75.69%	Head cabbages	0 / 0.09	3.78
99.28%	Basil and edible flowers	0 / 6.8	4.96	68.64%	Currants (red, black and white)	0 / 0.52	3.43
91.92%	Milk: Cattle	0 / 0.04	4.60	68.50%	Sweet peppers/bell peppers	0 / 0.21	3.43
88.25%	Strawberries	0 / 0.27	4.41	58.39%	Red mustards	0 / 0.55	2.92
88.23%	Roman rocket/rucola	0 / 1.64	4.41	50.37%	Strawberries	0 / 0.27	2.52
82.06%	Currants (red, black and white)	0 / 0.52	4.10	50.05%	Kales	0 / 0.13	2.50
79.63%	Head cabbages	0 / 0.09	3.98	47.24%	Gherkins	0 / 0.39	2.36
78.40%	Radishes	0 / 0.16	3.92	46.88%	Gooseberries (green, red and yellow)	0 / 0.52	2.34
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

The review of the existing MRLs for indoxacarb – proposed MRLs

729.0%	Escaroles/broad-leaved endives / boiled	0 / 0.55	36.45	446.86%	Rhubarbs / sauce/puree	0 / 1.53	22.34
691.8%	Pumpkins / boiled	0 / 0.39	34.59	430.90%	Pumpkins / boiled	0 / 0.39	21.54
456.2%	Spinaches / frozen; boiled	0 / 1.64	22.81	372.04%	Cardoons / boiled	0 / 1.53	18.60
342.3%	Chards/beet leaves / boiled	0 / 0.55	17.12	283.75%	Wine grapes / wine	0 / 1.5	14.19
332.9%	Peaches / canned	0 / 0.64	16.64	271.47%	Spinaches / frozen; boiled	0 / 1.64	13.57
330.9%	Broccoli / boiled	0 / 0.21	16.54	224.81%	Escaroles/broad-leaved endives / boiled	0 / 0.55	11.24
292.4%	Cauliflowers / boiled	0 / 0.21	14.62	178.38%	Courgettes / boiled	0 / 0.39	8.92
279.4%	Wine grapes / juice	0 / 0.32	13.97	174.99%	Cauliflowers / boiled	0 / 0.21	8.75
276.4%	Courgettes / boiled	0 / 0.39	13.82	172.73%	Table grapes / raisins	0 / 7.05	8.64
227.4%	Apples / juice	0 / 0.21	11.37	140.00%	Apples / juice	0 / 0.21	7.00
179.3%	Gherkins / pickled	0 / 0.39	8.97	137.67%	Chards/beet leaves / boiled	0 / 0.55	6.88
136.8%	Pears / juice	0 / 0.21	6.84	133.12%	Wine grapes / juice	0 / 0.32	6.66
71.7%	Kales / boiled	0 / 0.13	3.59	104.60%	Peaches / canned	0 / 0.64	5.23
Expand/collapse list							

Scenario 2

Table B.5 Chronic risk assessment undertaken using UK model version 1.1

Active substance: indoxacarb

ADI: 0.005 mg/kg bw/day

Source: GB Art 21, 2023

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00099	0.00236	0.00326	0.00257	0.00211	0.00146	0.00145	0.00101	0.00116	0.00092
% of ADI	20%	47%	65%	51%	42%	29%	29%	20%	23%	18%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.013		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.013		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.013		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.013		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.013		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Hazelnuts	0.013		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.013		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.013		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.013		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

The review of the existing MRLs for indoxacarb – proposed MRLs

Peanuts	0.013		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.051		0.00007	0.00013	0.00033	0.00019	0.00011	0.00009	0.00007	0.00010	0.00012	0.00006
Apricots	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Peaches	0.01		0.00001	0.00001	0.00003	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Plums	0.01		0.00001	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Cherries	0.01		0.00000	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Table grapes	0.01		0.00001	0.00002	0.00005	0.00002	0.00003	0.00001	0.00001	0.00002	0.00001	0.00000
Wine grapes	0.01		0.00010	0.00001	0.00001	0.00001	0.00000	0.00001	0.00004	0.00010	0.00007	0.00001
Strawberries	0.19		0.00011	0.00036	0.00038	0.00026	0.00017	0.00013	0.00010	0.00018	0.00019	0.00010
Blackberries	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Loganberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.26		0.00011	L/C	0.00062	0.00017	0.00026	0.00007	0.00002	0.00010	0.00022	0.00010
Gooseberries	0.58		0.00014	0.00030	0.00038	0.00014	0.00014	0.00014	0.00011	0.00042	0.00048	0.00014
Blackcurrants	0.58		0.00033	0.00069	0.00104	0.00104	0.00080	0.00059	0.00065	0.00021	0.00031	0.00016
Red currants	0.58		0.00004	L/C	0.00046	L/C	0.00003	0.00007	0.00003	0.00002	0.00020	L/C
White currants	0.58		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01		0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

The review of the existing MRLs for indoxacarb – proposed MRLs

Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.18		0.00007	L/C	0.00027	0.00007	0.00006	0.00006	0.00004	0.00009	0.00009	0.00003
Carrots	0.01		0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.02		0.00001	L/C	0.00002	L/C	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Salsify	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.055		0.00004	0.00006	0.00009	0.00007	0.00006	0.00004	0.00003	0.00004	0.00005	0.00002

The review of the existing MRLs for indoxacarb – proposed MRLs

Cauliflower	0.055		0.00005	0.00017	0.00012	0.00009	0.00005	0.00004	0.00005	0.00007	0.00006	0.00004
Brussels sprouts	0.02		0.00001	0.00005	0.00004	0.00003	0.00001	0.00002	0.00001	0.00002	0.00002	0.00001
Head cabbage	0.02		0.00001	0.00004	0.00003	0.00003	0.00001	0.00001	0.00001	0.00002	0.00002	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.27		0.00014	0.00027	0.00042	0.00023	0.00024	0.00017	0.00009	0.00018	0.00015	0.00010
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.27		0.00002	L/C	L/C	L/C	L/C	L/C	L/C	0.00002	L/C	L/C
Parsley	0.52		0.00009	L/C	0.00006	L/C	0.00008	0.00002	0.00001	0.00009	0.00009	0.00019
Beans with pods	0.16		0.00008	0.00019	0.00031	0.00021	0.00011	0.00006	0.00011	0.00006	0.00012	0.00005
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.035		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.02		0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002

The review of the existing MRLs for indoxacarb – proposed MRLs

Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.027		0.00009	0.00017	0.00020	0.00019	0.00015	0.00011	0.00010	0.00013	0.00009	0.00010
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Tea (dried leaves)	0.41		0.00009	0.00029	0.00011	0.00007	0.00005	0.00005	0.00006	0.00009	0.00009	0.00009
Hops (dried 0.25% of beer)	0.01		0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.06		0.00010	0.00010	0.00018	0.00017	0.00011	0.00009	0.00009	0.00010	0.00010	0.00005
Meat fat	0.38		0.00007	0.00016	0.00027	0.00016	0.00011	0.00010	0.00009	0.00004	0.00008	0.00006
Meat excl. poultry & offal	0.08		0.00015	0.00033	0.00033	0.00028	0.00024	0.00016	0.00017	0.00003	0.00014	0.00014
All types of kidney	0.014		0.00000	0.00001	0.00002	0.00000	0.00000	0.00000	0.00000	L/C	0.00001	0.00000
All types of Liver	0.02		0.00001	0.00004	0.00005	0.00001	0.00001	0.00001	0.00001	L/C	0.00001	0.00001
Other types of offal	0.02		0.00001	0.00003	0.00004	0.00002	0.00002	0.00002	0.00001	0.00000	0.00002	0.00001
Eggs	0.02		0.00002	0.00009	0.00007	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00003
0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012	0.01
Sugar beet	0.026		0.00036	0.00087	0.00145	0.00088	0.00082	0.00052	0.00050	0.00031	0.00028	0.00039

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.6 Chronic risk assessment undertaken using PRIMo revision 3.1

Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
		No of diets exceeding the ADI :		--				Exposure resulting from		
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
43.6%	NL toddler	2.18	11.9%	Milk: Cattle	4.4%	Pears	3.9%	Currants (red, black and white)	7.1%	31.4%
27.5%	NL child	1.38	4.9%	Milk: Cattle	4.4%	Sugar beet roots	2.9%	Currants (red, black and white)	4.2%	14.1%
22.4%	FR child 3 15 yr	1.12	4.6%	Milk: Cattle	2.4%	Bovine: Muscle/meat	2.4%	Swine: Muscle/meat	3.4%	8.8%
20.2%	FR toddler 2 3 yr	1.01	5.9%	Milk: Cattle	2.5%	Beans (with pods)	1.9%	Bovine: Muscle/meat	2.8%	10.8%
20.0%	DE child	1.00	4.0%	Milk: Cattle	2.5%	Apples	1.9%	Strawberries	6.7%	12.1%
17.9%	UK infant	0.89	7.7%	Milk: Cattle	2.0%	Bovine: Muscle/meat	0.8%	Strawberries	2.2%	11.1%
17.6%	GEMS/Food G11	0.88	2.0%	Soyabeans	1.9%	Swine: Muscle/meat	1.7%	Swine: Fat tissue	3.8%	4.7%
17.1%	GEMS/Food G08	0.85	3.1%	Swine: Muscle/meat	1.7%	Swine: Fat tissue	1.1%	Milk: Cattle	3.8%	4.7%
16.7%	UK toddler	0.84	4.1%	Milk: Cattle	2.0%	Bovine: Muscle/meat	1.7%	Sugar beet roots	2.5%	7.7%
16.3%	GEMS/Food G10	0.82	1.8%	Soyabeans	1.7%	Poultry: Muscle/meat	1.5%	Bovine: Muscle/meat	3.5%	4.3%
16.1%	SE general	0.81	7.0%	Bovine: Muscle/meat	2.5%	Milk: Cattle	0.8%	Potatoes	2.8%	6.0%
16.0%	GEMS/Food G15	0.80	2.3%	Swine: Muscle/meat	2.1%	Swine: Fat tissue	1.4%	Milk: Cattle	3.6%	4.4%
15.8%	GEMS/Food G07	0.79	1.8%	Swine: Muscle/meat	1.5%	Poultry: Muscle/meat	1.4%	Bovine: Muscle/meat	3.8%	4.2%
15.2%	DK child	0.76	3.6%	Swine: Muscle/meat	2.5%	Milk: Cattle	2.1%	Bovine: Muscle/meat	3.9%	5.3%
15.2%	ES child	0.76	2.5%	Milk: Cattle	2.3%	Bovine: Muscle/meat	2.0%	Swine: Muscle/meat	2.9%	5.1%
14.3%	IE adult	0.71	2.0%	Other farmed animals: Muscle/meat	1.1%	Tea (dried leaves of Camellia sinensis)	0.9%	Milk: Cattle	4.0%	4.9%
13.2%	DE general	0.66	2.5%	Milk: Cattle	2.2%	Sugar beet roots	1.8%	Swine: Muscle/meat	2.5%	5.1%
13.0%	DE women 14-50 yr	0.65	2.5%	Milk: Cattle	2.4%	Sugar beet roots	1.4%	Swine: Muscle/meat	2.6%	5.3%

