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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending and correcting Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for mandipropamid in or on certain products

Delegations will find attached document D089656/3.

Encl.: D089656/3



EUROPEAN
COMMISSION

Brussels, **XXX**
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[...](2023) **XXX** draft

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

of **XXX**

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

(Text with EEA relevance)

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

of **XXX**

amending and correcting Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for mandipropamid 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 mandipropamid, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) Pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005, an application was submitted for an import tolerance for mandipropamid used in Brazil on papayas. The applicant stated that the authorised uses of that substance on such crop in that country lead to residues exceeding the MRL provided for in Regulation (EC) No 396/2005 and that a higher MRL would be needed to avoid trade barriers when importing that crop.
- (3) In accordance with Article 8 and 9 of Regulation (EC) No 396/2005 the Member State concerned evaluated this application and forwarded the evaluation report to the Commission and the European Food Safety Authority ('the Authority').
- (4) The Authority assessed the application and the evaluation report. It examined in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL². It forwarded its reasoned opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) The Authority concluded that, for papayas, all data requirements had been 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. The Authority took into account the most recent information on the toxicological properties of mandipropamid. Neither the lifetime exposure to that substance via consumption of all food products that may contain it nor the short-term exposure due to high consumption of relevant products show that there is any 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 setting of import tolerances for mandipropamid in papayas. EFSA Journal 2023;21(1):7741.

- (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, it is concluded that the proposed modification to the MRL is acceptable.
- (7) In addition, in the framework of the review of all existing MRLs for mandipropamid conducted in accordance with Article 12 of Regulation (EC) No 396/2005³, as regards root crops the Authority identified some information on the toxicity of metabolite SYN 500003 as unavailable. As there was no risk for consumers, the MRLs for those products were set in Annex II to Regulation (EC) No 396/2005 by Commission Regulation (EU) 2019/1176⁴ along with a footnote requiring the provision of that missing information.
- (8) Due to a mistake, however, that same footnote requiring information on the toxicity of metabolite SYN 500003 was not included for the MRLs of mandipropamid for potatoes, beetroots and radishes, which belong to the root crops group. Therefore, it is appropriate to correct Annex II to Regulation (EC) No 396/2005 by including a footnote requiring the provision of the above-mentioned missing information on the toxicity of metabolite SYN 500003 as regards the residues of mandipropamid on potatoes, beetroots and radishes.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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*.

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

³ Review of the existing maximum residue levels for mandipropamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(5):5284.

⁴ Commission Regulation (EU) 2019/1176 of 10 July 2019 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2,5-dichlorobenzoic acid methylester, mandipropamid and profoxydim in or on certain products (OJ L 185, 11.7.2019, p. 1).