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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 3 April 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: D102375/03

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 acetamiprid in or on certain products

Delegations will find attached document D102375/03.

Encl.: D102375/03



Brussels, **XXX**
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D102375/03
[...] (2025) **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 acetamiprid 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 acetamiprid 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), thereof,

Whereas:

- (1) For the active substance acetamiprid, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) Applications pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting modifications of the existing MRLs for acetamiprid were submitted for plums, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, and "honey and other apiculture products".
- (3) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, those applications were evaluated by the Member State concerned and the evaluation reports were forwarded to the Commission. The Commission forwarded the applications, the evaluation reports and the supporting dossiers to the European Food Safety Authority (the 'Authority').
- (4) In accordance with Article 10 of Regulation (EC) No 396/2005, the Authority assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the requested MRLs². It forwarded those reasoned opinions to the applicants, the Commission and the Member States and made them available to the public.
- (5) The Authority concluded that, for plums, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, and "honey and other apiculture products", the requested modifications to the MRLs were acceptable with regard to consumer safety.

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

² European Food Safety Authority; Reasoned opinion on the modification of the existing maximum residue level for acetamiprid in various crops. EFSA Journal 2021;19(9):6830.
European Food Safety Authority; Reasoned opinion on the modification of the existing maximum residue levels for acetamiprid in honey and various oilseed crops; EFSA Journal. 2022;20(8):7535.

- (6) Furthermore, to ensure that the assessment of acetamiprid would reflect the current scientific knowledge, the Commission requested the Authority to provide a statement on the toxicological properties and MRLs of acetamiprid and its metabolites, on the basis of Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council³.
- (7) In its statement⁴, the Authority established a lower acceptable daily intake ('ADI') and a lower acute reference dose ('ARfD') for acetamiprid and included the metabolite IM-2-1 in the residue definition for the risk assessment of acetamiprid in fruit and leafy crops.
- (8) The Authority concluded that the requested modifications to the MRLs for plums, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, and "honey and other apiculture products", were acceptable with regard to consumer safety taking into account the new ARfD, ADI and residue definition for risk assessment. Neither the lifetime exposure to acetamiprid via consumption of all food products that may contain it nor the short-term exposure due to high consumption of the relevant products showed a risk that the ADI or the ARfD is exceeded.
- (9) Based on the opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the requested modifications to the MRLs for plums, linseeds, poppy seeds, mustard seeds, gold of pleasure seeds, and "honey and other apiculture products" are acceptable.
- (10) On 30 November 2024, the Codex Alimentarius Commission adopted a new Codex maximum residue limit (CXL) for acetamiprid in soyabean⁵.
- (11) In accordance with Article 5(3) of Regulation (EC) No 178/2002 where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of the Union food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with Article 13, point (e), of that Regulation, the Union is to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.
- (12) The Authority assessed the risks to consumers and produced a scientific report⁶. It confirmed that the CXL for acetamiprid in soyabean is safe for consumers in the Union.

³ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁴ European Food Safety Authority; Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites; EFSA Journal. 2024;22:e8759.

⁵ Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Forty-seventh Session, CICG, Geneva, Switzerland, 25-30 November 2024. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-47%252FFINAL%252FBREPORT%252FREPP24_CACe.pdf.

⁶ European Food Safety Authority; Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal. 2024;22:e8841.

- (13) Based on the scientific report of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the MRL for acetamiprid in soyabean, previously set at 0.01*mg/kg as a Limit of Determination, should be set at the level of the CXL of 0.01 mg/kg in Annex II to that Regulation.
- (14) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (15) 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

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*.

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