The review of the existing MRLs for indoxacarb – proposed MRLs

12.3%	NL general	0.62	1.7%	Milk: Cattle	1.5%	Swine: Muscle/meat	1.5%	Sugar beet roots	2.0%	4.8%
12.1%	RO general	0.61	2.3%	Milk: Cattle	1.8%	Swine: Muscle/meat	1.0%	Wheat	3.0%	5.3%
11.4%	GEMS/Food G06	0.57	1.4%	Wheat	0.8%	Sugar beet roots	0.7%	Tomatoes	5.3%	3.7%
10.7%	FR adult	0.53	1.2%	Tea (dried leaves of Camellia sinensis)	1.1%	Swine: Muscle/meat	1.0%	Bovine: Muscle/meat	1.9%	3.4%
10.5%	FR infant	0.52	3.4%	Milk: Cattle	1.5%	Beans (with pods)	0.7%	Sugar beet roots	1.3%	6.6%
9.3%	ES adult	0.46	1.2%	Bovine: Muscle/meat	1.1%	Swine: Muscle/meat	1.0%	Milk: Cattle	2.0%	3.2%
8.4%	DK adult	0.42	1.5%	Swine: Fat tissue	1.4%	Swine: Muscle/meat	1.1%	Milk: Cattle	1.4%	2.6%
7.3%	LT adult	0.37	1.5%	Swine: Muscle/meat	1.0%	Swine: Fat tissue	0.8%	Milk: Cattle	1.3%	2.6%
7.1%	FI 3 yr	0.36	1.4%	Strawberries	1.0%	Raspberries (red and yellow)	0.9%	Potatoes	2.1%	4.0%
5.6%	UK adult	0.28	1.1%	Bovine: Muscle/meat	0.6%	Milk: Cattle	0.5%	Poultry: Muscle/meat	1.3%	1.8%
5.4%	FI 6 yr	0.27	1.1%	Strawberries	0.8%	Potatoes	0.7%	Raspberries (red and yellow)	1.6%	3.0%
5.4%	IT toddler	0.27	1.3%	Wheat	0.6%	Other lettuce and other salad plants	0.5%	Strawberries	2.9%	2.1%
4.8%	IT adult	0.24	0.9%	Other lettuce and other salad plants	0.8%	Wheat	0.5%	Beans (with pods)	2.1%	1.9%
4.8%	PT general	0.24	1.1%	Potatoes	0.8%	Wheat	0.5%	Wine grapes	2.8%	1.8%
4.7%	UK vegetarian	0.23	0.7%	Milk: Cattle	0.4%	Wheat	0.4%	Tea (dried leaves of Camellia sinensis)	1.6%	2.2%
4.0%	FI adult	0.20	1.1%	Coffee beans	0.5%	Strawberries	0.4%	Currants (red, black and white)	2.2%	1.8%
3.8%	IE child	0.19	1.0%	Swine: Fat tissue	0.7%	Milk: Cattle	0.4%	Currants (red, black and white)	0.6%	1.5%
3.8%	PL general	0.19	0.8%	Beetroots	0.7%	Potatoes	0.5%	Gooseberries (green, red and yellow)	1.0%	2.7%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of indoxacarb (F) is unlikely to present a public health concern.

Table B.7A Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Almonds	0.05		0.00002	0.4	0.00009	1.9	0.00003	0.6	0.00004	0.9	0.00002	0.4
Brazil nuts	0.05		0.00003	0.6	0.00000	0.0	0.00002	0.4	0.00004	0.8	0.00002	0.3
Cashew nuts	0.05		0.00005	0.9	0.00000	0.0	0.00008	1.6	0.00006	1.1	0.00000	0.1
Chestnuts	0.05		0.00005	0.9	0.00000	0.0	0.00002	0.4	0.00019	3.9	0.00001	0.2
Coconuts	0.05		0.00002	0.5	0.00001	0.3	0.00004	0.7	0.00005	1.0	0.00003	0.6
Hazelnuts	0.05		0.00002	0.4	0.00001	0.1	0.00003	0.6	0.00002	0.4	0.00002	0.3
Pecan nuts	0.05		0.00001	0.3	0.00000	0.0	0.00001	0.2	0.00000	0.1	0.00000	0.1
Pistachios	0.05		0.00012	2.5	0.00000	0.0	0.00010	2.0	0.00002	0.4	0.00008	1.6
Walnuts	0.05		0.00003	0.6	0.00000	0.0	0.00007	1.4	0.00002	0.4	0.00002	0.5
Apples	0.01		0.00015	3.0	0.00098	19.6	0.00072	14.4	0.00056	11.1	0.00041	8.2
Pears	0.11		0.00194	38.8	0.00797	159.3	0.00934	186.7	0.00662	132.3	0.00440	87.9
Apricots	0.01		0.00007	1.4	0.00019	3.9	0.00021	4.2	0.00023	4.7	0.00016	3.1
Peaches	0.01		0.00012	2.5	0.00034	6.9	0.00055	11.0	0.00038	7.7	0.00026	5.1
Plums	0.01		0.00007	1.5	0.00022	4.3	0.00030	5.9	0.00022	4.4	0.00014	2.8
Cherries	0.01		0.00002	0.4	0.00003	0.6	0.00004	0.9	0.00005	1.1	0.00004	0.7
Wine grapes	0.01		0.00024	4.7	0.00008	1.6	0.00005	0.9	0.00006	1.3	0.00002	0.4
Table grapes	0.01		0.00020	3.9	0.00029	5.7	0.00061	12.2	0.00050	10.1	0.00046	9.3
Blackberries	0.01		0.00001	0.2	0.00002	0.3	0.00011	2.1	0.00000	0.1	0.00002	0.5
Gooseberries	1.04		0.00102	20.3	0.00337	67.4	0.00219	43.9	0.00177	35.3	0.00115	23.0
Blackcurrants	1.04		0.00164	32.8	0.00251	50.2	0.00374	74.9	0.00526	105.1	0.00351	70.1
Red currants	1.04		0.00043	8.5	0.00000	0.0	0.00210	42.0	0.00028	5.6	0.00020	3.9
White currants	1.04		0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Bananas	0.01		0.00012	2.4	0.00084	16.7	0.00056	11.2	0.00043	8.5	0.00030	5.9
Beetroot	0.22		0.00178	35.6	0.00000	0.0	0.00463	92.6	0.00300	60.1	0.00327	65.5
Tomatoes	0.01		0.00010	2.1	0.00048	9.7	0.00041	8.3	0.00031	6.2	0.00022	4.4
Peppers	0.01		0.00013	2.6	0.00000	0.0	0.00016	3.3	0.00012	2.3	0.00016	3.3

The review of the existing MRLs for indoxacarb – proposed MRLs

Aubergines	0.01		0.00010	2.0	0.00000	0.0	0.00021	4.3	0.00025	5.0	0.00009	1.9
Marrows	0.01		0.00013	2.6	0.00000	0.0	0.00021	4.3	0.00011	2.2	0.00014	2.8
Cucumbers	0.01		0.00007	1.4	0.00007	1.5	0.00030	5.9	0.00024	4.7	0.00018	3.5
Gourd	0.01		0.00015	2.9	0.00000	0.0	0.00000	0.0	0.00013	2.5	0.00000	0.0
Courgettes	0.01		0.00011	2.2	0.00032	6.3	0.00046	9.3	0.00040	8.0	0.00026	5.2
Melons	0.01		0.00037	7.4	0.00073	14.6	0.00072	14.4	0.00083	16.6	0.00073	14.6
Broccoli	0.14		0.00180	36.0	0.00288	57.6	0.00293	58.6	0.00346	69.1	0.00314	62.8
Cauliflower	0.14		0.00216	43.2	0.00811	162.2	0.00464	92.8	0.00487	97.4	0.00274	54.8
Chinese cabbage	0.01		0.00015	3.1	0.00000	0.0	0.00011	2.1	0.00000	0.0	0.00022	4.4
Cress	0.55		0.00009	1.9	0.00000	0.0	0.00016	3.2	0.00016	3.2	0.00009	1.8
Lettuce	0.01		0.00010	2.0	0.00013	2.5	0.00012	2.4	0.00018	3.6	0.00013	2.7
Spinach	0.01		0.00003	0.5	0.00005	1.1	0.00004	0.8	0.00006	1.1	0.00003	0.6
Chicory	0.01		0.00004	0.7	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00010	1.9
Parsley	0.01		0.00001	0.1	0.00000	0.0	0.00000	0.1	0.00000	0.1	0.00001	0.2
Beans with pods	0.59		0.00136	27.2	0.00296	59.1	0.00295	59.0	0.00221	44.1	0.00119	23.9
Celery	0.01		0.00006	1.2	0.00007	1.3	0.00006	1.2	0.00005	1.1	0.00004	0.8
Fennel	0.01		0.00014	2.9	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Rhubarb	0.01		0.00008	1.6	0.00034	6.8	0.00037	7.4	0.00012	2.4	0.00017	3.4
Maize	0.01		0.00000	0.1	0.00007	1.3	0.00004	0.8	0.00002	0.3	0.00001	0.2
Milk	0.01		0.00013	2.6	0.00124	24.8	0.00073	14.7	0.00047	9.3	0.00030	6.0

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Almonds	0.05		0.00002	0.5	0.00002	0.5	0.00003	0.5	0.00001	0.3	0.00001	0.2
Brazil nuts	0.05		0.00001	0.2	0.00001	0.1	0.00003	0.6	0.00001	0.1	0.00000	0.0
Cashew nuts	0.05		0.00002	0.3	0.00001	0.3	0.00003	0.7	0.00001	0.3	0.00000	0.0
Chestnuts	0.05		0.00000	0.0	0.00002	0.3	0.00008	1.7	0.00001	0.3	0.00000	0.1
Coconuts	0.05		0.00004	0.8	0.00003	0.6	0.00008	1.6	0.00001	0.2	0.00002	0.3
Hazelnuts	0.05		0.00001	0.3	0.00001	0.3	0.00002	0.4	0.00001	0.1	0.00001	0.1

The review of the existing MRLs for indoxacarb – proposed MRLs

Pecan nuts	0.05		0.00003	0.5	0.00000	0.0	0.00010	2.1	0.00002	0.3	0.00000	0.0
Pistachios	0.05		0.00002	0.3	0.00003	0.7	0.00004	0.7	0.00000	0.0	0.00000	0.0
Walnuts	0.05		0.00001	0.2	0.00003	0.6	0.00003	0.6	0.00003	0.6	0.00001	0.3
Apples	0.01		0.00026	5.2	0.00021	4.2	0.00018	3.5	0.00013	2.7	0.00013	2.6
Pears	0.11		0.00289	57.8	0.00221	44.2	0.00218	43.6	0.00203	40.6	0.00200	40.0
Apricots	0.01		0.00005	1.1	0.00008	1.5	0.00008	1.5	0.00007	1.4	0.00008	1.6
Peaches	0.01		0.00019	3.7	0.00013	2.7	0.00013	2.5	0.00012	2.3	0.00011	2.3
Plums	0.01		0.00009	1.7	0.00007	1.3	0.00008	1.6	0.00006	1.3	0.00005	1.1
Cherries	0.01		0.00005	1.0	0.00003	0.6	0.00002	0.5	0.00001	0.3	0.00000	0.0
Wine grapes	0.01		0.00007	1.4	0.00019	3.8	0.00021	4.3	0.00013	2.6	0.00003	0.7
Table grapes	0.01		0.00036	7.2	0.00018	3.6	0.00031	6.1	0.00011	2.3	0.00008	1.6
Blackberries	0.01		0.00002	0.3	0.00001	0.1	0.00002	0.4	0.00001	0.2	0.00000	0.0
Gooseberries	1.04		0.00171	34.2	0.00134	26.9	0.00229	45.9	0.00189	37.9	0.00098	19.7
Blackcurrants	1.04		0.00222	44.3	0.00309	61.8	0.00083	16.6	0.00134	26.9	0.00065	13.1
Red currants	1.04		0.00080	15.9	0.00032	6.4	0.00024	4.8	0.00094	18.9	0.00042	8.4
White currants	1.04		0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Bananas	0.01		0.00017	3.5	0.00015	2.9	0.00014	2.8	0.00011	2.3	0.00013	2.5
Beetroot	0.22		0.00239	47.9	0.00140	28.1	0.00200	39.9	0.00193	38.5	0.00102	20.5
Tomatoes	0.01		0.00014	2.8	0.00012	2.4	0.00014	2.7	0.00010	2.0	0.00012	2.4
Peppers	0.01		0.00011	2.1	0.00010	2.0	0.00016	3.3	0.00010	1.9	0.00005	1.0
Aubergines	0.01		0.00012	2.5	0.00008	1.6	0.00018	3.5	0.00007	1.3	0.00000	0.0
Marrows	0.01		0.00017	3.5	0.00008	1.5	0.00018	3.7	0.00016	3.2	0.00006	1.2
Cucumbers	0.01		0.00010	1.9	0.00009	1.8	0.00009	1.7	0.00006	1.3	0.00003	0.6
Gourd	0.01		0.00008	1.6	0.00004	0.9	0.00006	1.2	0.00007	1.4	0.00000	0.0
Courgettes	0.01		0.00011	2.3	0.00010	1.9	0.00013	2.7	0.00011	2.3	0.00013	2.5
Melons	0.01		0.00049	9.7	0.00039	7.8	0.00030	6.0	0.00026	5.3	0.00020	4.0
Broccoli	0.14		0.00218	43.6	0.00196	39.1	0.00234	46.8	0.00178	35.7	0.00097	19.3
Cauliflower	0.14		0.00233	46.6	0.00214	42.8	0.00325	64.9	0.00212	42.5	0.00142	28.3
Chinese cabbage	0.01		0.00002	0.4	0.00025	5.1	0.00009	1.8	0.00004	0.8	0.00000	0.0
Cress	0.55		0.00008	1.5	0.00007	1.4	0.00021	4.2	0.00013	2.7	0.00009	1.8
Lettuce	0.01		0.00008	1.7	0.00008	1.6	0.00011	2.2	0.00007	1.4	0.00004	0.8
Spinach	0.01		0.00003	0.6	0.00002	0.3	0.00004	0.7	0.00002	0.4	0.00001	0.3

The review of the existing MRLs for indoxacarb – proposed MRLs

Chicory	0.01		0.00000	0.0	0.00014	2.8	0.00002	0.4	0.00000	0.0	0.00000	0.0
Parsley	0.01		0.00000	0.1	0.00000	0.0	0.00001	0.2	0.00000	0.1	0.00000	0.1
Beans with pods	0.59		0.00116	23.1	0.00162	32.4	0.00164	32.8	0.00128	25.6	0.00064	12.8
Celery	0.01		0.00006	1.1	0.00004	0.8	0.00008	1.7	0.00006	1.3	0.00002	0.4
Fennel	0.01		0.00000	0.0	0.00000	0.0	0.00019	3.7	0.00010	2.1	0.00000	0.0
Rhubarb	0.01		0.00006	1.2	0.00008	1.6	0.00009	1.9	0.00008	1.6	0.00009	1.8
Maize	0.01		0.00001	0.1	0.00001	0.2	0.00002	0.4	0.00000	0.1	0.00000	0.0
Milk	0.01		0.00021	4.1	0.00018	3.5	0.00015	3.0	0.00011	2.2	0.00014	2.9

Pesticide indoxacarb
ARfD 0.005 mg/Kg bw/day

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value $\geq$ 0.000005 is rounded to 0.00001)

Table B.7B Acute risk assessment undertaken using UK model UK model 1.2 – surrogate commodities

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Oilseeds	0.01		0.00006	1.2	0.00012	2.3	0.00013	2.7	0.00014	2.9	0.00011	2.2
Blackberries	0.01		0.00001	0.2	0.00002	0.3	0.00011	2.1	0.00000	0.1	0.00002	0.5
Raspberries	0.01		0.00002	0.4	0.00004	0.8	0.00004	0.8	0.00003	0.5	0.00005	1.0
Blackcurrants	0.01		0.00002	0.3	0.00002	0.5	0.00004	0.7	0.00005	1.0	0.00003	0.7
Head cabbage	0.01		0.00012	2.4	0.00043	8.6	0.00025	5.1	0.00032	6.4	0.00018	3.5
Lettuce	0.01		0.00010	2.0	0.00013	2.5	0.00012	2.4	0.00018	3.6	0.00013	2.7
Parsley	0.01		0.00001	0.1	0.00000	0.0	0.00000	0.1	0.00000	0.1	0.00001	0.2

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Oilseeds	0.01		0.00008	1.6	0.00007	1.4	0.00010	1.9	0.00005	0.9	0.00005	1.1
Blackberries	0.01		0.00002	0.3	0.00001	0.1	0.00002	0.4	0.00001	0.2	0.00000	0.0
Raspberries	0.01		0.00002	0.4	0.00000	0.1	0.00002	0.3	0.00002	0.4	0.00001	0.3
Blackcurrants	0.01		0.00002	0.4	0.00003	0.6	0.00001	0.2	0.00001	0.3	0.00001	0.1
Head cabbage	0.01		0.00017	3.3	0.00012	2.4	0.00017	3.4	0.00013	2.6	0.00010	2.0
Lettuce	0.01		0.00008	1.7	0.00008	1.6	0.00011	2.2	0.00007	1.4	0.00004	0.8
Parsley	0.01		0.00000	0.1	0.00000	0.0	0.00001	0.2	0.00000	0.1	0.00000	0.1

Table B.8 Acute assessment undertaken PRIMo revision 3.1

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): 7				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI): 2			
IESTI				IESTI			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
304.68%	Pears	0 / 0.11	15.23	137.28%	Currants (red, black and white)	0 / 1.04	6.86
251.08%	Beetroots	0 / 0.22	12.55	101.30%	Beetroots	0 / 0.22	5.07
164.11%	Currants (red, black and white)	0 / 1.04	8.21	93.77%	Gooseberries (green, red and yellow)	0 / 1.04	4.69
162.21%	Cauliflowers	0 / 0.14	8.11	91.03%	Beans (with pods)	0 / 0.59	4.55
134.89%	Beans (with pods)	0 / 0.59	6.74	75.69%	Head cabbages	0 / 0.09	3.78
122.30%	Gooseberries (green, red and yellow)	0 / 1.04	6.12	67.19%	Pears	0 / 0.11	3.36
116.48%	Broccoli	0 / 0.14	5.82	66.74%	Broccoli	0 / 0.14	3.34
88.25%	Strawberries	0 / 0.27	4.41	64.92%	Cauliflowers	0 / 0.14	3.25
79.63%	Head cabbages	0 / 0.09	3.98	50.37%	Strawberries	0 / 0.27	2.52
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 7							
Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): 5				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI): 3			
IESTI				IESTI			

The review of the existing MRLs for indoxacarb – proposed MRLs

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
331.5%	Currants (red, black and white) / juice	0 / 0.58	16.57	171.1%	Beetroots / boiled	0 / 0.22	8.56
220.6%	Broccoli / boiled	0 / 0.14	11.03	147.91%	Currants (red, black and white) / juice	0 / 0.58	7.40
195.1%	Beetroots / boiled	0 / 0.22	9.75	116.66%	Cauliflowers / boiled	0 / 0.14	5.83
194.9%	Cauliflowers / boiled	0 / 0.14	9.75	67.40%	Broccoli / boiled	0 / 0.14	3.37
148.0%	Beans (with pods) / boiled	0 / 0.59	7.40	11.05%	Pumpkins / boiled	0.01 / 0.01	0.55
33.2%	Pears / juice	0 / 0.05	1.66	6.75%	Celeries / boiled	0.01 / 0.01	0.34
17.7%	Pumpkins / boiled	0.01 / 0.01	0.89	6.67%	Apples / juice	0.01 / 0.01	0.33
13.3%	Escaroles/broad-leaved endives / boiled	0.01 / 0.01	0.66	4.57%	Courgettes / boiled	0.01 / 0.01	0.23
10.8%	Apples / juice	0.01 / 0.01	0.54	4.16%	Wine grapes / juice	0.01 / 0.01	0.21
9.1%	Florence fennels / boiled	0.01 / 0.01	0.45	4.09%	Escaroles/broad-leaved endives / boiled	0.01 / 0.01	0.20
8.7%	Wine grapes / juice	0.01 / 0.01	0.44	3.88%	Florence fennels / boiled	0.01 / 0.01	0.19
8.1%	Brussels sprouts / boiled	0 / 0.04	0.41	3.76%	Head cabbages / canned	0 / 0.02	0.19

Scenario 3

Table B.9 Chronic risk assessment undertaken using UK model version 1.1

Active substance: indoxacarb ADI: 0.005 ^{mg/kg} _{bw/day} Source: GB Art 21, 2023

TOTAL INTAKE based on 97.5th percentile										
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00075	0.00230	0.00281	0.00172	0.00158	0.00104	0.00096	0.00074	0.00075	0.00090
% of ADI	15%	46%	56%	34%	32%	21%	19%	15%	15%	18%

STMR		P	COMMODITY INTAKES									
Commodity	(mg/kg)		(mg/kg bw/day)									
Grapefruit	0.01		0.00002	0.00002	0.00006	0.00005	0.00012	0.00002	0.00001	0.00002	0.00002	0.00002
Lemons	0.01		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Limes	0.01		0.00000	L/C	0.00002	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001
Mandarins	0.01		0.00001	L/C	0.00006	0.00004	0.00003	0.00002	0.00002	0.00001	0.00002	0.00001
Oranges	0.01		0.00004	0.00011	0.00016	0.00011	0.00008	0.00008	0.00007	0.00005	0.00004	0.00003
Almonds	0.013		0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.013		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.013		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.013		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.013		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Hazelnuts	0.013		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.013		0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.013		0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.013		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

The review of the existing MRLs for indoxacarb – proposed MRLs

Peanuts	0.013		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Apples	0.01		0.00003	0.00008	0.00015	0.00009	0.00008	0.00004	0.00004	0.00003	0.00002	0.00001
Pears	0.01		0.00001	0.00003	0.00007	0.00004	0.00002	0.00002	0.00001	0.00002	0.00002	0.00001
Apricots	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Peaches	0.01		0.00001	0.00001	0.00003	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00000
Plums	0.01		0.00001	0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Cherries	0.01		0.00000	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000
Table grapes	0.01		0.00001	0.00002	0.00005	0.00002	0.00003	0.00001	0.00001	0.00002	0.00001	0.00000
Wine grapes	0.01		0.00010	0.00001	0.00001	0.00001	0.00000	0.00001	0.00004	0.00010	0.00007	0.00001
Strawberries	0.19		0.00011	0.00036	0.00038	0.00026	0.00017	0.00013	0.00010	0.00018	0.00019	0.00010
Blackberries	0.11		0.00001	L/C	0.00021	0.00001	0.00004	0.00003	0.00001	0.00003	0.00003	0.00000
Loganberries	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Raspberries	0.26		0.00011	L/C	0.00062	0.00017	0.00026	0.00007	0.00002	0.00010	0.00022	0.00010
Gooseberries	0.11		0.00003	0.00006	0.00007	0.00003	0.00003	0.00003	0.00002	0.00008	0.00009	0.00003
Blackcurrants	0.15		0.00009	0.00018	0.00027	0.00027	0.00021	0.00015	0.00017	0.00005	0.00008	0.00004
Red currants	0.11		0.00001	L/C	0.00009	L/C	0.00001	0.00001	0.00000	0.00000	0.00004	L/C
White currants	0.11		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Avocados	0.01		0.00001	L/C	0.00001	L/C	L/C	L/C	0.00000	0.00001	0.00001	L/C
Bananas	0.01		0.00002	0.00007	0.00007	0.00004	0.00003	0.00002	0.00001	0.00002	0.00002	0.00002
Dates	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00001	0.00000
Figs	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Kiwi fruit	0.01		0.00001	L/C	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001	0.00000
Lychees	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Mangoes	0.01		0.00001	L/C	0.00002	0.00001	0.00002	0.00001	0.00004	0.00001	0.00000	L/C
Olives	0.01		0.00000	L/C	0.00001	0.00001	L/C	0.00000	L/C	0.00000	0.00000	L/C
Passion fruit	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C	L/C

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Pineapples	0.01		0.00001	0.00005	0.00005	0.00007	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
Pomegranates	0.01		0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000	0.00001	0.00001	0.00001
Beetroot	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Carrots	0.01		0.00001	0.00004	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Celeriac	0.01		0.00000	L/C	L/C	0.00000	0.00000	L/C	L/C	L/C	L/C	L/C
Horseradish	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	0.00000	L/C
Jerusalem artichokes	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Parsnips	0.01		0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Radishes	0.02		0.00001	L/C	0.00002	L/C	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Salsify	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Swedes	0.01		0.00000	0.00003	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Turnips	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00000
Yam	0.01		0.00003	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Garlic	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Onions	0.01		0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
Spring onions	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Tomatoes	0.01		0.00001	0.00002	0.00003	0.00002	0.00002	0.00001	0.00001	0.00002	0.00001	0.00001
Peppers	0.01		0.00000	L/C	0.00001	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Aubergines	0.01		0.00000	L/C	0.00002	0.00001	0.00000	0.00001	0.00000	0.00001	0.00000	L/C
Marrows	0.01		0.00001	L/C	0.00002	0.00000	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001
Cucumbers	0.01		0.00000	0.00000	0.00002	0.00002	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000
Gourd	0.01		0.00001	L/C	L/C	L/C	L/C	0.00000	L/C	0.00000	L/C	L/C
Courgettes	0.01		0.00000	0.00001	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Melons	0.01		0.00002	0.00003	0.00005	0.00004	0.00003	0.00002	0.00003	0.00003	0.00003	0.00001
Sweet corn	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00000	0.00001	0.00001	0.00001	0.00000
Broccoli	0.01		0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000

The review of the existing MRLs for indoxacarb – proposed MRLs

Cauliflower	0.01		0.00001	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Brussels sprouts	0.02		0.00001	0.00005	0.00004	0.00003	0.00001	0.00002	0.00001	0.00002	0.00002	0.00001
Head cabbage	0.02		0.00001	0.00004	0.00003	0.00003	0.00001	0.00001	0.00001	0.00002	0.00002	0.00001
Chinese cabbage	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	0.00000	L/C
Kohl Rabi	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Cress	0.01		0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Lettuce	0.01		0.00001	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00000
Spinach	0.27		0.00014	0.00027	0.00042	0.00023	0.00024	0.00017	0.00009	0.00018	0.00015	0.00010
Watercress	0.01		0.00000	L/C	L/C	0.00000	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Chicory	0.27		0.00002	L/C	L/C	L/C	L/C	L/C	L/C	0.00002	L/C	L/C
Parsley	0.52		0.00009	L/C	0.00006	L/C	0.00008	0.00002	0.00001	0.00009	0.00009	0.00019
Beans with pods	0.11		0.00006	0.00013	0.00021	0.00014	0.00007	0.00004	0.00008	0.00004	0.00008	0.00003
Runner Beans	0.01		0.00001	L/C	0.00001	0.00000	0.00001	0.00001	0.00000	0.00002	0.00001	0.00001
Beans without pods	0.01		0.00000	0.00001	0.00002	0.00000	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001
Peas with pods	0.01		0.00000	L/C	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
Peas without pods	0.01		0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001	0.00001
Beansprouts	0.01		0.00000	L/C	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Asparagus	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00001	0.00000	L/C
Bamboo shoots	0.01		0.00000	L/C	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Celery	0.01		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Fennel	0.01		0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Globe artichokes	0.035		0.00001	L/C	L/C	L/C	L/C	L/C	L/C	0.00001	L/C	L/C
Leeks	0.01		0.00000	L/C	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Rhubarb	0.01		0.00000	0.00001	0.00001	0.00000	0.00001	0.00000	0.00000	0.00000	0.00001	0.00000
Cultivated mushrooms	0.01		0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Beans	0.02		0.00003	0.00012	0.00009	0.00007	0.00006	0.00004	0.00004	0.00004	0.00003	0.00002

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Lentils	0.01		0.00001	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001	0.00000
dried Peas	0.02		0.00001	L/C	0.00003	0.00001	0.00001	0.00002	0.00001	0.00001	0.00002	0.00001
Oilseeds	0.027		0.00009	0.00017	0.00020	0.00019	0.00015	0.00011	0.00010	0.00013	0.00009	0.00010
Potatoes	0.01		0.00003	0.00011	0.00009	0.00008	0.00007	0.00005	0.00005	0.00004	0.00003	0.00003
Tea (dried leaves)	0.41		0.00009	0.00029	0.00011	0.00007	0.00005	0.00005	0.00006	0.00009	0.00009	0.00009
Hops (dried 0.25% of beer)	0.01		0.00000	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	0.00000	0.00000
Oats	0.01		0.00000	0.00002	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001	0.00001	0.00001
Barley	0.01		0.00000	L/C	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000
Millet	0.01		L/C	L/C	0.00000	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Buckwheat	0.01		L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C
Maize	0.01		0.00000	0.00005	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Wheat	0.01		0.00004	0.00003	0.00008	0.00009	0.00007	0.00005	0.00004	0.00004	0.00003	0.00003
Rice	0.01		0.00002	0.00003	0.00005	0.00004	0.00005	0.00004	0.00003	0.00002	0.00001	0.00000
Rye	0.01		0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000	0.00000
Poultry	0.06		0.00010	0.00010	0.00018	0.00017	0.00011	0.00009	0.00009	0.00010	0.00010	0.00005
Meat fat	0.38		0.00007	0.00016	0.00027	0.00016	0.00011	0.00010	0.00009	0.00004	0.00008	0.00006
Meat excl. poultry & offal	0.08		0.00015	0.00033	0.00033	0.00028	0.00024	0.00016	0.00017	0.00003	0.00014	0.00014
All types of kidney	0.014		0.00000	0.00001	0.00002	0.00000	0.00000	0.00000	0.00000	L/C	0.00001	0.00000
All types of Liver	0.02		0.00001	0.00004	0.00005	0.00001	0.00001	0.00001	0.00001	L/C	0.00001	0.00001
Other types of offal	0.02		0.00001	0.00003	0.00004	0.00002	0.00002	0.00002	0.00001	0.00000	0.00002	0.00001
Eggs	0.02		0.00002	0.00009	0.00007	0.00005	0.00003	0.00003	0.00002	0.00002	0.00002	0.00003
Milk	0.01		0.00008	0.00098	0.00056	0.00029	0.00018	0.00012	0.00009	0.00010	0.00009	0.00012
Sugar beet	0.026		0.00036	0.00087	0.00145	0.00088	0.00082	0.00052	0.00050	0.00031	0.00028	0.00039

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.10 Chronic risk assessment undertaken using PRIMo revision 3.1

Chronic risk assessment: JMPR methodology (IEDI/TMDI)										
		No of diets exceeding the ADI :		--				Exposure resulting from		
Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
34.9%	NL toddler	1.75	11.9%	Milk: Cattle	2.7%	Sugar beet roots	2.2%	Apples	8.2%	1.1%
23.5%	NL child	1.18	4.9%	Milk: Cattle	4.4%	Sugar beet roots	1.8%	Swine: Muscle/meat	4.5%	0.3%
21.3%	FR child 3 15 yr	1.07	4.6%	Milk: Cattle	2.4%	Bovine: Muscle/meat	2.4%	Swine: Muscle/meat	3.6%	0.1%
19.0%	FR toddler 2 3 yr	0.95	5.9%	Milk: Cattle	1.9%	Bovine: Muscle/meat	1.8%	Swine: Muscle/meat	3.0%	0.1%
18.3%	DE child	0.91	4.0%	Milk: Cattle	2.5%	Apples	1.9%	Strawberries	6.8%	0.2%
16.8%	UK infant	0.84	7.7%	Milk: Cattle	2.0%	Bovine: Muscle/meat	0.8%	Strawberries	2.3%	0.1%
16.2%	GEMS/Food G11	0.81	2.0%	Soyabeans	1.9%	Swine: Muscle/meat	1.7%	Swine: Fat tissue	3.9%	0.1%
15.7%	GEMS/Food G08	0.78	3.1%	Swine: Muscle/meat	1.7%	Swine: Fat tissue	1.1%	Milk: Cattle	3.9%	0.1%
15.3%	GEMS/Food G10	0.76	1.8%	Soyabeans	1.7%	Poultry: Muscle/meat	1.5%	Bovine: Muscle/meat	3.6%	0.1%
15.2%	UK toddler	0.76	4.1%	Milk: Cattle	2.0%	Bovine: Muscle/meat	1.7%	Sugar beet roots	2.6%	0.1%
15.1%	GEMS/Food G15	0.76	2.3%	Swine: Muscle/meat	2.1%	Swine: Fat tissue	1.4%	Milk: Cattle	3.7%	0.1%
15.1%	SE general	0.75	7.0%	Bovine: Muscle/meat	2.5%	Milk: Cattle	0.8%	Potatoes	2.9%	0.1%
14.8%	GEMS/Food G07	0.74	1.8%	Swine: Muscle/meat	1.5%	Poultry: Muscle/meat	1.4%	Bovine: Muscle/meat	3.9%	0.1%
14.6%	ES child	0.73	2.5%	Milk: Cattle	2.3%	Bovine: Muscle/meat	2.0%	Swine: Muscle/meat	3.0%	0.1%
14.5%	DK child	0.73	3.6%	Swine: Muscle/meat	2.5%	Milk: Cattle	2.1%	Bovine: Muscle/meat	4.1%	0.2%
13.2%	IE adult	0.66	2.0%	Other farmed animals: Muscle/meat	1.1%	Tea (dried leaves of Camellia sinensis)	0.9%	Milk: Cattle	4.2%	0.2%
12.5%	DE general	0.62	2.5%	Milk: Cattle	2.2%	Sugar beet roots	1.8%	Swine: Muscle/meat	2.5%	0.1%
12.3%	DE women 14-50 yr	0.61	2.5%	Milk: Cattle	2.4%	Sugar beet roots	1.4%	Swine: Muscle/meat	2.7%	0.1%
11.9%	RO general	0.59	2.3%	Milk: Cattle	1.8%	Swine: Muscle/meat	1.0%	Wheat	3.1%	0.0%

The review of the existing MRLs for indoxacarb – proposed MRLs

11.3%	NL general	0.56	1.7%	Milk: Cattle	1.5%	Swine: Muscle/meat	1.5%	Sugar beet roots	2.1%	0.1%
11.0%	GEMS/Food G06	0.55	1.4%	Wheat	0.8%	Sugar beet roots	0.7%	Tomatoes	5.3%	0.0%
10.2%	FR adult	0.51	1.2%	Tea (dried leaves of Camellia sinensis)	1.1%	Swine: Muscle/meat	1.0%	Bovine: Muscle/meat	2.0%	0.1%
9.6%	FR infant	0.48	3.4%	Milk: Cattle	1.1%	Beans (with pods)	0.7%	Sugar beet roots	1.4%	0.1%
8.8%	ES adult	0.44	1.2%	Bovine: Muscle/meat	1.1%	Swine: Muscle/meat	1.0%	Milk: Cattle	2.1%	0.1%
8.1%	DK adult	0.40	1.5%	Swine: Fat tissue	1.4%	Swine: Muscle/meat	1.1%	Milk: Cattle	1.4%	0.1%
6.6%	LT adult	0.33	1.5%	Swine: Muscle/meat	1.0%	Swine: Fat tissue	0.8%	Milk: Cattle	1.3%	0.1%
5.8%	FI 3 yr	0.29	1.4%	Strawberries	1.0%	Raspberries (red and yellow)	0.9%	Potatoes	2.2%	0.1%
5.3%	UK adult	0.26	1.1%	Bovine: Muscle/meat	0.6%	Milk: Cattle	0.5%	Poultry: Muscle/meat	1.3%	0.0%
5.0%	IT toddler	0.25	1.3%	Wheat	0.6%	Other lettuce and other salad plants	0.5%	Strawberries	3.0%	0.1%
4.5%	PT general	0.23	1.1%	Potatoes	0.8%	Wheat	0.5%	Wine grapes	2.9%	0.1%
4.5%	FI 6 yr	0.22	1.1%	Strawberries	0.8%	Potatoes	0.7%	Raspberries (red and yellow)	1.7%	0.1%
4.4%	IT adult	0.22	0.9%	Other lettuce and other salad plants	0.8%	Wheat	0.3%	Other spinach and similar	2.2%	0.1%
4.3%	UK vegetarian	0.21	0.7%	Milk: Cattle	0.4%	Wheat	0.4%	Tea (dried leaves of Camellia sinensis)	1.6%	0.1%
3.4%	IE child	0.17	1.0%	Swine: Fat tissue	0.7%	Milk: Cattle	0.3%	Swine: Muscle/meat	0.6%	0.0%
3.4%	FI adult	0.17	1.1%	Coffee beans	0.5%	Strawberries	0.2%	Potatoes	2.2%	0.0%
2.4%	PL general	0.12	0.7%	Potatoes	0.4%	Apples	0.2%	Tomatoes	1.1%	0.1%

Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of indoxacarb (F) is unlikely to present a public health concern.

