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## **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 isopyrazam in or  
on certain products**

(Text with EEA relevance)

# 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 isopyrazam 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/EEC<sup>1</sup>, and in particular Article 14(1), point (a), and Article 49(2) thereof,

Whereas:

- (1) For the active substance isopyrazam maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The approval of the active substance isopyrazam was withdrawn by Commission Implementing Regulation (EU) 2022/782<sup>2</sup>. All authorisations for plant protection products containing isopyrazam have been revoked.
- (3) The European Food Safety Authority (the 'Authority') submitted a reasoned opinion on the review of the existing MRLs for isopyrazam in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>3</sup>. The Authority proposed to change the residue definition to isopyrazam (sum of isomers). The Commission considers this new residue definition to be appropriate.
- (4) The MRLs for isopyrazam in or on azaroles/Mediterranean medlars, kaki/Japanese persimmons, sweet peppers/bell peppers, peanuts, barley, muscle, fat, liver and kidney of swine, bovine, sheep, goat and equine, milk of cattle, sheep, goat and horse, and birds' eggs result from the implementation of Codex MRLs ('CXLs'), which the Authority has confirmed as safe for consumers. Those MRLs should therefore be maintained and set in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

<sup>2</sup> Commission Implementing Regulation (EU) 2022/782 of 18 May 2022 withdrawing the approval of the active substance isopyrazam 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, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Implementing Regulation (EU) No 1037/2012 (OJ L 140, 19.5.2022, p. 3, ELI: [http://data.europa.eu/eli/reg\\_impl/2022/782/oj](http://data.europa.eu/eli/reg_impl/2022/782/oj)).

<sup>3</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for isopyrazam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(7):6684.

- (5) The MRLs for isoprazam in or on pome fruits, carrots, tomatoes, aubergines/eggplants, cucumbers, melons, rapeseeds/canola seeds, rye and wheat were based on uses in the Union which are no longer authorised. There are CXLs for those products, which the Authority has confirmed as safe for consumers. The MRLs for those products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels of the CXLs in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.
- (6) The Authority concluded that the MRL set for isoprazam in or on bananas was derived from import tolerance, which was supported by data and is considered safe for consumers. However, the calculation methodology to calculate MRLs has been changed since the MRL was first set for bananas, resulting in a higher MRL. The MRL for bananas should therefore be set in Annex II to Regulation (EC) No 396/2005 at that new higher level in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.
- (7) For all other products, as the MRLs were based on uses in the Union which are no longer authorised and there are no CXL or import tolerances, it is appropriate to lower the MRLs and set the MRLs in Annex II to Regulation (EC) No 396/2005 to product-specific limit of determination ('LOD') in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a) thereof.
- (8) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. Those laboratories proposed product-specific LODs that are analytically achievable.
- (9) 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.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been placed on the market before the new MRLs become applicable and for which a high level of consumer protection is maintained.
- (12) 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.
- (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*

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which have been placed on the market in the Union before

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

### *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*.

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*