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Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diethofencarb, fenoxycarb, flutriafol and pencycuron in or on certain products

Delegations will find attached document D087773/4.

Encl.: D087773/4



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

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diethofencarb, fenoxycarb, flutriafol and pencycuron in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diethofencarb, fenoxycarb, flutriafol and pencycuron 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 diethofencarb, fenoxycarb, flutriafol and pencycuron, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) The approval of the active substance diethofencarb expired on 31 May 2021 and no application for renewal of its approval has been submitted. All authorisations for plant protection products containing that active substance have been revoked.
- (3) The MRL for diethofencarb in and on bananas corresponds to an import tolerance and is safe for consumers at the existing level². Therefore, this MRL should be maintained in Annex II to Regulation (EC) No 396/2005 in accordance with Article 3(2), point (g) and Article 14(2), point (e) of Regulation (EC) No 396/2005.
- (4) For diethofencarb in and on pears, wine grapes, tomatoes and aubergines/eggplants, the existing MRLs were based on uses in the Union. Following the withdrawal of authorisations for these uses of that substance, it is appropriate to delete those MRLs set for diethofencarb in Annex II 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. The MRLs for those products should therefore be set at the limit of determination ('LOD') in Annex II to Regulation (EC) No 396/2005 in accordance with Article 18(1) point (b) of that Regulation. Additionally, as those MRLs are deleted, there is no need for additional information, therefore, the respective footnotes indicating lack of information on residue trials for pears and wine grapes, and on

¹ OJ L 70, 16.3.2005, p. 1.

² European Food Safety Authority (EFSA), 'Reasoned opinion on the setting of import tolerance for diethofencarb in bananas', EFSA Journal 2016;14(9):4576.

storage stability for pears, wine grapes, tomatoes and aubergines/eggplants should be deleted.

- (5) The approval of the active substance fenoxycarb expired on 31 May 2021, and no application has been submitted for its renewal. All authorisations for plant protection products containing that active substance have been revoked.
- (6) For fenoxycarb in and on pecans, walnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, peaches, plums, table grapes, wine grapes, table olives and olives for oil production, the existing MRLs were based on uses in the Union. Following the withdrawal of authorisations for these uses of that substance, it is appropriate to delete those MRLs set for fenoxycarb in Annex II 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. The MRLs for those products should therefore be set at the LOD in Annex V to Regulation (EC) No 396/2005 in accordance with article 18(1) point (b) of that Regulation. Additionally, as those MRLs are deleted, there is no need for additional information, therefore, the respective footnote indicating lack of information on residue trials for table olives should be deleted.
- (7) The approval of the active substance flutriafol expired on 31 May 2021. According to Commission Implementing Regulation (EU) 2021/726³, an application for the renewal of its approval had been submitted, but was no longer supported by the applicant. All authorisations for plant protection products containing that active substance have been revoked.
- (8) The MRLs for flutriafol in and on table grapes, bananas, tomatoes, sweet peppers/bell peppers, lettuces, peanuts/groundnuts, rapeseeds/canola seeds, soyabeans, cotton seeds, sorghum, wheat and coffee beans are based on Codex MRLs ('CXLs') and are safe for consumers at the existing levels^{4,5}. These MRLs should therefore be maintained in accordance with Article 3(2), point (e) and Article 14(2), point (e) of Regulation (EC) No 396/2005.
- (9) The MRL for flutriafol in and on sugar beet roots is based on a use of that substance in the Union which is no longer authorised. However, the lower CXL that is available for that product is also safe for consumers⁵. Therefore, this MRL should be lowered to the corresponding CXL in Annex II to Regulation (EC) 396/2005 in accordance with Article 3(2), point (e) and Article 14(2), point (e) of that Regulation.
- (10) The MRLs for flutriafol in and on apples, pears, quinces, medlars, loquats/Japanese medlars, cherries (sweet), peaches, plums, wine grapes, strawberries, cucurbits with edible peel, cucurbits with inedible peel and hops are based on import tolerances and are safe for consumers^{4,6,7,8,9}. Therefore, these MRLs should be maintained at the

³ OJ L 155, 5.5.2021, p.20.

⁴ European Food Safety Authority (EFSA), 'Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flutriafol according to Article 12 of Regulation (EC) No 396/2005'. EFSA Journal 2014;12(5):3687.

⁵ European Food Safety Authority (EFSA), 'Scientific support for preparing an EU position in the 48th Session of the Codex Committee on Pesticide Residues (CCPR)'. EFSA Journal 2016;14(8):4571.

⁶ European Food Safety Authority (EFSA), 'Reasoned opinion on the setting of import tolerance for flutriafol in strawberries'. EFSA Journal 2016;14(3):4427.

existing level in accordance with Article 3(2), point (g) and Article 14(2), point (e) of Regulation (EC) No 396/2005.

- (11) For flutriafol in and on beetroots, mustard seeds, gold of pleasure seeds, rice, rye, the existing MRLs were based on uses in the Union. Following the withdrawal of authorisations for these uses of that substance, it is appropriate to delete those MRLs set for flutriafol in Annex II 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. The MRLs for those products should therefore be set at the LOD in Annex II to Regulation (EC) No 396/2005 in accordance with article 18(1) point (b) of that Regulation.
- (12) The approval of the active substance pencycuron expired on 31 May 2021, and no application has been submitted for its renewal. All authorisations for plant protection products containing pencycuron have been revoked. It is therefore appropriate to delete the MRLs set for this substance in Annex II 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 all products should therefore be set at the LOD in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1) point (b) of that Regulation.
- (13) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories have proposed product specific LODs that are analytically achievable.
- (14) 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.
- (15) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (16) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (17) 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 amendments to the relevant MRLs.
- (18) 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:

⁷ European Food Safety Authority (EFSA), 'Reasoned opinion on the setting of import tolerance for flutriafol in cucurbits with edible peel'. EFSA Journal 2016;14(9):4577.

⁸ European Food Safety Authority (EFSA), 'Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for flutriafol in cucurbits (inedible peel)'. EFSA Journal 2020;18(12):6315.

⁹ European Food Safety Authority (EFSA), 'Reasoned opinion on the setting of import tolerance for flutriafol in hops'. EFSA Journal 2017;15(7):4875.

Article 1

Annexes II and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before [*Office of Publications: please insert date 6 months after date of entry into force of this Regulation*].

Article 3

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 6 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