Table B.11 Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Pears	0.01		0.00018	3.5	0.00072	14.5	0.00085	17.0	0.00060	12.0	0.00040	8.0
Beetroot	0.01		0.00008	1.6	0.00000	0.0	0.00021	4.2	0.00014	2.7	0.00015	3.0
Broccoli	0.01		0.00013	2.6	0.00021	4.1	0.00021	4.2	0.00025	4.9	0.00022	4.5
Cauliflower	0.01		0.00015	3.1	0.00058	11.6	0.00033	6.6	0.00035	7.0	0.00020	3.9
Milk	0.01		0.00013	2.6	0.00124	24.8	0.00073	14.7	0.00047	9.3	0.00030	6.0

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Pears	0.01		0.00026	5.3	0.00020	4.0	0.00020	4.0	0.00018	3.7	0.00018	3.6
Beetroot	0.01		0.00011	2.2	0.00006	1.3	0.00009	1.8	0.00009	1.8	0.00005	0.9
Broccoli	0.01		0.00016	3.1	0.00014	2.8	0.00017	3.3	0.00013	2.5	0.00007	1.4
Cauliflower	0.01		0.00017	3.3	0.00015	3.1	0.00023	4.6	0.00015	3.0	0.00010	2.0
Milk	0.01		0.00021	4.1	0.00018	3.5	0.00015	3.0	0.00011	2.2	0.00014	2.9

Table B.12 Acute assessment undertaken PRIMo revision 3.1

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	27.70%	Pears	0.01 / 0.01	1.38	7.71%	Milk: Cattle	0 / 0.01	0.39
	24.84%	Milk: Cattle	0 / 0.01	1.24	6.11%	Pears	0.01 / 0.01	0.31
	11.59%	Cauliflowers	0.01 / 0.01	0.58	4.77%	Broccoli	0.01 / 0.01	0.24
	11.41%	Beetroots	0.01 / 0.01	0.57	4.64%	Cauliflowers	0.01 / 0.01	0.23
8.32%	Broccoli	0.01 / 0.01	0.42	4.60%	Beetroots	0.01 / 0.01	0.23	
4.83%	Milk: Goat	0 / 0.01	0.24	3.68%	Milk: Goat	0 / 0.01	0.18	
0.71%	Milk: Sheep	0 / 0.01	0.04	3.02%	Milk: Sheep	0 / 0.01	0.15	
Expand/collapse list								
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	15.8%	Broccoli / boiled	0.01 / 0.01	0.79	8.3%	Cauliflowers / boiled	0.01 / 0.01	0.42
	13.9%	Cauliflowers / boiled	0.01 / 0.01	0.70	7.78%	Beetroots / boiled	0.01 / 0.01	0.39
	8.9%	Beetroots / boiled	0.01 / 0.01	0.44	4.81%	Broccoli / boiled	0.01 / 0.01	0.24

	6.5%	Pears / juice	0.01 / 0.01	0.33	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

DRAFT

TTC assessment – Metabolites formed on processing (IN-KT413)

Table B.13 Chronic risk assessment undertaken using UK model version 1.1

	TOTAL INTAKE based on 97.5th percentile									
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00019	0.00064	0.00071	0.00046	0.00040	0.00026	0.00026	0.00019	0.00019	0.00022
% of ADI	13%	43%	47%	31%	27%	17%	17%	13%	13%	15%

Commodity	STMR	P	COMMODITY INTAKES									
	(mg/kg)		(mg/kg bw/day)									
Almonds	0.013	0.30	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Brazil nuts	0.013	0.30	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C
Cashew nuts	0.013	0.30	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Chestnuts	0.013	0.30	0.00000	L/C	L/C	L/C	L/C	L/C	0.00000	0.00000	0.00000	L/C
Coconuts	0.013	0.30	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Hazelnuts	0.013	0.30	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Pecan nuts	0.013	0.30	0.00000	L/C	0.00000	L/C	0.00000	0.00000	L/C	0.00000	0.00000	L/C
Pistachios	0.013	0.30	0.00000	L/C	0.00000	L/C	0.00000	L/C	L/C	0.00000	L/C	L/C
Walnuts	0.013	0.30	0.00000	L/C	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Peanuts	0.01	0.30	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Strawberries	0.19	0.30	0.00003	0.00011	0.00011	0.00008	0.00005	0.00004	0.00003	0.00006	0.00006	0.00003
Gooseberries	0.11	0.30	0.00001	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00002	0.00003	0.00001
Blackcurrants	0.15	0.30	0.00003	0.00005	0.00008	0.00008	0.00006	0.00005	0.00005	0.00002	0.00002	0.00001
Red currants	0.11	0.30	0.00000	L/C	0.00003	L/C	0.00000	0.00000	0.00000	0.00000	0.00001	L/C
White currants	0.11	0.30	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C	L/C

The review of the existing MRLs for indoxacarb – proposed MRLs

Sweet corn	0.01	0.30	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Head cabbage	0.02	0.30	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00001	0.00000
Beans with pods	0.11	0.30	0.00002	0.00004	0.00006	0.00004	0.00002	0.00001	0.00002	0.00001	0.00002	0.00001
Beans	0.02	0.30	0.00001	0.00004	0.00003	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001	0.00001
dried Peas	0.02	0.30	0.00000	L/C	0.00001	0.00000	0.00000	0.00001	0.00000	0.00000	0.00001	0.00000
Oilseeds	0.027	0.30	0.00003	0.00005	0.00006	0.00006	0.00005	0.00003	0.00003	0.00004	0.00003	0.00003
Potatoes	0.01	0.30	0.00001	0.00003	0.00003	0.00002	0.00002	0.00002	0.00001	0.00001	0.00001	0.00001
Tea (dried leaves)	0.41	0.30	0.00003	0.00009	0.00003	0.00002	0.00001	0.00001	0.00002	0.00003	0.00003	0.00003
Maize	0.01	0.30	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Meat fat	0.38	0.30	0.00002	0.00005	0.00008	0.00005	0.00003	0.00003	0.00003	0.00001	0.00002	0.00002
Meat excl. poultry & offal	0.08	0.30	0.00005	0.00010	0.00010	0.00008	0.00007	0.00005	0.00005	0.00001	0.00004	0.00004
All types of kidney	0.03	0.30	0.00000	0.00000	0.00001	0.00000	0.00000	0.00000	0.00000	L/C	0.00000	0.00000
All types of Liver	0.03	0.30	0.00000	0.00002	0.00002	0.00000	0.00000	0.00001	0.00000	L/C	0.00001	0.00000
Other types of offal	0.03	0.30	0.00001	0.00001	0.00002	0.00001	0.00001	0.00001	0.00000	0.00000	0.00001	0.00001
Eggs	0.01	0.30	0.00000	0.00001	0.00001	0.00001	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Milk	0.01	0.30	0.00002	0.00029	0.00017	0.00009	0.00005	0.00004	0.00003	0.00003	0.00003	0.00004
Sugar beet	0.026	0.30	0.00011	0.00026	0.00043	0.00026	0.00025	0.00016	0.00015	0.00009	0.00008	0.00012

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.14 Chronic risk assessment undertaken using PRIMo revision 3.1

			No of diets exceeding the ADI :		--				Exposure resulting from		
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	23.3%	NL toddler	0.35	11.9%	Milk: Cattle			1.8%	Beans (with pods)		
	17.0%	NL child	0.26	4.9%				1.8%	Swine: Muscle/meat		
	15.8%	FR child 3 15 yr	0.24	4.6%				2.4%	Swine: Muscle/meat		
	14.9%	FR toddler 2 3 yr	0.22	5.9%				1.8%	Swine: Muscle/meat		
	13.4%	UK infant	0.20					0.8%	Strawberries		
	11.7%	SE general	0.17					0.8%	Potatoes		
	11.1%	UK toddler	0.17					1.7%	Sugar beet roots		
	11.0%	GEMS/Food G11	0.16				Swine: Muscle/meat	1.7%	Swine: Fat tissue		
	10.1%	GEMS/Food G08	0.15				Swine: Fat tissue	1.1%	Milk: Cattle		
	10.1%	ES child	0.15				Bovine: Muscle/meat	2.0%	Swine: Muscle/meat		
	9.7%	DK child	0.15				Milk: Cattle	2.1%	Bovine: Muscle/meat		
	9.7%	GEMS/Food G15	0.15				Swine: Fat tissue	1.4%	Milk: Cattle		
	9.3%	GEMS/Food G07	0.14				Bovine: Muscle/meat	1.3%	Milk: Cattle		
	9.2%	DE general	0.14				Sugar beet roots	1.8%	Swine: Muscle/meat		
	9.0%	GEMS/Food G10	0.14				Bovine: Muscle/meat	1.4%	Swine: Muscle/meat		
	8.8%	DE child	0.13			1.9%	Strawberries	0.9%	Swine: Muscle/meat		
	8.8%	DE women 14-50 yr	0.13			2.4%	Sugar beet roots	1.4%	Swine: Muscle/meat		
	8.4%	NL general	0.13			1.5%	Swine: Muscle/meat	1.5%	Sugar beet roots		

The review of the existing MRLs for indoxacarb – proposed MRLs

8.2%	IE adult	0.12	2.0%	Other farmed animals: Muscle/meat	1.1%	Tea (dried leaves of Camellia sinensis)	0.9%	Milk: Cattle
7.8%	FR infant	0.12	3.4%	Milk: Cattle	1.1%	Beans (with pods)	0.7%	Sugar beet roots
7.7%	RO general	0.12	2.3%	Milk: Cattle	1.8%	Swine: Muscle/meat	0.7%	Potatoes
6.8%	FR adult	0.10	1.2%	Tea (dried leaves of Camellia sinensis)	1.1%	Swine: Muscle/meat	1.0%	Bovine: Muscle/meat
6.3%	DK adult	0.09	1.5%	Swine: Fat tissue	1.4%	Swine: Muscle/meat	1.1%	Milk: Cattle
5.8%	ES adult	0.09	1.2%	Bovine: Muscle/meat	1.1%	Swine: Muscle/meat	1.0%	Milk: Cattle
4.8%	LT adult	0.07	1.5%	Swine: Muscle/meat	1.0%	Swine: Fat tissue	0.8%	Milk: Cattle
4.4%	GEMS/Food G06	0.07	0.8%	Sugar beet roots	0.7%	Soyabeans	0.5%	Milk: Cattle
3.4%	UK adult	0.05	1.1%	Bovine: Muscle/meat	0.6%	Milk: Cattle	0.4%	Tea (dried leaves of Camellia sinensis)
2.5%	IE child	0.04	1.0%	Swine: Fat tissue	0.7%	Milk: Cattle	0.3%	Swine: Muscle/meat
2.5%	FI 3 yr	0.04	1.4%	Strawberries	0.9%	Potatoes	0.0%	Head cabbages
2.4%	UK vegetarian	0.04	0.7%	Milk: Cattle	0.4%	Tea (dried leaves of Camellia sinensis)	0.3%	Strawberries
2.0%	FI 6 yr	0.03	1.1%	Strawberries	0.8%	Potatoes	0.0%	Beans
1.5%	PT general	0.02	1.1%	Potatoes	0.2%	Soyabeans	0.2%	Strawberries
1.0%	PL general	0.02	0.7%	Potatoes	0.1%	Head cabbages	0.1%	Gooseberries (green, red and yellow)
0.9%	IT toddler	0.01	0.5%	Strawberries	0.2%	Beans (with pods)	0.2%	Potatoes
0.9%	FI adult	0.01	0.5%	Strawberries	0.2%	Potatoes	0.0%	Head cabbages
0.7%	IT adult	0.01	0.3%	Beans (with pods)	0.2%	Strawberries	0.1%	Potatoes

