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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for indoxacarb in or on certain products

Delegations will find attached document D(2023)87938.

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Brussels, **XXX**
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[...] (2023) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for indoxacarb in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for indoxacarb in or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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/EEC¹, and in particular Article 14(1), point (a), and Article 18(1), point (b) thereof,

Whereas:

- (1) For the active substance indoxacarb, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of the procedure for the renewal of the approval of indoxacarb in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council², the European Food Safety Authority ('the Authority') published a conclusion on the peer review of the risk assessment of that active substance³, establishing a lower acceptable daily intake ('ADI') and a lower acute reference dose ('ARfD').
- (3) The approval of the active substance indoxacarb expired on 19 December 2021 and was non-renewed⁴. All authorisations for plant protection products containing that active substance have been revoked.
- (4) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion on the risks that the current MRLs for indoxacarb based on import tolerances and Codex maximum residue limits ('CXLs') may pose to consumers in light of the lower ADI and ARfD. In its reasoned opinion⁵, the Authority identified unacceptable risks concerning the current MRLs based on CXLs for apples, pears, apricots, cherries, peaches, plums, table and wine

¹ OJ L 70, 16.3.2005, p. 1.

² Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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).

³ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. EFSA Journal 2018;16(1):5140.

⁴ Commission Implementing Regulation (EU) 2021/2081 of 26 November 2021 concerning the non-renewal of approval of the active substance indoxacarb, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 426, 29.11.2021, p. 28).

⁵ European Food Safety Authority; Targeted review of maximum residues levels (MRLs) for indoxacarb. EFSA Journal 2022;20(8):7527.

grapes, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflower and lettuce. Therefore, MRLs for these products should be lowered to the relevant limit of determination (LOD) in Annex II to Regulation (EC) No 396/2005.

- (5) Furthermore, in its conclusion⁶ on the peer review published in the context of the procedure for the renewal of the approval of indoxacarb, the Authority explained that, due to insufficient data on the toxicity and genotoxicity of various metabolites and degradation products formed during processing at high temperature, risks for human health could not be excluded. Therefore, further decision by risk managers was needed. For products that are usually processed at high temperature, the MRLs based on CXLs cannot be confirmed as being safe for consumers. This concerns the MRLs for basil, potatoes, sweet corn, beans (dry), peas (dry), peanuts, soya beans, cotton seeds, as well as for fat, liver, kidney and edible offal of swine, bovine, sheep, goat and equine, for poultry tissues, milks and eggs. Therefore, MRLs for these products should be lowered to the relevant LOD in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. For products that are usually not processed at high temperature, and thus for which those metabolites and degradation products would not be formed, existing MRLs based on CXLs can be maintained. This concerns the MRLs for cranberries and teas. Therefore, the MRLs for cranberries and teas should be maintained in Annex II to Regulation (EC) No 396/2005. Additionally, as the MRLs on apples, broccoli, cauliflowers, rucola, baby leaf crops, poultry tissues and eggs are set at the product specific LODs, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.
- (6) As regards products for which no import tolerances or CXLs exist, MRLs should be set at the product specific LOD or the default MRL should apply, as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.
- (7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product specific LODs that are analytically achievable.
- (8) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (9) Annexes II and V to Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the modification of the MRLs.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

⁶ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance indoxacarb. EFSA Journal 2018;16(1):5140.

Article 1

Annex II to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [*Office of publications: please insert date 6 months after the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN