Targeted review of maximum residues levels (MRLs) for indoxacarb

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Abstract

In compliance with Article 43 of Regulation (EC) No 396/2005, EFSA received a mandate from the European Commission to perform a targeted review of the maximum residue levels (MRLs) for indoxacarb based on Codex maximum residue limits (CXLs) or on import tolerances which might still be maintained after the expire of the approval of the active substance. EFSA screened the existing MRLs based on CXLs or on import tolerances considering the new toxicological reference values established during the peer review process for the renewal of the approval of indoxacarb and identified the MRLs for which an acute risk could not be excluded and several MRLs that are unlikely to pose a risk for consumers. Fall-back MRLs could not be proposed for the commodities exceeding the new toxicological reference values as no further data were provided during the call for data. Therefore, risk managers may consider maintaining only the MRLs identified during the screening as safe for consumers. However, for some of the proposed MRLs, further consideration by risk managers is needed due to the uncertainties identified.

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Keywords: indoxacarb, MRLs, Regulation (EC) No 396/2005, consumer risk assessment, toxicological reference values

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Summary

Indoxacarb was approved on 1 April 2006 by means of Commission Directive 2006/10/EC in the framework of Directive 91/414/EEC for use as an insecticide.

On 24 August 2011, the European Food Safety Authority (EFSA) published its reasoned opinion on the review of the existing maximum residues levels (MRLs) for the active substance indoxacarb in compliance with Article 12(2) of Regulation (EC) No 396/2005 and the proposed MRLs were implemented in Regulation EU No 668/2013. After completion of the MRL review, EFSA has provided scientific support for preparing an EU position on Codex maximum residue limits (CXLs) in indoxacarb for the 45th and 46th Session of the Codex Committee on Pesticide Residues. The CXLs adopted by the Codex Alimentarius Commission (CAC) have been included in Commission Regulation (EU) No 2015/845.

On 25 January 2018, EFSA finalised the conclusion on the peer review of the active substance according to Article 13 of Regulation (EU) No 844/2012 in the framework of the renewal of the approval under Regulation (EC) No 1107/2009. In the conclusion EFSA proposed to lower the existing acceptable daily intake (ADI) from 0.006 mg/kg body weight per day to 0.005 mg/kg body weight per day and the acute reference dose (ARfD) from 0.125 mg/kg body weight to 0.005 mg/kg body weight for indoxacarb.

Commission Implementing Regulation (EU) 2021/2081 concerning the non-renewal of approval of the active substance indoxacarb was adopted on 26 November 2021. The approval of indoxacarb was not renewed and a grace period was granted until 19 September 2022.

After the expiry of the grace period, when the EU authorisations will have been withdrawn, the maximum residue levels based on former EU uses will be lowered to the limit of quantification (LOQ) according to Reg (EC) No 396/2005. However, CXLs and some MRLs based on import tolerances exist for a range of commodities for which MRLs could be maintained in case they are safe for consumers.

To identify these MRLs considering the new toxicological reference values, EFSA was mandated by the European commission to perform a preliminary risk assessment of the existing EU MRLs covering CXLs or import tolerances. According to the exposure calculations (scenario 1), an acute risk could not be excluded for 20 commodities. For these commodities, EFSA asked MSs and the UK to report import tolerance fall-back Good Agricultural Practices (GAPs) together with supporting residue data. Since no fall-back GAPs were received and no refinement was possible, fall-back MRLs could not be derived.

A second exposure calculation (scenario 2) was performed replacing the risk assessment values for the commodities of concern identified in the first scenario with the LOQ of 0.01 mg/kg in the calculation. According to the results of this calculation, the highest chronic exposure declined to 53% of the ADI (Dutch toddler) and the highest acute exposure was calculated for basil, representing 99% of the ARfd.

Overall, the existing MRLs covering CXLs or import tolerance for cranberries, potatoes, sweet corn, basil, dry beans, dry peas, peanuts, soya beans, cotton seed, tea, milk, ruminants, swine and poultry tissues, and eggs are not expected to pose an unacceptable risk for consumers, and therefore risk managers may consider maintaining these MRLs. Nevertheless, further considerations are needed by risk managers regarding the MRLs for basil and milk for which the consumer risk assessment was affected by high level of uncertainty.
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Background

Indoxacarb was first evaluated in the framework of Directive 91/414/EEC\(^1\) with the Netherlands designated as rapporteur Member State (RMS). Following the peer review, which was not carried out by the European Food Safety Authority (EFSA), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC for the use as an insecticide was taken by means of Commission Directive 2006/10/EC\(^2\).

The EU maximum residue levels (MRLs) for indoxacarb are established in Annex II of Regulation (EC) No 396/2005\(^3\). The existing MRLs were assessed in 2011 by EFSA according to Article 12 of Regulation (EFSA, 2011) and the proposed MRLs were implemented by Commission Regulation (EU) No 668/2013\(^4\). After completion of the MRL review, EFSA provided scientific support for preparing an EU position on Codex maximum residue limits (CXLs) in indoxacarb for the 45th and 46th Session of the Codex Committee on Pesticide Residues (EFSA, 2013c, 2014). The CXLs adopted by the Codex Alimentarius Commission (CAC) have been included, respectively, in Commission Regulation (EU) No 491/2014 and in Commission Regulation (EU) No 2015/845.

On 25 January 2018, EFSA finalised the conclusion on the peer review of the active substance according to Article 13 of Regulation (EU) No 844/2012\(^5\) in the framework of the renewal of the approval under Regulation (EC) No 1107/2009\(^6\) (EFSA, 2018a). In the conclusion EFSA proposed to lower the existing acceptable daily intake (ADI) from 0.006 mg/kg body weight per day to 0.005 mg/kg body weight per day and the acute reference dose (ARfD) from 0.125 mg/kg body weight to 0.005 mg/kg body weight for indoxacarb.

Commission Implementing Regulation (EU) 2021/2081 concerning the non-renewal of approval of the active substance indoxacarb was adopted on 26 November 2021. The approval of indoxacarb was not renewed because a critical area of concern was identified in relation to the high long-term risk to wild mammals, in particular the long-term risk to small herbivorous mammals. In addition, a high risk was identified to consumers and workers for the representative use in lettuce and to bees for the representative use in maize, sweet corn and lettuce for seed production. The grace period will expire on 19 September 2022.