Table B.15 Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Almonds	0.05	0.3	0.00001	0.1	0.00003	0.6	0.00001	0.2	0.00001	0.3	0.00001	0.1
Brazil nuts	0.05	0.3	0.00001	0.2	0.00000	0.0	0.00001	0.1	0.00001	0.2	0.00000	0.1
Cashew nuts	0.05	0.3	0.00001	0.3	0.00000	0.0	0.00002	0.5	0.00002	0.3	0.00000	0.0
Chestnuts	0.05	0.3	0.00001	0.3	0.00000	0.0	0.00001	0.1	0.00006	1.2	0.00000	0.0
Coconuts	0.05	0.3	0.00001	0.1	0.00000	0.1	0.00001	0.2	0.00001	0.3	0.00001	0.2
Hazelnuts	0.05	0.3	0.00001	0.1	0.00000	0.0	0.00001	0.2	0.00001	0.1	0.00001	0.1
Pecan nuts	0.05	0.3	0.00000	0.1	0.00000	0.0	0.00000	0.1	0.00000	0.0	0.00000	0.0
Pistachios	0.05	0.3	0.00004	0.7	0.00000	0.0	0.00003	0.6	0.00001	0.1	0.00002	0.5
Walnuts	0.05	0.3	0.00001	0.2	0.00000	0.0	0.00002	0.4	0.00001	0.1	0.00001	0.1
Peanuts	0.01	0.3	0.00001	0.1	0.00001	0.2	0.00001	0.2	0.00001	0.1	0.00001	0.1
Oilseeds	0.03	0.3	0.00005	1.0	0.00009	1.9	0.00011	2.2	0.00012	2.3	0.00009	1.8
Potatoes	0.01	0.3	0.00007	1.4	0.00046	9.2	0.00032	6.4	0.00024	4.8	0.00017	3.3
Strawberries	0.27	0.3	0.00021	4.3	0.00036	7.3	0.00040	7.9	0.00056	11.2	0.00039	7.8
Gooseberries	0.52	0.3	0.00015	3.1	0.00051	10.1	0.00033	6.6	0.00026	5.3	0.00017	3.4
Blackcurrants	0.69	0.3	0.00033	6.5	0.00050	10.0	0.00075	14.9	0.00105	20.9	0.00070	14.0
Red currants	0.52	0.3	0.00006	1.3	0.00000	0.0	0.00032	6.3	0.00004	0.8	0.00003	0.6
White currants	0.52	0.3	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Sweet corn	0.01	0.3	0.00006	1.3	0.00011	2.1	0.00016	3.1	0.00013	2.5	0.00015	3.0
Head cabbage	0.09	0.3	0.00033	6.6	0.00116	23.2	0.00069	13.7	0.00087	17.4	0.00047	9.5
Beans with pods	0.24	0.3	0.00017	3.3	0.00036	7.2	0.00036	7.2	0.00027	5.4	0.00015	2.9
Beans	0.02	0.3	0.00003	0.7	0.00011	2.2	0.00007	1.5	0.00007	1.4	0.00005	1.0
dried Peas	0.02	0.3	0.00002	0.4	0.00000	0.0	0.00003	0.5	0.00002	0.4	0.00002	0.4
Tea (dried leaves)	0.41	0.3	0.00004	0.7	0.00011	2.3	0.00005	1.0	0.00003	0.6	0.00003	0.5
Maize	0.01	0.3	0.00000	0.0	0.00002	0.4	0.00001	0.2	0.00000	0.1	0.00000	0.0
Poultry	0.01	0.3	0.00002	0.3	0.00002	0.4	0.00003	0.5	0.00003	0.6	0.00002	0.4
Meat fat	1.07	0.3	0.00021	4.3	0.00067	13.4	0.00060	12.0	0.00064	12.9	0.00044	8.8

The review of the existing MRLs for indoxacarb – proposed MRLs

Meat excl.poultry & offal	0.08	0.3	0.00012	2.4	0.00028	5.7	0.00024	4.9	0.00022	4.4	0.00019	3.7
All types of kidney	0.03	0.3	0.00002	0.3	0.00002	0.4	0.00003	0.7	0.00002	0.4	0.00001	0.3
All types of liver	0.03	0.3	0.00002	0.5	0.00007	1.5	0.00006	1.2	0.00002	0.3	0.00002	0.5
Other types of offal	0.03	0.3	0.00003	0.5	0.00007	1.3	0.00006	1.3	0.00005	1.0	0.00005	1.0
Eggs	0.02	0.3	0.00002	0.3	0.00007	1.5	0.00005	0.9	0.00004	0.8	0.00003	0.6
Milk	0.01	0.3	0.00004	0.8	0.00037	7.5	0.00022	4.4	0.00014	2.8	0.00009	1.8
Sugar Beet	0.03	0.3	0.00020	4.0	0.00043	8.7	0.00061	12.1	0.00050	10.0	0.00041	8.2

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Almonds	0.05	0.3	0.00001	0.1	0.00001	0.1	0.00001	0.2	0.00000	0.1	0.00000	0.1
Brazil nuts	0.05	0.3	0.00000	0.1	0.00000	0.0	0.00001	0.2	0.00000	0.0	0.00000	0.0
Cashew nuts	0.05	0.3	0.00001	0.1	0.00000	0.1	0.00001	0.2	0.00000	0.1	0.00000	0.0
Chestnuts	0.05	0.3	0.00000	0.0	0.00000	0.1	0.00003	0.5	0.00000	0.1	0.00000	0.0
Coconuts	0.05	0.3	0.00001	0.2	0.00001	0.2	0.00002	0.5	0.00000	0.1	0.00000	0.1
Hazelnuts	0.05	0.3	0.00000	0.1	0.00000	0.1	0.00001	0.1	0.00000	0.0	0.00000	0.0
Pecan nuts	0.05	0.3	0.00001	0.2	0.00000	0.0	0.00003	0.6	0.00001	0.1	0.00000	0.0
Pistachios	0.05	0.3	0.00000	0.1	0.00001	0.2	0.00001	0.2	0.00000	0.0	0.00000	0.0
Walnuts	0.05	0.3	0.00000	0.1	0.00001	0.2	0.00001	0.2	0.00001	0.2	0.00000	0.1
Peanuts	0.01	0.3	0.00001	0.1	0.00000	0.1	0.00000	0.1	0.00000	0.1	0.00000	0.0
Oilseeds	0.03	0.3	0.00007	1.3	0.00006	1.1	0.00008	1.6	0.00004	0.8	0.00004	0.9
Potatoes	0.01	0.3	0.00012	2.3	0.00009	1.7	0.00009	1.8	0.00007	1.4	0.00008	1.6
Strawberries	0.27	0.3	0.00024	4.8	0.00019	3.8	0.00027	5.5	0.00021	4.3	0.00009	1.9
Gooseberries	0.52	0.3	0.00026	5.1	0.00020	4.0	0.00034	6.9	0.00028	5.7	0.00015	3.0
Blackcurrants	0.69	0.3	0.00044	8.8	0.00062	12.3	0.00017	3.3	0.00027	5.3	0.00013	2.6
Red currants	0.52	0.3	0.00012	2.4	0.00005	1.0	0.00004	0.7	0.00014	2.8	0.00006	1.3
White currants	0.52	0.3	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0	0.00000	0.0
Sweet corn	0.01	0.3	0.00007	1.3	0.00009	1.8	0.00008	1.6	0.00005	1.0	0.00003	0.7
Head cabbage	0.09	0.3	0.00045	9.0	0.00032	6.5	0.00046	9.2	0.00036	7.1	0.00027	5.3

The review of the existing MRLs for indoxacarb – proposed MRLs

Beans with pods	0.24	0.3	0.00014	2.8	0.00020	4.0	0.00020	4.0	0.00016	3.1	0.00008	1.6
Beans	0.02	0.3	0.00004	0.9	0.00004	0.8	0.00004	0.8	0.00002	0.4	0.00002	0.4
dried Peas	0.02	0.3	0.00004	0.8	0.00001	0.3	0.00002	0.4	0.00002	0.3	0.00001	0.2
<i>Tea (dried leaves)</i>	0.41	0.3	0.00003	0.6	0.00003	0.6	0.00004	0.8	0.00003	0.6	0.00003	0.6
Maize	0.01	0.3	0.00000	0.0	0.00000	0.1	0.00001	0.1	0.00000	0.0	0.00000	0.0
Poultry	0.01	0.3	0.00002	0.4	0.00002	0.3	0.00004	0.7	0.00001	0.3	0.00001	0.2
Meat fat	1.07	0.3	0.00032	6.4	0.00031	6.1	0.00016	3.2	0.00016	3.1	0.00014	2.9
Meat excl.poultry & offal	0.08	0.3	0.00014	2.8	0.00014	2.7	0.00006	1.3	0.00009	1.8	0.00008	1.5
All types of kidney	0.03	0.3	0.00001	0.2	0.00002	0.4	0.00000	0.0	0.00002	0.3	0.00001	0.2
All types of liver	0.03	0.3	0.00004	0.8	0.00002	0.4	0.00000	0.0	0.00002	0.4	0.00002	0.3
Other types of offal	0.03	0.3	0.00004	0.8	0.00002	0.4	0.00001	0.2	0.00002	0.4	0.00002	0.4
Eggs	0.02	0.3	0.00002	0.5	0.00002	0.4	0.00002	0.5	0.00001	0.2	0.00001	0.3
Milk	0.01	0.3	0.00006	1.2	0.00005	1.1	0.00004	0.9	0.00003	0.7	0.00004	0.9
Sugar Beet	0.03	0.3	0.00030	6.1	0.00028	5.6	0.00016	3.3	0.00011	2.2	0.00015	2.9

