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From:	European Commission
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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for phosmet in or on certain products

Delegations will find attached document D085711/03.

Encl.: D085711/03



Brussels, **XXX**
PLAN/2022/2311
(POOL/E4/2022/2311/2311-EN.docx)
D085711/03
[...] (2023) **XXX** draft

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

of XXX

amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for phosmet in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for phosmet 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), and Article 18(1), point (b), thereof,

Whereas:

- (1) For phosmet, maximum residue levels ('MRLs') 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 phosmet in accordance with Article 12(1) of Regulation (EC) No 396/2005². It proposed to change the residue definition for enforcement purposes from "phosmet and phosmet-oxon expressed as phosmet" to "phosmet". The Commission considers this new residue definition to be appropriate in the context of Regulation (EC) 396/2005.
- (3) In its reasoned opinion on the review of the existing MRLs for phosmet in accordance with Article 12(1) of Regulation (EC) No 396/2005, the Authority identified a risk for consumers concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, coconuts, apples, pears, quinces, medlars, loquats, apricots, peaches, table grapes, wine grapes, blueberries, cranberries, kumquats and potatoes. In addition, in the context of a decision on non-renewal of the approval of the active substance phosmet³, the Authority published a conclusion⁴ on the peer review of the pesticide risk assessment of the active substance phosmet explaining that the consumer dietary risk assessment for phosmet could not be finalised because data including the toxicological profile and genotoxicity potential of the metabolite phosmet-oxon was incomplete. In

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for phosmet according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(7):7448.

³ Commission Implementing Regulation (EU) 2022/94 of 24 January 2022 concerning the non-renewal of the approval of the active substance phosmet, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 16, 25.1.2022, p. 33).

⁴ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance phosmet, EFSA Journal 2021;19(3):6237.

view of the data gaps, the Authority could not rule out harmful effects on human health with the existing MRLs for phosmet in all products. Therefore, none of the existing MRLs for phosmet, including those based on Codex maximum residue limits (CXLs), could be confirmed as being safe for consumers. It is therefore appropriate to delete the MRLs for phosmet in Part A of Annex III 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 phosmet in all products should be set at the limits of determination ('LODs'), specific to each product and safe for consumers, which should be set in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b) of that Regulation.

- (4) Additionally, the Authority and a Member State identified that the default value of 0.01* mg/kg for oranges, potatoes, apples, pears, pineapples, melons, watermelons, sugar beet roots, and milk (cattle), does not provide a sufficient level of protection for consumers. Therefore, the LODs for these products should be set at the lower and achievable level of 0.005* mg/kg, which is safe for consumers.
- (5) 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.
- (6) 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.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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.
- (9) 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 III and V to Regulation (EC) No 396/2005 are 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 3 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