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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 mandestrobin in grapes and strawberries

Delegations will find attached document D072920/02.

Encl.: D072920/02



Brussels, **XXX**
SANTE/12818/2020
(POOL/E4/2020/12818/12818-EN.docx)
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[...](2021) **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 mandestrobin in grapes and strawberries

(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 mandestrobin in grapes and strawberries

(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)(a) thereof,

Whereas:

- (1) For mandestrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005.
- (2) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerance was submitted for mandestrobin used in Canada on strawberries and grapes. The applicant claims that the authorised uses of that substance on such crops in Canada lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of grapes and strawberries.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, the 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 the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs². It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) The Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substance. The lifetime exposure to the substance via consumption of all food products that may contain it showed that there is no risk that the acceptable daily intake is exceeded. Moreover, the Authority concluded that the

¹ OJ L 70, 16.3.2005, p. 1.

² EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the setting of import tolerances for mandestrobin in strawberries and table and wine grapes. EFSA Journal 2018;16(8):5395.

establishment of an acute reference dose is not necessary due to the low acute toxicity profile of the substance.

- (6) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (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