After the expiry of the grace period, when the EU authorisations will have been withdrawn, the maximum residue levels based on former EU uses will be lowered to the limit of quantification. However, Codex maximum residue limits (CXLs) and some MRLs based on import tolerances exist for a range of commodities for which MRLs could be maintained in case they are safe for consumers.

Therefore, according to Article 43 of Regulation (EC) No 396/2005, EFSA has been requested by EC to perform a targeted review of the existing MRLs for the active substance indoxacarb covering CXLs or import tolerances.

On the basis of the data available in the MRL Review and in the Joint Meeting on Pesticide residues (JMPR) Evaluation reports, the data submitted by the EURLs and taking into account the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 for the renewal of approval of indoxacarb, EFSA prepared in May 2022 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 10 June 2022 were considered during the finalisation of this reasoned opinion.

The evaluation report submitted by the EURLs (2022) during the collection of data is considered as a supporting document to this reasoned opinion and, thus, made publicly available.

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\(^1\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

\(^2\) Commission Directive 2006/10/EC of 27 January 2006, OJ L 25, 28.1.2006, p. 24–27.

\(^3\) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^4\) Commission Regulation (EU) No 668/2013 of 12 July 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, dimethomorph, indoxacarb and pyraclostrobin in or on certain products. OJ L 192, 13.7.2013, p. 39–71.

\(^5\) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

\(^6\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
In addition, further supporting document to this reasoned opinion is the **Member States consultation report** (EFSA, 2022). Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) are key supporting documents made publicly available as background document to this reasoned opinion. A screenshot of the report sheets of the PRIMo are presented in Appendix C.

### Terms of Reference

According to Article 43 of Regulation (EC) No 396/2005, EFSA was requested to:

- perform a preliminary assessment of the chronic and acute risk to consumers limited to existing MRLs based on Good Agricultural Practices authorised in third countries and/or on CXLs, considering the new lowered toxicological reference values and the newest version of PRIMo;
- consult the EURLs on the LOQs achievable during routine analyses and Member States and the UK on information about Good Agricultural Practices authorised in third countries on the commodities of concern and already evaluated at Member State level, which might support setting of fall-back safe MRLs, where this is necessary in view of consumer protection;
- consult the Member States and the EURLs on the draft reasoned opinion.
- EFSA should base the assessment on the residue definitions for risk assessment and enforcement derived during the MRL review. EFSA should deliver the reasoned opinion by 18 August 2022.

### The active substance and its use pattern

Indoxacarb is the ISO common name for methyl (S)-N-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)inden[1,2-e][1,3,4]oxadiazin-2-ylcarbonyl]-4′-(trifluoromethoxy)carbamate or methyl (S)-7-chloro-2,3,4a,5-tetrahydro-2-[methoxycarbonyl]((4-trifluoromethoxyphenyl)carbamoyl]inden[1,2-e][1,3,4]oxadizine-4a-carboxylate (IUPAC).

The chemical structure of the active substance is reported in Appendix D.

The EU MRLs for indoxacarb are established in Annexes II of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for indoxacarb were also established by the Codex Alimentarius Commission (CAC).

An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

#### Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure                  | Legal implementation | Remarks                                                                 |
|----------------------------|----------------------|------------------------------------------------------------------------|
| MRL application            | Reg. (EC) No 822/2009(a) | European uses on Brussels sprouts, raspberries, blackberries (EFSA, 2009a,b) |
| MRL application            | Reg. (EC) No 1050/2009(b) | European uses on small fruits and berries except gooseberries and currants (EFSA, 2009c) |
| MRL application            | Reg. (EC) No 459/2010(c) | European uses on cherries and sugar beets (EFSA, 2009d)                |
| Implementation of CAC 2010 | Reg. (EU) No 520/2011(d) | CXLs for stone fruits, cucurbits, basil and edible flowers, beans, swine, bovine, sheep, goat, equine tissues, poultry muscle, milk (FAO, 2009) |
| Art 12 review              | Reg. (EU) No 668/2013(e) | Based on the assessment of European uses, import tolerances and existing CXLs, MRLs were modified for several commodities of plant and animal origin (EFSA, 2011) |
| MRL application            | Reg. (EU) No 35/2013(f) | European uses on strawberries, raspberries, Chinese cabbage, lamb's lettuce, escarole, witloof, beans with pods, cardoons, fennel, rhubarb and soya beans (EFSA, 2012) |
| MRL application            | Reg. (EU) No 51/2014(g) | European uses on cress, land cress, red mustard, other lettuce and salad plants, purslane, beet leaves and other spinach and similar (leaves) (EFSA, 2013a) |
| MRL application            | Reg. (EU) No 737/2014(h) | European uses on beans (with pods) and mustard seed (EFSA, 2013b) |
### Assessment

EFSA has based its assessment on the following documents:

- the conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb (EFSA, 2018a);
- the reasoned opinion on the review of the existing MRLs for indoxacarb according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2005, 2009, 2012, 2013).

The reasoned opinions published after the MRL review concerned European uses only and, therefore, were not further considered in the assessment.

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**Targeted review of maximum residues levels (MRLs) for indoxacarb**

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| Implementation of CAC 2013 | Reg. (EU) No 491/2014 | CXL for lettuce (EFSA, 2013c) |
| Implementation of CAC 2014 | Reg. (EU) 2015/845 | CXL for teas (EFSA, 2014) |

(a): Commission Regulation (EC) No 822/2009 of 27 August 2009 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, atrazine, chlorimuron, cyprodinil, dithiocarbamates, fluoroxyamide, fluroxypyr, indoxacarb, mandipropamid, potassium tri-iodide, spirotetramat, tetraconazole, and thiram in or on certain products. OJ L 239, 10.9.2009, p. 5–45.

(b): Commission Regulation (EC) No 1050/2009 of 28 October 2009 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, acetamiprid, clomazone, cyflufenamid, emamectin benzoate, farnoxadone, fenbutatin oxide, flufenoxuron, flupicinol, indoxacarb, isoxaflutole, mefenpyr, prothioconazole, pyridazinyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 290, 6.11.2009, p. 7–55.

(c): Commission Regulation (EU) No 459/2010 of 27 May 2010 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 129, 28.5.2010, p. 3–49.

(d): Commission Regulation (EU) No 520/2011 of 25 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbofuran, Cypermethrin, flupicinol, heptachlor, indoxacarb, metflumizone, methoxyfenozide, parquat, prochloraz, spiroidifen, prothioconazole and zoxamide in or on certain products. OJ L 140, 27.5.2011, p. 2–47.

(e): Commission Regulation (EU) No 668/2013 of 12 July 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,4-DB, dimethomorph, indoxacarb, and pyraclostrobin in or on certain products. OJ L 192, 13.7.2013, p. 39–71.

(f): Commission Regulation (EU) No 35/2013 of 18 January 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, indoxacarb, pyraclostrobin and trifloxystrobin in or on certain products OJ L 25, 26.1.2013, p. 49–73.

(g): Commission Regulation (EU) No 51/2014 of 20 January 2014 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimethomorph, indoxacarb and pyraclostrobin in or on certain products. OJ L 16, 21.1.2014, p. 13–27.

(h): Commission Regulation (EU) No 737/2014 of 24 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, chlormequat, cyflufenamid, cyfluthrin, dicamba, flupicinol, flutriafol, fenoxycarb, indoxacarb, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picloram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products. OJ L 192, 13.7.2013, p. 39–71.

(i): Commission Regulation (EU) No 491/2014 of 5 May 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chlorothalonil, dicamba, difenoconazole, difenconazole, fenbuconazole, fenfural, glufosinate-ammonium, imidacloprid, indoxacarb, MCPA, methoxyfenozide, penthiopyrad, piperonyl butoxide, prosulfocarb and trifloxystrobin in or on certain products. OJ L 192, 13.7.2013, p. 39–71.

(j): Commission Regulation (EU) 2015/845 of 27 May 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, chlorantraniliprole, cyrantraniliprole, dicamba, difenoconazole, fenpyroximate, fludioxonil, glufosinate-ammonium, imazapyr, imazapyr, indoxacarb, isoxaflutole, mandipropamid, penthiopyrad, propiconazole, pyrinethiol, spirotetramat and trinexapac in or on certain products. OJ L 138, 4.6.2015, p. 1–69.
The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011.

As the basis for this targeted assessment, EFSA performed a preliminary risk assessment considering the new toxicological reference values derived by EFSA in the framework of the renewal for the approval of the active substance (EFSA, 2018a), the MRLs and risk assessment values derived from the import tolerances assessed in the MRL review (EFSA, 2011), as well as all the CXLs and risk assessment values derived by the JMPR and covered by the MRLs implemented in the EU Legislation. In this preliminary assessment, the residue definitions for enforcement and risk assessment as derived during the MRL review were considered. In line with the terms of reference of the mandate existing MRLs based on EU uses and derived in the framework of the MRL review and in consequent MRL assessments were not considered, assuming that all European uses will be withdrawn.

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019). All input values considered in the risk assessment are reported in Appendix A to this reasoned opinion while the results of the calculations are reported under Appendices B and C.

According to the results of the preliminary risk assessment (scenario 1), the highest chronic exposure was calculated for the Dutch toddler, representing 128% of the ADI. Main contributors of the exposure were apples (45%), milk (44%) and pears (18%). Regarding the acute exposure, concerns were identified for 20 existing MRLs derived from CXLs and/or import tolerances (apples, pears, apricots, cherries, peaches, plums, table and wine grapes, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower, lettuce) with exposure exceeding up to 2,188% of the ARFD. The ARFD was not exceeded for the existing MRLs based on CXLs/import tolerance for cranberries, potatoes, sweet corn, basil, dry beans, dry peas, peanuts, soya beans, cotton seed, tea, milk, swine, ruminants and poultry tissues and eggs. It should be noted that no acute consumption data is included in PRIMo 3.1 for cotton seeds and therefore it was not possible to calculate the exposure for this commodity. Nevertheless, due to the low relevance of cotton seeds in European diets, residues in this commodity at the level of the existing MRL (1 mg/kg) are not expected to pose an unacceptable risk for European consumers.

Following preliminary risk assessment, as a second step, Member States and the United Kingdom were requested to submit by 7 April 2022 information about Good Agricultural Practices authorised in third countries and already evaluated at Member State level, which might support setting of fall-back import tolerance for the commodities of concern or any additional data allowing to refine the risk assessment. In parallel, the EURLs were invited to provide an Evaluation Report on the availability of analytical methods for enforcement and the LOQ achievable during routine analysis. In response to the data call, no fall-back Good Agricultural Practice (GAP) nor additional data were submitted by the Member States nor the UK while the EURLs provided the requested information confirming that for the enforcement of indoxacarb in plant and animal matrices the default LOQ of 0.01 mg/kg is achievable during routine analysis (EURs, 2022).

A second exposure calculation (scenario 2) was therefore performed replacing the risk assessment values for the commodities of concern identified in the first scenario with the LOQ of 0.01 mg/kg in the calculation. According to the results of this calculation, the highest chronic exposure declined to 53% of the ADI (Dutch toddler) and the highest acute exposure was calculated for basil, representing 99% of the ARFD.

In addition, to support risk managers in the decision-making process, the LOQ for all the commodities for which no CXLs nor import tolerances are in place were screened, confirming that the default LOQ of 0.01 mg/kg is sufficiently protective for consumers.

EFSA notes that, although according to the internationally agreed methodology for acute risk assessment (which is based on the highest residue found in the supervised field trials) no acute consumer intake concerns were identified in the second calculation, for the uses on basil, cattle milk and meat (swine, bovine and sheep) the safety margin for acute exposure is narrow. If these commodities contain residues at the existing MRLs, an exceedance of the ARFD cannot be excluded as the calculated acute exposure accounts for 219%, 248% and up to 484% of the ARFD, respectively.

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7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
8 The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.
Furthermore, EFSA highlights that the current residue definitions for enforcement and risk assessment were considered in this assessment, in line with the terms of reference. However, during the peer review for the renewal of the approval of indoxacarb, additional metabolites were also included provisionally in the residue definition for risk assessment for processed commodities, for milk, poultry tissues and eggs pending additional information on their levels and their toxicological profile. The additional uncertainties associated with these data gaps may be particularly relevant for commodities for which a narrow safety margin was noted (basil and milk). For milk the calculated consumer exposure might be underestimated, given that the additional metabolite proposed for inclusion in the residue definition for risk assessment was identified in the metabolism study at up to 29% of the total radioactive residues. Regarding basil, there is a high level of uncertainty due to the absence of data on the magnitude and toxicity of residues potentially formed during processing, as well as on the consumption data of processed basil.

