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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 October 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.:	D099962/02
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 D099962/02.

Encl.: D099962/02



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2024/1403 Rev. 1
(POOL/E4/2024/1403/1403R1-EN.docx)
D099962/02
[...](2024) **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) The Commission requested the European Food Safety Authority ('the Authority') to provide a statement on the toxicological properties and MRLs of acetamiprid and its metabolites, in line with Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council².
- (3) In its statement³, 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.
- (4) The Authority identified an exceedance of the ARfD with the MRLs for currants, bananas, lettuces, escaroles/ broad-leaved endives, spinaches, and chards/beet leaves. The Authority consulted the Member States and requested them to report potential fall-back Good Agricultural Practices ('GAPs') authorised in Member States or third countries and already evaluated at Member State level that would not lead to an unacceptable risk for consumers. There were no fall-back GAPs reported. It is therefore appropriate to lower the MRLs for these commodities in Annex II to Regulation (EC) No 396/2005 to the relevant limit of determination ('LOD').

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

² 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. 1–24, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

³ European Food Safety Authority; Statement on the toxicological properties and maximum residue levels of acetamiprid and its metabolites; EFSA Journal. 2024;22:e8759.

- (5) The Authority further identified an exceedance of the ARfD with the MRLs for medlars, cherries, peaches, table and wine grapes, blackberries, raspberries, blueberries, cranberries, gooseberries, elderberries, table olives, tomatoes, aubergines, melons, pumpkins, watermelons, broccoli, cauliflowers, head cabbages, lamb's lettuce, roman rocket, red mustards, asparagus, bovine liver, and bovine other edible offals. The Authority consulted the Member States and requested them to report potential fall-back GAPs authorised in Member States or third countries and already evaluated at Member State level that would not lead to an unacceptable risk for consumers. Fall-back GAPs that do not lead to exceedances of the ARfD were reported for these commodities. It is therefore appropriate to lower the MRLs for these commodities in Annex II to Regulation (EC) No 396/2005 to the values proposed by the Authority.
- (6) The Authority also identified an exceedance of the ARfD with the MRLs for apples, pears, quinces, apricots, sweet peppers, cucumbers and courgettes. The Authority consulted the Member States and requested them to report potential fall-back GAPs authorised in Member States or third countries and already evaluated at Member State level that would not lead to an unacceptable risk for consumers. Fall-back GAPs that do not lead to exceedances of the ARfD, were reported for these commodities. However, as some information was not available, further consideration by risk managers was required. Therefore, while the MRLs for these commodities are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation. As there is no risk for consumers, it is appropriate to lower the MRLs for these commodities in Annex II to Regulation (EC) No 396/2005 to the values proposed by the Authority.
- (7) 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.
- (8) Annex II to Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (9) 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.
- (10) 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*.

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