Table B.16 Acute assessment undertaken PRIMo revision 3.1

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	26.48%	Strawberries	0 / 0.08	1.32	22.71%	Head cabbages	0 / 0.03	1.14
	23.89%	Head cabbages	0 / 0.03	1.19	15.11%	Strawberries	0 / 0.08	0.76
	18.57%	Cranberries	0 / 0.21	0.93	14.06%	Gooseberries (green, red and yellow)	0 / 0.16	0.70
	18.35%	Gooseberries (green, red and yellow)	0 / 0.16	0.92	13.03%	Swine: Fat tissue	0 / 0.32	0.65
	18.17%	Swine: Muscle/meat	0 / 0.08	0.91	11.11%	Beans (with pods)	0 / 0.07	0.56
	16.46%	Beans (with pods)	0 / 0.07	0.82	8.55%	Bovine: Muscle	0 / 0.08	0.43
	13.36%	Bovine: Fat tissue	0 / 0.32	0.67	8.40%	Other farmed animals: Muscle/meat	0 / 0.08	0.42
	10.91%	Swine: Fat tissue	0 / 0.32	0.55	7.25%	Swine: Muscle/meat	0 / 0.08	0.36
	10.82%	Bovine: Muscle/meat	0 / 0.08	0.54	7.20%	Equine: Muscle/meat	0 / 0.08	0.36
	10.37%	Other farmed animals: Muscle/meat	0 / 0.08	0.52	7.10%	Sheep: Muscle/meat	0 / 0.08	0.36
	9.23%	Potatoes	0 / 0	0.46	6.22%	Bovine: Fat tissue	0 / 0.32	0.31
	9.02%	Equine: Muscle/meat	0 / 0.08	0.45	4.70%	Cranberries	0 / 0.21	0.24
	8.15%	Sheep: Muscle/meat	0 / 0.08	0.41	2.37%	Coconuts	0 / 0.01	0.12
	7.45%	Milk: Cattle	0 / 0	0.37	2.34%	Goat: Muscle	0 / 0.08	0.12
	3.98%	Coconuts	0 / 0.01	0.20	2.31%	Milk: Cattle	0 / 0	0.12
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities	Results for children				Results for adults			
	No of processed commodities for which ARfD/ADI is exceeded (IESTI):				No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	18.1%	Beans (with pods) / boiled	0 / 0.07	0.90	6.8%	Sugar beets (root) / sugar	0 / 0.09	0.34
	17.2%	Sugar beets (root) / sugar	0 / 0.09	0.86	6.06%	Elderberries / juice	0 / 0.03	0.30
	10.5%	Elderberries / juice	0 / 0.03	0.53	1.13%	Head cabbages / canned	0 / 0.01	0.06
	5.6%	Potatoes / fried	0 / 0	0.28	0.86%	Beans / canned	0 / 0.01	0.04
	5.2%	Cranberries / juice	0 / 0.05	0.26	0.68%	Cranberries / dried	0 / 0.05	0.03
	3.7%	Azarole (mediteranean medlar) / juice	0 / 0.03	0.18	0.51%	Potatoes / chips	0 / 0	0.03
	3.6%	Potatoes / dried (flakes)	0 / 0.01	0.18	0.50%	Tea (dried leaves of Camellia sinensis) / infusion	0 / 0	0.02
	0.9%	Tea (dried leaves of Camellia sinensis) / infusion	0 / 0	0.04	0.35%	Potatoes / dried (flakes)	0 / 0.01	0.02
	0.9%	Peas / canned	0 / 0	0.04	0.32%	Peas / canned	0 / 0	0.02
	0.7%	Head cabbages / canned	0 / 0.01	0.03	0.28%	Coconuts / drink	0 / 0	0.01
	0.7%	Soyabeans / soya drink	0 / 0.01	0.03	#NUM!	#NUM!	#NUM!	#NUM!
	0.7%	Coconuts / drink	0 / 0	0.03	#NUM!	#NUM!	#NUM!	#NUM!
	0.2%	Soyabeans / boiled	0 / 0	0.01	#NUM!	#NUM!	#NUM!	#NUM!
	0.2%	Peanuts / peanut butter	0 / 0	0.01	#NUM!	#NUM!	#NUM!	#NUM!
	0.0%	Rapeseeds / oils	0 / 0.01	0.00	#NUM!	#NUM!	#NUM!	#NUM!
Expand/collapse list								

TTC assessment – IN-MP819 (milk only – current MRL for milk)

Table B.17 Chronic risk assessment undertaken using UK model version 1.1

TOTAL INTAKE based on 97.5th percentile										
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00028	0.00332	0.00190	0.00100	0.00062	0.00040	0.00032	0.00033	0.00029	0.00040
% of ADI	19%	221%	126%	67%	41%	27%	21%	22%	20%	27%

STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)										
Milk	0.034	0.00028	0.00332	0.00190	0.00100	0.00062	0.00040	0.00032	0.00033	0.00029	0.00040

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.18 Chronic risk assessment undertaken using PRIMo revision 3.1

			No of diets exceeding the ADI :						Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MRLs set at the LOQ (in % of ADI)
TMD/NEDI/IEDI calculation (based on average food consumption)	87.7%	UK infant	1.32	87.7%	Milk: Cattle					
	67.2%	FR toddler 2 3 yr	1.01					0.0%	Milk: Others	
	55.5%	NL child	0.83					0.0%	Milk: Sheep	
	52.1%	FR child 3 15 yr	0.78					0.0%	Milk: Others	
	46.8%	UK toddler	0.70	46.8%						
	44.9%	DE child	0.67	44.8%				0.0%	Milk: Sheep	
	38.1%	FR infant	0.57							
	28.6%	DK child	0.43							
	28.5%	DE women 14-50 yr	0.43			0.3%	Milk: Sheep	0.1%	Milk: Goat	
	28.4%	ES child	0.43			0.0%	Milk: Goat			
	28.3%	DE general	0.42				Milk: Sheep	0.1%	Milk: Goat	
	28.1%	SE general	0.42				Grapefruits			
	26.3%		0.39				Grapefruits			
	19.2%		0.29			0.0%	Milk: Sheep	0.0%	Milk: Goat	
	17.7%		0.27			0.0%	Milk: Sheep			
	16.5%		0.25			0.5%	Milk: Sheep	0.0%	Milk: Goat	
	14.7%		0.22			0.1%	Milk: Goat	0.0%	Milk: Sheep	
	12.7%		0.19			0.0%	Milk: Goat	0.0%	Milk: Sheep	
	12.5%		0.19		Milk: Cattle	0.1%	Milk: Goat	0.0%	Milk: Sheep	
	12.0%		0.18		Milk: Cattle		Grapefruits			
	11.2%		0.17		Milk: Cattle	0.0%	Milk: Goat			
	10.4%		0.16		Milk: Cattle	0.2%	Milk: Goat	0.0%	Milk: Others	

The review of the existing MRLs for indoxacarb – proposed MRLs

	9.9%	IE adult	0.15	9.9%	Milk: Cattle					
	9.0%	LT adult	0.13	9.0%	Milk: Cattle					
	8.1%	IE child	0.12	8.1%	Milk: Cattle					
	7.4%	UK vegetarian	0.11	7.4%	Milk: Cattle					
	6.8%	UK adult	0.10	6.8%	Milk: Cattle					
	6.4%	GEMS/Food G06	0.10	5.7%	Milk: Cattle				Milk: Goat	
		IT toddler			Grapefruits					
		IT toddler					Grapefruits			
		IT toddler								
		IT toddler								
		IT toddler			Grapefruits					
		IT toddler								
		IT toddler								

Table B.19 Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Milk	0.03		0.00044	8.8	0.00422	84.5	0.00249	49.9	0.00158	31.7	0.00101	20.3

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Milk	0.03		0.00070	14.0	0.00060	11.9	0.00050	10.1	0.00038	7.5	0.00049	9.7

Table B.20 Acute assessment undertaken PRIMo revision 3.1

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	84.47%	Milk: Cattle	0 / 0.03	4.22	26.22%	Milk: Cattle	0 / 0.03	1.31
	16.44%	Milk: Goat	0 / 0.03	0.82	12.51%	Milk: Goat	0 / 0.03	0.63
	2.43%	Milk: Sheep	0 / 0.03	0.12	10.27%	Milk: Sheep	0 / 0.03	0.51
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

TTC assessment – 5-OH-indoxacarb (free and conjugated)

Table B.21 Chronic risk assessment undertaken using UK model UK model 1.1

TOTAL INTAKE based on 97.5th percentile										
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00002	0.00008	0.00009	0.00003	0.00003	0.00003	0.00002	#NUM!	0.00003	0.00002
% of ADI	2%	5%	6%	2%	2%	2%	1%	#NUM!	2%	2%

STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)										
All types of kidney	0.003		0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	L/C	0.00000
All types of Liver	0.02		0.00001	0.00004	0.00005	0.00001	0.00001	0.00001	0.00001	L/C	0.00001
Other types of offal	0.02		0.00001	0.00003	0.00004	0.00002	0.00002	0.00002	0.00001	0.00000	0.00002

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.22 Chronic risk assessment undertaken using PRIMo

			No of diets exceeding the ADI :						Exposure resulting from	
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MR Ls set at the LO Q (in % of ADI)
TMD/NED/IEDI calculation (based on average food)	0.4%	IE adult	0.01	0.3%	Sheep: Liver					
	0.4%	NL toddler	0.01	0.2%						
	0.4%	UK infant	0.01	0.2%				0.0%	Bovine: Kidney	
	0.3%	GEMS/Food G07	0.01	0.2%				0.0%	Sheep: Liver	
	0.2%	GEMS/Food G15	0.00	0.1%				0.0%	Sheep: Liver	
	0.2%	NL child	0.00	0.1%						
	0.2%	DK child	0.00							
	0.2%	GEMS/Food G10	0.00					0.0%	Sheep: Liver	
	0.1%	ES child	0.00					0.0%	Bovine: Liver	
	0.1%	GEMS/Food G08	0.00					0.0%	Sheep: Liver	
	0.1%	GEMS/Food G06	0.00					0.0%	Goat: Liver	
	0.1%	FR adult	0.00			0.0%	Swine: Edible offals (other than liver and kidney)	0.0%	Bovine: Liver	
	0.1%	UK toddler	0.00			0.0%	Bovine: Liver	0.0%	Bovine: Kidney	
	0.1%	FR child 3 15 yr	0.00			0.0%	Bovine: Liver	0.0%	Swine: Edible offals (other than liver and kidney)	

The review of the existing MRLs for indoxacarb – proposed MRLs

0.1%	GEMS/Food G11	0.00	0.0%	Swine: Liver	0.0%	Bovine: Liver	0.0%	Sheep: Liver
0.1%	FR toddler 2 3 yr	0.00	0.1%	Bovine: Liver	0.0%	Swine: Liver	0.0%	Bovine: Edible offals (other than liver and kidney)
0.1%	DK adult	0.00	0.1%	Swine: Liver	0.0%	Bovine: Liver		
0.1%	NL general	0.00	0.0%	Swine: Liver	0.0%	Bovine: Liver		
0.1%	ES adult	0.00	0.0%	Swine: Liver	0.0%	Bovine: Edible offals (other than liver and kidney)	0.0%	Bovine: Liver
0.1%	LT adult	0.00	0.0%	Swine: Liver	0.0%	Bovine: Liver		
0.0%	DE general	0.00	0.0%	Swine: Liver	0.0%	Bovine: Liver	0.0%	Swine: Edible offals (other than liver and kidney)
0.0%	FR infant	0.00	0.0%	Bovine: Liver	0.0%	Sheep: Liver	0.0%	Other farmed animals: Edible offals (other than liver and kidney)
0.0%	UK adult	0.00	0.0%	Bovine: Liver	0.0%	Bovine: Kidney		
0.0%	DE women 14-50 yr	0.00	0.0%	Swine: Liver	0.0%	Bovine: Liver	0.0%	Swine: Edible offals (other than liver and kidney)
0.0%	UK vegetarian	0.00	0.0%	Bovine: Edible offals (other than liver and kidney)		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		
	DE child			Grapefruits		Grapefruits		

Table B.23 Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

commodity	HR	P	adult		infant		toddler		4-6 year old child		7-10 year old child	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
All types of kidney	0.01		0.00001	0.2	0.00001	0.3	0.00002	0.5	0.00001	0.3	0.00001	0.2
All types of liver	0.04		0.00012	2.3	0.00035	6.9	0.00029	5.7	0.00008	1.6	0.00011	2.2
Other types of offal	0.04		0.00013	2.5	0.00031	6.3	0.00031	6.1	0.00025	4.9	0.00024	4.7

commodity	HR	P	11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
			NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
All types of kidney	0.01		0.00001	0.2	0.00001	0.3	0.00000	0.0	0.00001	0.2	0.00001	0.2
All types of liver	0.04		0.00018	3.6	0.00009	1.7	0.00000	0.0	0.00010	1.9	0.00008	1.6
Other types of offal	0.04		0.00020	3.9	0.00010	1.9	0.00004	0.8	0.00011	2.1	0.00011	2.1

