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

Delegations will find attached document D085455/02.

Encl.: D085455/02



EUROPEAN
COMMISSION

Brussels, **XXX**
SANTE/10644/2021
(POOL/E4/2021/10644/10644-EN.docx)
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[...](2022) **XXX** draft

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

(Text with EEA relevance)

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 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), point (a), Article 18(1), point (b) and Article 49(2) thereof,

Whereas:

- (1) For 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 in Part B of Annex III to that Regulation depending on the product. For imazaquin, MRLs were set in Part A of Annex III to that Regulation.
- (2) Bromopropylate has never been approved in the Union as an active substance in plant protection products. MRLs for that substance are established at the limit of determination (LOD). They should therefore be moved into Annex V to Regulation (EC) No 396/2005.
- (3) The approvals of the active substances chloridazon and imazaquin expired on 31 December 2018, those of fenpropimorph and tralkoxydim expired on 30 April 2019².
- (4) All existing authorisations for plant protection products containing active substances chloridazon, fenpropimorph, imazaquin and tralkoxydim have been revoked. It is therefore appropriate to delete the existing MRLs set out for those active substances in Annexes II and III to Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation, in conjunction with Article 14(1), point (a) and (2) thereof. Some MRLs can be maintained, in particular those that are based on import tolerance requests that are safe for consumers and those that are based on Codex maximum residue limits ('CXLs'), that were not established on the basis of now obsolete Union uses, and that are safe for consumers.
- (5) The MRL for fenpropimorph in bananas corresponds to an import tolerance request from Venezuela and is safe for consumers³. The MRLs for fenpropimorph in barley,

¹ OJ L 70, 16.3.2005, p. 1.

² 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).

oat, rye, wheat, sugar beet roots, all tissues from mammals and milk correspond to CXLs that are safe for consumers⁴. Those MRLs should be kept at the existing levels according to Article 3(2), point (g) and Article 14 (2), points (a), (c) and (e) of Regulation (EC) No 396/2005. For all other products, it is appropriate to lower the existing MRLs set out for fenpropimorph in Annex II to Regulation (EC) No 396/2005 to the LOD in accordance with Article 14(1), point (a) in conjunction with Article 17 of that Regulation.

- (6) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. Those laboratories recommended analytically achievable LODs for all substances and products.
- (7) 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.
- (8) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (9) For all active substances covered by this Regulation, to allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the modified MRLs start applying and for which information shows that a high level of consumer protection is maintained.
- (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.

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 Publication: please insert date 6 months after the 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 Publication: please insert date 6 months after entry into force*].

³ 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.

⁴ Scientific and technical support for preparing a EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16(7):5306.

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