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

of XXX

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 bifenthrin, bromopropylate, chloridazon, fenpropimorph, imazaquin and tralkoxydim in or on certain products

(Text with EEA relevance)

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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 bifenthrin, bromopropylate, chloridazon, fenpropimorph, imazaquin and tralkoxydim 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)(a) and Article 18(1)(b) thereof,

Whereas:

- (1) For bifenthrin, chloridazon, fenpropimorph and tralkoxydim maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For bromopropylate, MRLs were set in Annex II and Part B of Annex III to that Regulation. For imazaquin, MRLs were set in annex II and Part A of Annex III to that Regulation.
- (2) The active substance bromopropylate was never approved in the Union for the use in plant protection products and all MRLs are established at the Limit of determination (LOD). It should therefore be moved into Annex V to Regulation (EC) No 396/2005.
- (3) The approval of the active substance bifenthrin expired on 31 July 2019². The approvals of the active substances chloridazon and imazaquin expired on 31 December 2018, those of fenpropimorph and tralkoxydim on 30 April 2019³.
- (4) All existing authorisations for plant protection products containing those active substances have been revoked. It is therefore appropriate to delete the existing MRLs set out for those substances in Annexes II and III of Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation in conjunction with Article 14(1)(a) thereof. Some MRLs can be maintained, in particular those that are based on import tolerance requests that are safe for consumers or on Codex maximum residue limits (CXLs) which were not established on the basis of now obsolete EU uses and that are safe for consumers.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Implementing Regulation (EC) No 2019/324 of 25 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances bifenthrin, carboxin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate (OJ L 57, 26.2.2019, p. 1–3).

³ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1–186)

- (5) The MRLs for bifenthrin in maize grain and sweet corn correspond to import tolerance requests from the United States of America and are safe for consumers⁴. The MRLs for bifenthrin in citrus fruits, tree nuts, grapes, cane fruits, blueberries, bananas, mangoes, papayas, potatoes, tropical root and tuber vegetables, other root and tuber vegetables, tomatoes, peppers, aubergines, okra, brassicas, baby leaf crops, peas with and without pods, pulses, rapeseeds, soyabeans, cotton seeds, wheat, teas, hops, fruit and root spices and all tissues from mammals correspond to CXLs that are safe for consumers⁴⁵. Those MRLs should be maintained at the existing levels. As the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005 on storage stability for bifenthrin in citrus fruits, cane fruits and bird eggs, the MRLs are fully supported by data⁴ and the respective footnotes highlighting the need for additional data can be deleted. As recent monitoring data for herbal infusions showed that a lower MRL than 0,1 mg/kg is currently not achievable, those MRLs should be maintained and the respective footnotes can be deleted. As regard strawberries, the existing CXL gives rise to consumer health concerns and should therefore be deleted from Annex II to Regulation (EC) No 396/2005⁶.
- (6) The MRL for fenpropimorph in bananas corresponds to an import tolerance request from Venezuela and is safe for consumers⁷.
- (7) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products technical development permits the setting of lower LODs. For the active substances for which all MRLs should be reduced to the relevant LOD, default values should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.
- (8) 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.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (11) 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

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

⁴ Evaluation of confirmatory data following the Article 12 MRL review and setting of import tolerances for bifenthrin in maize grain and sweet corn. EFSA Journal 2020;18(12):6361.

⁵ Scientific and technical support for preparing a EU position in the 42nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2010;8(11):1560.

⁶ Scientific support for preparing an EU position for the 52nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2021; 19 (8). <https://doi.org/10.2903/j.efsa.2021.6766>

⁷ Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fenpropimorph according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(3):4050

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 [*Office of Publication: please insert date 6 months after entry into force*].

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