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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 Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for folpet in or on certain products

Delegations will find attached document D087770/02.

Encl.: D087770/02



Brussels, **XXX**
PLAN/2022/2599
(POOL/E4/2022/2599/2599-EN.docx)
D087770/02
[...] (2023) **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 folpet 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 folpet 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) Maximum residue levels ('MRLs') for folpet were set in Annex II to Regulation (EC) No 396/2005.
- (2) An application pursuant to Article 6(1) of Regulation (EC) No 396/2005 was submitted requesting a modification of the existing MRL for folpet in lettuces.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL². It forwarded the opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) As regards the modification to the MRL requested by the applicant, the Authority concluded that all requirements with respect to completeness of data submission were met and that the modification to the MRL requested by the applicant was acceptable with regard to consumer safety, on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substance. Neither the long-term exposure to this substance 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 acceptable daily intake or the acute reference dose is exceeded.

¹ OJ L 70, 16.3.2005, p. 1.

² Reasoned opinion on the modification of the existing maximum residue level for folpet in lettuces. EFSA Journal 2022;20(4):7309.

- (6) Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the proposed modification to the MRL fulfils the requirements of Article 14(2) of that Regulation.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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