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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 acequinocyl in or on certain products

Delegations will find attached document D080364/03.

Encl.: D080364/03



Brussels, **XXX**
SANTE/10180/2022
(POOL/E4/2022/10180/10180-EN.docx)
D080364/03
[...] (2022) **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 acequinocyl 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 acequinocyl 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 acequinocyl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acequinocyl on sweet peppers/bell peppers, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005, requesting a modification of the existing MRL, was submitted.
- (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 consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL². 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 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 information on the toxicological properties of the substance. Neither the lifetime 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 that there is 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 acequinocyl in sweet peppers/bell peppers. EFSA Journal 2022;20(3):7175. EFSA scientific reports available online: <http://www.efsa.europa.eu>.

- (6) An application pursuant to Article 6(1) of Regulation (EC) No 396/2005, requesting a modification of the existing MRL for acequinocyl in kaki/Japanese persimmons, was submitted.
- (7) As regards this application, a Member State made a request to use the fast-track procedure, foreseen in the Technical Guidelines on the MRL setting procedure³, to set an MRL based on residue trials on apples.
- (8) The Authority has recently assessed residue trials on apples in the framework of the review of the existing MRLs for acequinocyl, and gave a reasoned opinion on the proposed MRL⁴. This opinion from the Authority relies on the current scientific and technical knowledge on the subject. As it is appropriate to extrapolate from the residue trials on apples to kaki/Japanese persimmons, as confirmed by the existing Union guidelines on extrapolation of MRLs⁵, it is unnecessary to request the Authority to provide a reasoned opinion on kaki/Japanese persimmons.
- (9) It is therefore appropriate to set the MRL for kaki/Japanese persimmons at 0.05 mg/kg on the basis of the residue trials performed on apples.
- (10) Based on the reasoned opinions 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) 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*.

It shall apply from 23 February 2023 as regards all proposed MRLs.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

³ Technical guidelines MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 6.1).

⁴ Reasoned Opinion on the review of the existing maximum residue levels for acequinocyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5983. EFSA scientific reports available online: <http://www.efsa.europa.eu>.

⁵ Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752 - 23 November 2020).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN