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COVER NOTE

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

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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimoxystrobin, ethephon and propamocarb in or on certain products (Text with EEA relevance)

Delegations will find attached document D(2025) 100229.

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[...] (2025) XXX

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

of XXX

**amending Annexes II and V to Regulation (EC) No 396/2005 of the European
Parliament and of the Council as regards maximum residue levels for dimoxystrobin,
ethephon and propamocarb in or on certain products**

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dimoxystrobin, ethephon and propamocarb 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), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

- (1) For dimoxystrobin, ethephon and propamocarb, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance dimoxystrobin was not renewed by Commission Implementing Regulation (EU) 2023/1436². All existing authorisations for plant protection products containing that active substance have been revoked. No MRLs based on Codex maximum residue limits ('CXLs') or import tolerance requests exist for dimoxystrobin. It is therefore appropriate to delete the MRLs set out for that active substance 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. MRLs for all products should be set at the product-specific limit of determination ('LOD') in Annex V to that Regulation. In addition, as the MRLs on all products should be 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.
- (3) The approval of the active substance ethephon was renewed by Commission Implementing Regulation (EU) 2023/2591³. In the framework of the renewal of the approval of ethephon, the European Food Safety Authority (the 'Authority') on 31 January 2023 published a conclusion proposing to lower the existing acceptable

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

² Commission Implementing Regulation (EU) 2023/1436 of 10 July 2023 concerning the non-renewal of the approval of the active substance dimoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408 (OJ L 176, 11.7.2023, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2023/1436/oj).

³ Commission Implementing Regulation (EU) 2023/2591 of 21 November 2023 renewing the approval of the active substance ethephon in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2023/2591, 22.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2591/oj).

daily intake ('ADI') from 0.03 mg/kg to 0.02 mg/kg bodyweight per day. Consequently, the Authority was asked to review⁴ all MRLs for ethephon based on the lowered ADI. In addition, the Authority proposed a new residue definition for enforcement in cereals as "sum of ethephon free and conjugates, expressed as ethephon" instead of the currently applicable residue definition "ethephon". The Commission considers this new residue definition to be appropriate.

- (4) The MRLs for ethephon in walnuts, blueberries, pineapples barley, rye and wheat ⁵ are based on revoked CXLs and should be reconsidered. The Authority identified revised MRLs, except for blueberries for which no additional data is available. Therefore, it is appropriate to maintain the MRL for walnuts and to lower the MRL for pineapples in Annex II to Regulation (EC) No 396/2005. It also concluded that concerning the MRLs for barley, rye and wheat, 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 be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. In addition, it could not be excluded that the acute reference dose ('ARfD') of ethephon would be exceeded in blueberries. The MRL for blueberries should be lowered in Annex II to Regulation (EC) No 396/2005 to the LOD.
- (5) The MRLs for ethephon in hazelnuts/cobnuts, cherries, figs, table olives, kaki/Japanese persimmons, tomatoes, and olives for oil production, should be maintained in Annex II to Regulation (EC) No 396/2005 at the current level.
- (6) The Authority further concluded that concerning the MRLs for pears, table grapes, wine grapes, cotton seeds, muscle, fat, liver, kidney and edible offals other than liver and kidney (swine, bovine, sheep, goat, equine, poultry, and other farmed terrestrial animals), milk and birds eggs, 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 be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (7) In addition, the MRL for ethephon in plums should be maintained in Annex II to Regulation (EC) No 396/2005 at the current level based on the use authorised in France notified during the decision-making process.
- (8) In addition, the Authority found that it could not be excluded that the ARfD of ethephon would be exceeded in apples. Consequently, risk managers proposed to set a lower MRL for apples based on the less critical and safe fall-back Good Agricultural Practices ('GAP'). It is therefore appropriate to lower the existing MRL for ethephon in apples in Annex II to Regulation (EC) No 396/2005.
- (9) For propamocarb, the Authority published on 24 November 2023 a reasoned opinion on modification of the existing maximum residue level in honey⁶. In its reasoned opinion, the Authority found that it could not be excluded that the ARfD would be

⁴ European Food Safety Authority: Statement on targeted review of the maximum residue levels (MRLs) for ethephon (EFSA Journal, 22(4), e8757).

⁵ Joint FAO/WHO food standards programme Codex Alimentarius Commission. REP16/PR, Appendix III. Thirty-Nine Session. Rome, Italy, 27 June-1 July 2016.

⁶ European Food Safety Authority: Reasoned opinion on modification of the existing maximum residue level for propamocarb in honey (EFSA Journal, 21(11), e8422).

exceeded for lettuce. The Authority published on 26 May 2025⁷ a statement where an MRL based on the less critical and safe fall-back GAP which is fully supported by data was proposed. It is therefore appropriate to lower the MRL for propamocarb in lettuce in Annex II to Regulation (EC) No 396/2005.

- (10) 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.
- (11) Through the World Trade Organisation, the trading partners of the Union were consulted on the modified MRLs and their comments have been taken into account.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) 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 in the Union before the modified MRLs become applicable and for which information shows that a high level of consumer protection is maintained. This is the case for all products except for ethephon in or on apples and blueberries, and for propamocarb in or on lettuces.
- (14) 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 adapt themselves to the requirements which result from the modification of the MRLs.
- (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

Annexes II and V 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*], except for ethephon in or on apples and blueberries and for propamocarb in or on lettuces.

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*].

⁷ European Food Safety Authority: Statement on the MRL for propamocarb in lettuces (EFSA Journal, 2025;23:e9455).

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