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COVER NOTE

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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 11 August 2021 |
| To: | Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union |

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| No. Cion doc.: | D071924/04 |
| Subject: | COMMISSION REGULATION (EU) .../... of XXX 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 imidacloprid in or on certain products |

Delegations will find attached document D071924/04.

Encl.: D071924/04



Brussels, **XXX**
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(POOL/E4/2020/10118/10118-EN.docx)
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[...](2021) **XXX** draft

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

of **XXX**

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 imidacloprid in or on certain products

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

of **XXX**

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 imidacloprid in or on certain products

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/EEC⁽¹⁾, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) Maximum residue levels (MRLs) for imidacloprid were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority ("the Authority") submitted a reasoned opinion on the review of the existing MRLs for imidacloprid in accordance with Article 12(1) of Regulation (EC) No 396/2005⁽²⁾. The Authority recommended setting the residue definition as imidacloprid only. It identified a risk for consumers concerning the MRLs for escaroles/broad-leaved endives. It is therefore appropriate to lower this MRL to the specific limit of determination (LOD). The Authority recommended lowering the MRLs for pecans, bananas, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, gherkins, courgettes and products of animal origin. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (3) The Authority concluded that concerning the MRLs for citrus fruits, grapes, blueberries, cranberries, okra/lady's fingers, cucurbits with inedible peel, beans (with and without pods), peas (with and without pods), beans, peanuts/groundnuts, coffee beans and hops, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should also be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within one year from the publication of this Regulation.
- (4) Existing Codex maximum residue limits (CXLs) were taken into account in the reasoned opinions of the Authority. Concerning the CXLs, the Authority concluded that they are not compatible with the EU residue definition and recommended not to include the existing CXLs in Annex II to Regulation (EC) No 396/2005. It is therefore appropriate to set those MRLs to the level identified by the Authority.

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for imidacloprid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5570.

- (5) As regards products on which the use of the plant protection product concerned is not authorised, and for which no import tolerances or CXLs exist, MRLs should be set at the specific LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (6) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. Those laboratories concluded that for certain commodities technical development requires the setting of specific LODs.
- (7) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (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) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (11) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (12) The approval of imidacloprid expired on 1 December 2020³. Any grace periods that may have been granted by Member States will expire on 1 June 2022. A further review of maximum residue levels is envisaged after that date.
- (13) 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:

Article 1

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

As regards the active substance imidacloprid in and on all products except escaroles, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products, which were produced in the Union or imported into the Union before [*Office of Publication: please insert date 6 months after entry into force*].

Article 3

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

³ OJ L 370, 6.11.2020, p. 18–20

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

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