Conclusions and recommendations

Based on the assessment performed it is concluded that the existing MRLs covering CXLs/import tolerance for cranberries, potatoes, sweet corn, basil, dry beans, dry peas, peanuts, soya beans, cotton seed, tea, milk, ruminants, swine and poultry tissues and eggs are not expected to pose an unacceptable risk for consumers, and therefore risk managers may consider maintaining these MRLs. Moreover, the default LOQ of 0.01 mg/kg is sufficiently protective for the remaining commodities.

EFSA highlights that this conclusion was reached based on the calculations performed according to the internationally agreed methodology and the current residue definitions, demonstrating that the uses under consideration will not result in consumer intake exceeding the ARfD. However, a narrow safety margin was noted. Hence, if residues of indoxacarb occur in basil, cattle milk and meat (swine, bovine and sheep) at the relevant existing MRL value, the dietary exposure of certain consumers may exceed the ARfD under certain conditions (i.e. consumption of a large portion of the product without washing/peeling/processing which would lead to a reduction of the residues in the product). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is sufficient, considering that residues in individual units/lot consumed at the proposed MRL might occur.

Moreover, during the peer review for the renewal of the approval of indoxacarb, additional metabolites which were not considered in this assessment, were included provisionally (pending additional information on their levels and their toxicological profile) in the residue definition for risk assessment for processed commodities, for milk, poultry tissues and eggs. Therefore, the additional uncertainties associated with these data gaps may need further attention by risk managers particularly for basil and milks for which a narrow safety margin was also noted.

Once additional data addressing the data gaps identified during the peer review would become available in the future, the conclusions from this assessment will need to be re-considered.

Furthermore, the information identified during the MRL Review as required for poultry tissue and eggs are still unavailable and therefore, they require further consideration by risk managers. In particular, these CXLs need to be confirmed by the following data:

- Further information on the nature and occurrence of the metabolite F in poultry tissues and eggs.

A summary of the MRL values and recommendations is provided in Table 2.

Table 2: Summary table

| Code number (a) | Commodity      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-----------------|----------------|-------------------------|----------------------|-----------------------|-----------------------|
| Enforcement residue definition: Indoxacarb (sum of indoxacarb and its R enantiomer) | | | | | |
| 154020          | Cranberries    | 1                       | 1                    | 1                     | Recommended(b)        |
| 211000          | Potatoes       | 0.02*                   | 0.02*                | 0.02                  | Recommended(b)        |
| 234000          | Sweet corn     | 0.02*                   | 0.02*                | 0.02                  | Recommended(b)        |
| 256080          | Basil          | 15                      | 15                   | 15                    | Further consideration needed(c) |
| 300010          | Beans (dry)    | 0.2                     | 0.2                  | 0.2                   | Recommended(b)        |
| Code number (a) | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|----------------|-----------|------------------------|---------------------|----------------------|---------|
| 300030         | Peas (dry)| 0.2                    | 0.2                 | 0.2                  | Recommended<sup>(b)</sup> |
| 401020         | Peanuts   | 0.02*                  | 0.02*               | 0.02                 | Recommended<sup>(b)</sup> |
| 401070         | Soya bean | 0.5                    | 0.5                 | 0.5                  | Recommended<sup>(d)</sup> |
| 401090         | Cotton seed| 1                     | 1                   | 1                    | Recommended<sup>(b)</sup> |
| 610000         | Teas      | 5                      | 5                   | 5                    | Recommended<sup>(b)</sup> |
| 1011010        | Swine muscle| 2                     | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1011020        | Swine fat (free of lean meat)| 2       | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1011030        | Swine liver| 0.05                  | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1011040        | Swine kidney| 0.05                | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1011050        | Swine edible offal| 0.05            | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1012010        | Bovine muscle| 2                     | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1012020        | Bovine fat | 2                      | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1012030        | Bovine liver| 0.05                  | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1012040        | Bovine kidney| 0.05              | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1012050        | Bovine edible offal| 0.05            | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1013010        | Sheep muscle| 2                     | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1013020        | Sheep fat | 2                      | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1013030        | Sheep liver| 0.05                  | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1013040        | Sheep kidney| 0.05                | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1013050        | Sheep edible offal| 0.05          | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1014010        | Goat muscle| 2                     | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1014020        | Goat fat | 2                      | 2                   | 2                    | Recommended<sup>(b)</sup> |
| 1014030        | Goat liver| 0.05                  | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1014040        | Goat kidney| 0.05                | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1014050        | Goat edible offal| 0.05          | 0.05                | 0.05                 | Recommended<sup>(b)</sup> |
| 1016010        | Poultry muscle| 0.01*              | 0.01*               | 0.01*                | Further consideration needed<sup>(e)</sup> |
| 1016020        | Poultry fat| 0.01*                 | 0.01*               | 0.01*                | Further consideration needed<sup>(e)</sup> |
| 1016030        | Poultry liver| 0.01*               | 0.01*               | 0.01*                | Further consideration needed<sup>(e)</sup> |
| 1016040        | Kidney    | 0.01*                  | 0.01*               | 0.01*                | Further consideration needed<sup>(e)</sup> |
| 1016050        | Edible offal| 0.01*               | 0.01*               | 0.01*                | Further consideration needed<sup>(e)</sup> |
| 1020010        | Cattle milk| 0.1                   | 0.1                 | 0.1                  | Further consideration needed<sup>(c)</sup> |
| 1020020        | Sheep milk | 0.1                   | 0.1                 | 0.1                  | Further consideration needed<sup>(c)</sup> |
| 1020030        | Goat milk | 0.1                   | 0.1                 | 0.1                  | Further consideration needed<sup>(c)</sup> |
| 1030000        | Eggs      | 0.02                   | 0.02                | 0.02                 | Further consideration needed<sup>(f)</sup> |
| –              | Other commodities of plant and/or animal origin | See Regulation 2015/845 | –                   | –                   | Further consideration needed<sup>(g)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): The existing EU MRL is based on a CXL; considering the current residue definitions for enforcement and risk assessment, the use was not identified as a potential MRL of concern and risk managers may consider maintaining this MRL.

c: The existing EU MRL is based on a CXL; considering the current residue definitions for enforcement and risk assessment, the use was not identified as a potential MRL of concern. However, risk managers should consider the narrow margin of safety and additional uncertainties related to data gaps identified during the peer review for the renewal when deciding on maintaining this MRL.

d: The existing EU MRL is based on a CXL which is the same as the MRL derived from an import tolerance; considering the current residue definitions for enforcement and risk assessment, the use was not identified as a potential MRL of concern and risk managers may consider maintaining this MRL.

e: The existing EU MRL was based on a GAP evaluated at EU level and covering the CXL, which is not sufficiently supported by data but for which considering the current residue definitions for enforcement and risk assessment, no risk to consumers is identified.

f: The existing EU MRL is based on a CXL which is not sufficiently supported by data; considering the current residue definitions for enforcement and risk assessment, the EU MRL was not identified as a potential MRL of concern.

g: The existing EU MRL was identified as a potential MRL of concern and/or was based on European uses expected to be withdrawn as indoxacarb is no longer approved for use in Europe, there are no relevant import tolerances reported at EU level and no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered by risk managers.

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Abbreviations

ADI acceptable daily intake
ARfD acute reference dose
bw body weight
CAC Codex Alimentarius Commission
CCPR Codex Committee on Pesticide Residues
CXL codex maximum residue limit
EURLs European Union Reference Laboratories for Pesticide Residues (former GC)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ISO International Organization for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LOQ limit of quantification
MRL maximum residue level
NEDI national estimated daily intake
NESTI national estimated short-term intake
NTMDI national theoretical maximum daily intake
OECD Organisation for Economic Co-operation and Development
PRIMo (EFSA) Pesticide Residues Intake Model
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TMDI theoretical maximum daily intake
WHO World Health Organization
## Appendix A – Input values for the exposure calculations

| Commodity                     | Existing EU MRL (mg/kg) | Chronic risk assessment | Acute risk assessment |
|-------------------------------|-------------------------|-------------------------|-----------------------|
|                               | Input value (mg/kg)     | Comment                 | Input value (mg/kg)   |
| Risk assessment residue definition: Indoxacarb (sum of indoxacarb and its R enantiomer) |
| Apples                        | 0.5                     | 0.21                    | 0.26                  |
|                               | 0.01*                   | STMR (FAO, 2005; EFSA, 2011) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2005; EFSA, 2011) (scenario 1) LOQ (scenario 2) |                     |
| Pears                         | 0.5(b)                  | 0.21                    | 0.26                  |
|                               | 0.01*                   | STMR (EFSA, 2011) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (EFSA, 2011) (scenario 1) LOQ (scenario 2) |                     |
| Apricots                      | 1                       | 0.17                    | 0.64                  |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Cherries                      | 1                       | 0.17                    | 0.64                  |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Peaches                       | 1                       | 0.17                    | 0.64                  |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Plums                         | 1                       | 0.17                    | 0.64                  |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Table and wine grapes         | 2                       | 0.32                    | 1.5                   |
|                               | 0.01*                   | STMR (FAO, 2005; EFSA, 2011) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2005; EFSA, 2011) (scenario 1) LOQ (scenario 2) |                     |
| Cranberries                   | 1                       | 0.15                    | 0.69                  |
|                               |                         | STMR (FAO, 2009) |                     |
|                               |                         | HR (FAO, 2009) |                     |
| Potatoes                      | 0.02*                   | 0.01                    | 0.01                  |
|                               |                         | STMR (FAO, 2005) |                     |
|                               |                         | HR (FAO, 2005) |                     |
| Tomatoes                      | 0.5                     | 0.11                    | 0.3                   |
|                               | 0.01*                   | STMR (FAO, 2005) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2005) (scenario 1) LOQ (scenario 2) |                     |
| Peppers                       | 0.3                     | 0.04                    | 0.21                  |
|                               | 0.01*                   | STMR (FAO, 2005) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2005) (scenario 1) LOQ (scenario 2) |                     |
| Aubergines (egg plants)       | 0.5                     | 0.11                    | 0.3                   |
|                               | 0.01*                   | STMR (FAO, 2005) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2005) (scenario 1) LOQ (scenario 2) |                     |
| Cucurbits with edible and inedible peel | 0.5 | 0.06 | 0.39 |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Sweet corn                    | 0.02*                   | 0.01                    | 0.012                 |
|                               |                         | STMR (FAO, 2005) |                     |
|                               |                         | HR (FAO, 2005) |                     |
| Flowering brassicas           | 0.2 (0.3)(c)            | 0.02                    | 0.14                  |
|                               | 0.01*                   | STMR (FAO, 2009) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (FAO, 2009) (scenario 1) LOQ (scenario 2) |                     |
| Lettuce                       | 3                       | 0.52                    | 1.6                   |
|                               | 0.01*                   | STMR (JMPR, 2012) (scenario 1) LOQ (scenario 2) | 0.01*             |
|                               |                         | HR (JMPR, 2012) (scenario 1) LOQ (scenario 2) |                     |
| Commodity                          | Existing EU MRL (mg/kg) | Input value (mg/kg) | Comment                        | Input value (mg/kg) | Comment                        |
|-----------------------------------|-------------------------|---------------------|--------------------------------|---------------------|--------------------------------|
| Basil                             | 15                      | 3.5                 | STMR (FAO, 2009)               | 6.8                 | HR (FAO, 2009)                 |
| Beans and peas (dry)              | 0.2                     | 0.02                | STMR (FAO, 2009)               | 0.02                | STMR (FAO, 2009)               |
| Peanuts                           | 0.02*                   | 0.01                | STMR (FAO, 2005)               | 0.01                | STMR (FAO, 2005)               |
| Soya bean                         | 0.5                     | 0.027               | STMR (FAO, 2005; EFSA, 2011)   | 0.027               | STMR (FAO, 2005; EFSA, 2011)   |
| Cotton seed                       | 1                       | 0.36                | STMR (FAO, 2005)               | 0.36                | STMR (FAO, 2005)               |
| Teas                              | 5                       | 0.41                | STMR (JMPR, 2013)              | 0.41                | STMR (JMPR, 2013)              |
| Swine-, bovine-, sheep-, goat meat (a) | 2                       | 0.08                | STMR (FAO, 2009)               | 0.25                | HR (FAO, 2009)                 |
| Swine-, bovine-, sheep-, goat fat | 2                       | 0.38                | STMR (FAO, 2009)               | 1.07                | HR (FAO, 2009)                 |
| Swine-, bovine-, sheep-, goat liver | 0.05                   | 0.014               | STMR (FAO, 2009)               | 0.03                | HR (FAO, 2009)                 |
| Swine-, bovine-, sheep-, goat kidney | 0.05                  | 0.014               | STMR (FAO, 2009)               | 0.03                | HR (FAO, 2009)                 |
| Swine-, bovine-, sheep-, goat edible offal | 0.05                   | 0.014               | STMR (FAO, 2009)               | 0.03                | HR (FAO, 2009)                 |
| Cattle-, sheep-, goat milk        | 0.1                     | 0.037               | STMR (FAO, 2009)               | 0.037               | STMR (FAO, 2009)               |