Table B.24 Acute risk assessment undertaken using PRIMo

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	6.94%	Bovine: Liver	0 / 0.04	0.35	3.44%	Bovine: Liver	0 / 0.04	0.17
	6.26%	Bovine: Edible offals (other than liver and kidney)	0 / 0.04	0.31	2.86%	Bovine: Edible offals (other than liver and kidney)	0 / 0.04	0.14
	2.58%	Swine: Edible offals (other than liver and kidney)	0 / 0.04	0.13	2.41%	Sheep: Liver	0 / 0.04	0.12
	1.05%	Swine: Liver	0 / 0.04	0.05	2.24%	Swine: Edible offals (other than liver and kidney)	0 / 0.04	0.11
	0.45%	Bovine: Kidney	0 / 0.01	0.02	1.21%	Swine: Liver	0 / 0.04	0.06
	0.15%	Swine: Kidney	0 / 0.01	0.01	0.59%	Sheep: Edible offals (other than liver and kidney)	0 / 0.04	0.03
Expand/collapse list				0.26% Swine: Kidney 0 / 0.01 0.01 0.25% Bovine: Kidney 0 / 0.01 0.01 0.01% Sheep: Kidney 0 / 0.01 0.00				
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								
Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			

The review of the existing MRLs for indoxacarb – proposed MRLs

IESTI				IESTI			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

TTC assessment – IN-JT333

Table B.25 Chronic risk assessment undertaken using UK model UK model 1.1

Active substance: 5-OH-indoxacarb

ADI: 0.0015 mg/kg bw/day

Source: TTC

		TOTAL INTAKE based on 97.5th percentile									
		ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day		0.00000	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000
% of ADI		<1%	<1%	1%	<1%	<1%	<1%	<1%	<1%	<1%	<1%
STMR	P	COMMODITY INTAKES									
Commodity	(mg/kg)	(mg/kg bw/day)									
Meat fat	0.0266	0.00000	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001	0.00000	0.00001	0.00000

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

Table B.26 Chronic risk assessment undertaken using PRIMo

			No of diets exceeding the ADI : --								Exposure resulting from
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMD/NEDI/IEDI calculation (based on average food consumption)	0.6%	GEMS/Food G15	0.01	0.5%				0.0%	Poultry: Fat tissue		
	0.6%	GEMS/Food G11	0.01	0.4%				0.0%	Poultry: Fat tissue		
	0.5%	DK adult	0.01	0.4%							
	0.5%	IE adult	0.01	0.5%							
	0.5%	GEMS/Food G08	0.01					0.0%	Poultry: Fat tissue		
	0.3%	FR child 3 15 yr	0.00					0.0%	Poultry: Fat tissue		
	0.3%	IE child	0.00				Poultry: Fat tissue	0.0%	Sheep: Fat tissue		
	0.3%	ES child	0.00				Other farmed animals: Muscle/meat				
	0.3%	GEMS/Food G10	0.00				Swine: Fat tissue	0.0%	Sheep: Fat tissue		
	0.2%	LT adult	0.00				Grapefruits				
	0.2%	ES adult	0.00				Swine: Fat tissue				
	0.2%	UK toddler	0.00				Grapefruits				
	0.2%	GEMS/Food G07	0.00				Bovine: Fat tissue	0.0%	Sheep: Fat tissue		
	0.2%	DE general	0.00			0.0%	Bovine: Fat tissue	0.0%	Other farmed animals: Muscle/meat		
	0.2%	FR adult	0.00			0.1%	Swine: Fat tissue	0.0%	Poultry: Fat tissue		
	0.2%	DE women 14-50 yr	0.00			0.0%	Bovine: Fat tissue	0.0%	Other farmed animals: Muscle/meat		
	0.2%	NL child	0.00			0.1%	Bovine: Fat tissue				

The review of the existing MRLs for indoxacarb – proposed MRLs

0.1%	FR toddler 2 3 yr	0.00	0.1%	Swine: Fat tissue	0.0%	Other farmed animals: Muscle/meat	0.0%	Poultry: Fat tissue		
0.1%	NL toddler	0.00	0.0%	Swine: Fat tissue	0.0%	Bovine: Fat tissue				
0.1%	FR infant	0.00	0.1%	Other farmed animals: Muscle/meat	0.0%	Swine: Fat tissue	0.0%	Poultry: Fat tissue		
0.1%	NL general	0.00	0.0%	Swine: Fat tissue	0.0%	Bovine: Fat tissue	0.0%	Other farmed animals: Muscle/meat		
0.1%	UK adult	0.00	0.1%	Bovine: Fat tissue		Grapefruits				
0.0%	UK infant	0.00	0.0%	Bovine: Fat tissue		Grapefruits				
0.0%	GEMS/Food G06	0.00	0.0%	Bovine: Fat tissue	0.0%	Swine: Fat tissue	0.0%	Sheep: Fat tissue		
0.0%	UK vegetarian	0.00	0.0%	Bovine: Fat tissue		Grapefruits				
0.0%	RO general	0.00	0.0%	Swine: Fat tissue		Grapefruits				
0.0%	DE child	0.00	0.0%	Other farmed animals: Muscle/meat		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				
	DK child			Grapefruits		Grapefruits				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of is unlikely to present a public health concern.

Table B.27 Acute risk assessment undertaken using UK model UK model 1.2

Acute Intakes (97.5th percentiles)

			adult		infant		toddler		4-6 year old child		7-10 year old child	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Meat fat	0.08		0.00005	1.0	0.00016	3.1	0.00014	2.8	0.00015	3.0	0.00010	2.1

			11-14 year old child		15-18 year old child		vegetarian		Elderly - own home		Elderly - residential	
commodity	HR	P	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD	NESTI	%ARfD
Meat fat	0.08		0.00008	1.5	0.00007	1.4	0.00004	0.7	0.00004	0.7	0.00003	0.7

Pesticide 5-OH-indoxacarb

ARfD 0.005 mg/Kg bw/day

Source TTC

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value $\geq$ 0.000005 is rounded to 0.00001)

Table B.28 Acute risk assessment undertaken using PRIMo

Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	3.12%	Bovine: Fat tissue	0 / 0.08	0.16	3.05%	Swine: Fat tissue	0 / 0.08	0.15
	2.55%	Swine: Fat tissue	0 / 0.08	0.13	1.45%	Bovine: Fat tissue	0 / 0.08	0.07
	0.04%	Poultry: Fat tissue	0 / 0.02	0.00	0.11%	Poultry: Fat tissue	0 / 0.02	0.01
	Expand/collapse list							
	Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):			
	---				---			
	IESTI				IESTI			
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

Appendix C - Detailed evaluation of the additional studies relied on

No additional data submitted.

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Appendix D – List of endpoints

The endpoints outlined in table D.1 were derived during the Article 21 review of the active substance (HSE, 2024).

The endpoints outlined in Tables D.2-D.4 have been derived as a result of this assessment. All other endpoints remained unchanged – the remaining endpoints are outlined in the EFSA conclusion on the renewal of the active substance (EFSA, 2018).

Table D.1 Mammalian toxicology

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.005	Rat, developmental toxicity study	100
Acute Reference Dose (ARfD)	0.005	Rat, developmental toxicity study	100

Table D.2 Nature of the residue on processing

Conditions	Stability	Comment
Pasteurisation (20 min, 90°C, pH 4)	Yes	
Baking, brewing and boiling (60 min, 100°C, pH 5)	Yes – minor breakdown to IN-KT413 possible (1-14% AR)	More recent study suggests active is stable under baking, brewing and boiling conditions
Sterilisation (20 min, 120°C, pH 6)	No	The following metabolites are observed at ≥10% AR: IN-KT413, IN-MP819, IN-MK638, IN-P0036, IN-TMG00

Conditions	Stability	Comment
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes – TTC exposure assessment has been conducted based on the observed metabolites under sterilisation conditions – no exceedances of the CCIII TTC chronic or acute threshold values are seen based on the proposed GB MRLs. Further consideration may be required if further MRLs are requested in future.	

Table D.3 Plant residue definitions and methods for monitoring/enforcement

Plant residue definition for enforcement (RD-Enf) (for compliance with MRLs)	Indoxacarb (and its R- enantiomer)
Plant residue definition for risk assessment (RD-RA) (for estimation of dietary exposure)	Indoxacarb (and its R- enantiomer)
Conversion factors (enforcement to risk assessment)	N/A
Methods of analysis for monitoring/enforcement of residues (analytical technique, crop groups, LOQs)	Yes – LOQ of 0.01* mg/kg in all matrices, except those considered as difficult to analyse.

Table D.4 Animal residue definitions and methods for monitoring/enforcement

Animal residue definition for enforcement (RD-Enf) (for compliance with MRLs)	Indoxacarb (and its R- enantiomer)
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Animal residue definition for risk assessment (RD-RA) (for estimation of dietary exposure)	Poultry and ruminants (except poultry fat and milk): Indoxacarb (and its R- enantiomer) Poultry fat: • Indoxacarb (and its R-enantiomer) • Metabolite F (provisional pending additional information to allow formal identification, as well as relevant toxicological information and/or feeding studies to elucidate its occurrence) Milk: • Indoxacarb (and its R-enantiomer) • IN-MP819 (provisional – pending additional toxicological information; and/or feeding studies which elucidate its occurrence)
Conversion factors (enforcement to risk assessment)	N/A
Methods of analysis for monitoring/enforcement of residues (analytical technique, crop groups, LOQs)	Yes – LOQ of 0.01* mg/kg in all matrices
Fat soluble	Yes

Appendix E – Import Tolerances

Not relevant.

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Appendix F – Compound codes

No new metabolism studies were evaluated during this assessment and hence this section has not been completed.

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Appendix G – Abbreviations

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism and excretion
Animal model 2017	EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables
ARfD	Acute reference dose
a.s.	Active substance
BBCH	Growth stages of mono- and dicotyledonous plants
bw	Body weight
CF	Conversion factor
cGAP	Critical GAP
CXL	Codex maximum residue limit
DAR	Draft assessment report
DAT	Days after treatment
DT ₉₀	Period required for 90% dissipation (define method of estimation)
DT ₅₀	Period required for 50% dissipation (define method of estimation)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GB	Great Britain
GC-MS	Gas chromatography with mass spectrometry

GLP	Good laboratory practice
HPLC-MS/MS (LC-MS/MS)	High-performance liquid chromatography with tandem mass spectrometry
HR	Highest residue
HSE	Health and Safety Executive
IEDI	International estimate of daily intake
IESTI	International estimate of short-term intake
ILV	Independent laboratory validation
ISO	International Organisation for Standardization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC ₅₀	Lethal concentration, median
LD ₅₀	Lethal dose, median
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection or limit of determination (should be defined)
LoEP	List of endpoints
LOQ	Limit of quantification NB the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification
MRL	Maximum residue level
NEDI	National estimate of dietary intake
NESTI	National estimate of short-term intake

NOAEL	No observed adverse effect level
NRL	National reference laboratory
OECD	Organisation for Economic Co-operation and Development
PBI	Plant-back interval
PES	Post-extraction solids
Pf	Processing factor
PHI	Preharvest interval
PRIMo	(EFSA) Pesticide Residue Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	Risk assessment
RD	Residue definition
RD-Enf	Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)
RD-RA	Residue definition for risk assessment
RTI	Re-treatment interval
STMR	Supervised trials median residue
TRR	Total radioactive residue
TTC	Threshold of toxicological concern
WG	Water dispersible granule
WHO	World Health Organization

Additional studies relied upon

Not required.

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