**Risk assessment residue definition: sum of indoxacarb, its R enantiomer and IN-JT333, expressed as indoxacarb**

| Commodity                          | Input value (mg/kg) | Comment                        | Input value (mg/kg) | Comment                        |
|-----------------------------------|---------------------|--------------------------------|---------------------|--------------------------------|
| Poultry: Muscle/meat (b)          | 0.01*               | 0.01                           | STMR (FAO, 2009)    | 0.01                           | HR (FAO, 2009)                 |
| Poultry: Fat tissue               | 0.01*               | 0.025                          | STMR (FAO, 2009)    | 0.05                           | HR (FAO, 2009)                 |
| Poultry: Liver                    | 0.01*               | 0.01*                          | STMR (FAO, 2009)    | 0.01*                          | HR (FAO, 2009)                 |
| Poultry: Kidney                   | 0.01*               | 0.01*                          | STMR (FAO, 2009)    | 0.01*                          | HR (FAO, 2009)                 |
| Poultry: Edible offal             | 0.01*               | 0.01*                          | STMR (FAO, 2009)    | 0.01*                          | HR (FAO, 2009)                 |
| Eggs                              | 0.02                 | 0.01                           | STMR (FAO, 2009)    | 0.02                           | HR (FAO, 2009)                 |

STMR: median residue levels in the raw agricultural commodities.
HR: the highest residue levels in the raw agricultural commodities.
*: Indicates that the MRL/input value is proposed at the limit of quantification.
(a): Consumption figures in the EFSA PRIMo are expressed as meat. Since the active substance is fat-soluble, residue values were calculated considering a 80% muscle and 20% fat content for mammalian meat, and 90% muscle and 10% fat content for poultry muscle (FAO, 2016).
(b): A CXL exists which is lower than the existing MRL but for which a risk for consumers is also identified.
(c): The current MRL of 0.3 mg/kg reported into parentheses was based on an EU GAP. Therefore, the existing CXL of 0.2 mg/kg was considered in the preliminary risk assessment.
Appendix B – Consumer risk assessment

ARfD

Highest IESTI, according to EFSA PRIMo (3.1)

| % ARfD | Preliminary risk assessment (scenario 1): |
|--------|------------------------------------------|
|        | Table grapes: 2188% of ARfD              |
|        | Lettuces: 1218% of ARfD                   |
|        | Peaches: 1216% of ARfD                    |
|        | Melons: 1183% of ARfD                     |
|        | Watermelons: 954% of ARfD                 |
|        | Pears: 720% of ARfD                       |
|        | Apples: 560% of ARfD                      |
|        | Plums: 539% of ARfD                       |
|        | Cucumbers: 511% of ARfD                   |
|        | Apricots: 448% of ARfD                    |
|        | Courgettes: 363% of ARfD                  |
|        | Tomatoes: 349% of ARfD                    |
|        | Wine grapes: 278% of ARfD                 |
|        | Sweet peppers/bell peppers: 250% of ARfD |
|        | Pumpkins: 208% of ARfD                    |
|        | Gherkins (pickled): 179% of ARfD          |
|        | Cauliflower: 162% of ARfD                 |
|        | Cherries: 157% of ARfD                    |
|        | Aubergines: 150% of ARfD                  |
|        | Broccoli: 116% of ARfD                    |
|        | Basil: 99% of ARfD                        |
|        | Milk: up to 92% of ARfD (cattle)           |
|        | Cranberries: 62% of ARfD                  |
|        | Meat: up to 61% of ARfD (swine)            |
|        | Fat: up to 45% of ARfD (cattle)            |
|        | Potatoes: 31% of ARfD                     |
|        | Tea: 13% of ARfD                           |
|        | Sweet corn: 10% of ARfD                   |
|        | Beans, dry: 7% of ARfD                    |
|        | Liver: up to 5% of ARfD (cattle)           |
|        | Eggs: up to 5% of ARfD                    |
|        | Peas, dry: 3% of ARfD                     |
|        | Kidney: up to 2% of ARfD (cattle)          |
|        | Peanuts: 0.6% of ARfD                     |
|        | Soya bean: 1% of ARfD                     |
|        | Cotton seed: -                            |

NESTI (% ARfD)

| % ARfD |
|--------|
|        |

Second risk assessment (scenario 2):

Up to 99% of ARfD (basil)

NESTI (% ARfD)

Not assessed in this review.
Assumptions made for the calculations

| Preliminary risk assessment (scenario 1): |
|------------------------------------------|
| The calculation is based on the highest residue levels in the raw agricultural commodities, except for bulk commodities where the median residue levels were considered. The contributions of commodities where no CXL or import tolerance was reported were not included in the calculation. |

| Second risk assessment (scenario 2): |
|-------------------------------------|
| The same calculation as in scenario 1, except for the commodities of concern, for which the highest/median residue levels were replaced by the LOQ of 0.01 mg/kg. |

| ARID: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; IESTI: international estimated short-term intake. |

| ADI |
|-----|
| Not assessed in this review. |

| TMDI according to EFSA PRIMo |
|-----------------------------|
| Not assessed in this review. |

| NTMDI, according to (to be specified) |
|---------------------------------------|
| Not assessed in this review. |

| Highest IEDI, according to EFSA PRIMo (rev.3.1) |
|-----------------------------------------------|
| Not assessed in this review. |

| NEDI (% ADI) |
|--------------|
| Not assessed in this review. |

Assumptions made for the calculations

| Preliminary risk assessment (scenario 1): |
|------------------------------------------|
| The calculation is based on the median residue levels in the raw agricultural commodities for which an import tolerance and/or CXL was available. The contributions of other commodities were not included in the calculation. |

| Second risk assessment (scenario 2): |
|-------------------------------------|
| The same calculation as in scenario 1, except for the commodities of concern, for which the median residue levels were replaced by the LOQ of 0.01 mg/kg. |

| ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake. IEDI: international estimated daily intake. |

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003)

| Metabolite(s) |
|---------------|
| Not assessed in this review. |

| ADI (mg/kg bw per day) |
|------------------------|
| Not assessed in this review. |

| Intake of groundwater metabolites (% ADI) |
|------------------------------------------|
| Not assessed in this review. |
Appendix C – Pesticide Residue Intake Model (PRIMo)

**PRIMo (scenario 1)**

- **LOQs (mg/kg)** range from: 0.01 to: 0.02
- **ADI (mg/kg bw per day)**: 0.005
- **ARfD (mg/kg bw)**: 0.005
- **Source of ADI**: EFSA
- **Source of ARfD**: EFSA

EFSA PRIMo revision 3.1; 2021/01/06

Year of evaluation: 2018

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Pears                          | 128%                              | 91%                                           |
| Table grapes                   | 64%                               | 45%                                           |
| Bovine: Muscle/meat            | 45%                               | 22%                                           |
| Table grapes                   | 43%                               | 18%                                           |
| Table grapes                   | 41%                               | 13%                                           |
| Table grapes                   | 39%                               | 11%                                           |
| Table grapes                   | 37%                               | 9%                                            |
| Table grapes                   | 35%                               | 7%                                            |
| Table grapes                   | 34%                               | 5%                                            |
| Table grapes                   | 32%                               | 3%                                            |
| Table grapes                   | 30%                               | 1%                                            |
| Table grapes                   | 26%                               | 1%                                            |
| Table grapes                   | 25%                               | 1%                                            |
| Table grapes                   | 24%                               | 1%                                            |
| Swine: Muscle/meat             | 22%                               | 1%                                            |
| Apples                         | 18%                               | 1%                                            |
| Swine: Muscle/meat             | 16%                               | 1%                                            |
| Apples                         | 15%                               | 1%                                            |
| Apples                         | 11%                               | 1%                                            |
| Apples                         | 9%                                | 1%                                            |
| Apples                         | 7%                                | 1%                                            |
| Apples                         | 6%                                | 1%                                            |
| Apples                         | 4%                                | 1%                                            |
| Apples                         | 3%                                | 1%                                            |
| Apples                         | 2%                                | 1%                                            |
| Apples                         | 1%                                | 1%                                            |

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Input values

Details – chronic risk assessment/children
Details – acute risk assessment/children
Details – acute risk assessment/adults

**Conclusion:**

The estimated TMDI/IEDI was in the range of 0 % to 128.4 % of the ADI.

For 1 diet(s) the ADI is exceeded.

DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

www.efsa.europa.eu/efsajournal
| Commodity                        | MRL/input (mg/kg) | Exposure (µg/kg bw) |
|--------------------------------|-------------------|--------------------|
| Table grapes                   | 2/1.5             | 109                |
| Lettuces                        | 0.5/0.39          | 38                 |
| Pears                           | 0.5/0.26          | 36                 |
| Apples                          | 0.5/0.26          | 28                 |
| Plums                           | 1/0.64            | 27                 |
| Cucumbers                       | 0.5/0.39          | 26                 |
| 44% Apple juice                 | 1/0.64            | 22                 |
| 12% Gherkins/pickled            | 0.5/0.39          | 14                 |
| 22% Broccoli/boiled             | 0.2/0.14          | 11                 |
| 20% Pumpkins                    | 0.5/0.39          | 10                 |
| 69% Pumpkins/boiled             | 0.5/0.39          | 36                 |
| 33% Pear/raisin                 | 0.5/0.39          | 28                 |
| 27% Wine/raisin                 | 0.5/0.39          | 14                 |
| 27% Courgettes/boiled           | 0.5/0.39          | 14                 |
| 22% Apple/raisin                | 0.5/0.39          | 11                 |
| 22% Broccoli/boiled             | 0.2/0.14          | 11                 |
| 19% Cauliflower/boiled          | 0.5/0.39          | 9.0                |
| 36% Wine/raisin                 | 0.5/0.39          | 14                 |
| 27% Gherkins/pickled            | 0.5/0.39          | 14                 |
| 22% Apple/raisin                | 0.5/0.39          | 11                 |
| 20% Tomato/raisin/sauce/puree   | 0.5/0.39          | 11                 |
| 19% Pear/raisin                 | 0.5/0.39          | 11                 |
| 17% Cauliflower/boiled          | 0.5/0.39          | 10                 |

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 19 commodities. For processed commodities, the toxicological reference value was exceeded in one or several cases.
Targeted review of maximum residues levels (MRLs) for indoxacarb

**Normal mode**

**Input values**

**Supplementary results – chronic risk assessment**

**Details – acute risk assessment/adults**

**Details – acute risk assessment/children**

**Conclusion:** The long-term intake of residues of indoxacarb is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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**The toxicological reference values**

| Input values | 0.01 | LOQs (mg/kg) range from: | 0.02 |
|--------------|------|-------------------------|------|
| indoxacarb   |      |                         |      |

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Calculation of residues and exposure**

| Commodity/ group of commodities | MS Diet | % of ADI | Highest contributor to MS diet | % of ADI | 2nd contributor to MS diet | % of ADI | 3rd contributor to MS diet | % of ADI |
|--------------------------------|---------|----------|-------------------------------|----------|---------------------------|----------|----------------------------|----------|
| Bovine: Muscle/meat            | 1.07    | 44%      | 1.07 Bovine: Muscle/meat       | 0.07     | 0.7%                      |          |                            |          |
| NL toddler                     | 1.06    | 2%       | 1.06 Bovine: Muscle/meat       | 0.01     | 0.5%                      |          |                            |          |
| FR toddler 2-3 yr              | 1.05    | 2%       | 1.05 Bovine: Muscle/meat       | 0.00     | 0.1%                      |          |                            |          |
| NL child                       | 1.02    | 2%       | 1.02 Bovine: Muscle/meat       | 0.00     | 0.2%                      |          |                            |          |
| DE child                       | 1.00    | 2%       | 1.00 Bovine: Muscle/meat       | 0.00     | 0.1%                      |          |                            |          |

**Exposure exceeding the ADI:**

**LOQs (mg/kg) range from:**

0.02 to:

0.005

**Toxicological reference values**

| Toxicological reference values | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|--------------------------------|------------------------|-----------------|
| Source of ADI                  | 0.005                  | 0.005           |
| Source of ARfD                 |                        |                 |

**Year of evaluation:**

EFSA PRIMo revision 3.1; 2021/01/06

**Comments:**

Normal mode

**Details:**

**Input values**

**Supplementary results – chronic risk assessment**

**Details – acute risk assessment/adults**

**Details – acute risk assessment/children**

**Conclusion:**

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

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
### Targeted review of maximum residues levels (MRLs) for indoxacarb

**Acute risk assessment / children**

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

#### Results for children

| No. of commodities for which ARfD/ADI is exceeded (ESTI): | — |
|----------------------------------------------------------|---|
| **Highest % of ARfD/ADI** | **Commodities** | **MRL/input for RA (mg/kg)** | **Exposure (µg/kg bw)** |
| 99% | Basil and edible flowers | 15/6.8 | 5.0 |
| 92% | Milk: Cattle | 0.1/0.04 | 4.6 |
| 62% | Cranberries | 1/0.69 | 3.1 |
| 61% | Salami/Muscle/meat | 2/0.25 | 3.0 |
| 48% | Beans | 0.2/0.13 | 2.4 |
| 45% | Beef: Fat tissue | 2/0.07 | 2.2 |
| 36% | Beef: Muscle/meat | 2/0.25 | 1.8 |
| 36% | Potatoes | 0.02/0.01 | 1.5 |
| 30% | Melons | 0.0/0.01 | 1.0 |
| 27% | Peaches | 0.01/0.01 | 0.95 |
| 24% | Apples | 0.01/0.01 | 0.89 |
| 22% | Apples | 0.01/0.01 | 0.87 |
| 19% | Potatoes/chips | 0.01/0.01 | 0.93 |
| 18% | Pumpkins/boiled | 0.01/0.01 | 0.89 |
| 17% | Cranberries/juice | 1/0.15 | 1.0 |
| 16% | Broccoli/boiled | 0.01/0.01 | 0.70 |
| 14% | Cauliflower/boiled | 0.01/0.01 | 0.70 |
| 12% | Potatoes/boiled (fries) | 0.02/0.05 | 0.59 |
| 11% | Apples/juice | 0.01/0.01 | 0.54 |
| 9% | Wine grapes/juice | 0.01/0.01 | 0.44 |
| 7% | Courgettes/boiled | 0.01/0.01 | 0.35 |
| 7% | Peaches | 0.01/0.01 | 0.33 |
| 5% | Peaches | 0.01/0.01 | 0.26 |
| 4% | Tomatoes/juice | 0.01/0.01 | 0.19 |
| 3% | Peaches | 0.01/0.01 | 0.17 |

#### Details – acute risk assessment / adults

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of indoxacarb is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.

#### Total number of commodities exceeding the ARfD/ADI in children (ESTI calculated):

| No. of commodities for which ARfD/ADI is exceeded (ESTI): | — |
|----------------------------------------------------------|---|
| **Highest % of ARfD/ADI** | **Commodities** | **MRL/input for RA (mg/kg)** | **Exposure (µg/kg bw)** |
| 19% | Potatoes/fried | 0.02/0.01 | 0.93 |
| 19% | Peas/canned | 0.2/0.05 | 0.93 |
| 18% | Pumpkins/boiled | 0.01/0.01 | 0.89 |
| 17% | Cranberries/juice | 1/0.15 | 1.0 |
| 16% | Broccoli/boiled | 0.01/0.01 | 0.70 |
| 14% | Cauliflower/boiled | 0.01/0.01 | 0.70 |
| 12% | Potatoes/boiled (fries) | 0.02/0.05 | 0.59 |
| 11% | Apples/juice | 0.01/0.01 | 0.54 |
| 9% | Wine grapes/juice | 0.01/0.01 | 0.44 |
| 7% | Courgettes/boiled | 0.01/0.01 | 0.35 |
| 7% | Peaches | 0.01/0.01 | 0.33 |
| 5% | Peaches | 0.01/0.01 | 0.26 |
| 4% | Tomatoes/juice | 0.01/0.01 | 0.19 |
| 3% | Peaches | 0.01/0.01 | 0.17 |

#### Details – acute risk assessment / adults

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of indoxacarb is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Used compound codes

| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|--------------------------------------------------|---------------------------------|
| **indoxacarb**<br>DPX-KN128    | methyl (S)-7-chloro-2,3,4a,5-tetrahydro-2-<br>{(methoxycarbonyl)[4-(trifluoromethoxy)<br>phenyl]carbamoyl}indenono[1,2-e][1,3,4]oxadiazine-<br>4a-carboxylate<br>FC(F)(F)Oc1ccc(cc1)N(C(=O)OC)C(=O)N1N=C2c3ccc(C)cC@@(OC1)C(=O)OC<br>VBCVMZEGZULK-NRFANRFHSAN | ![Structural formula](image1.png) |
| **IN-JT333**                   | methyl (4aR)-7-chloro-2-{[4-(trifluoromethoxy)<br>phenyl]carbamoyl}-2,5-dihydroindenono[1,2-e][1,3,4]<br>oxadiazine-4a(3H)-carboxylate<br>FC(F)(F)Oc1ccc(cc1)NC(=O)N2N=C3c4ccc(Cl)cc4C<br>[C@]3(OC2)C(=O)OC | ![Structural formula](image2.png) |
| **IN-VRN79** (Metabolite "F") | Structure currently unknown. | ![Structural formula](image3.png) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup>: The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 Jul 2021).

<sup>(c)</sup>: ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 Aug 2021).