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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 fipronil in or on certain products

Delegations will find attached document D089865/3.

Encl.: D089865/3



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 fipronil 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 fipronil 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 the active substance fipronil, maximum residue levels ('MRLs') were set at the relevant limit of determination ('LOD') in Annex V to Regulation (EC) No 396/2005 by Commission Regulation (EU) 2019/1792² following the expiry of the approval of that active substance.
- (2) Pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005, an application was submitted for import tolerances for fipronil used on sugar canes in Brazil and on potatoes in Brazil, the United States and Ukraine. The applicant stated that the uses of fipronil on such crops that are authorised in those countries would lead to residues that exceed the MRLs provided for in Regulation (EC) No 396/2005 and that higher MRLs would be needed to avoid trade barriers when importing those crops. As sugar canes and potatoes can be fed to animals, the applicant also proposed raising some of the existing MRLs for fipronil in animal commodities.
- (3) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the Member State concerned evaluated this application and forwarded the evaluation report to the Commission. In the evaluation report, the Member State assessed the livestock dietary burden taking into account the livestock intake of commodities produced from those crops, and proposed raising some of the existing MRLs for fipronil in animal commodities.

¹ OJ L 70, 16.3.2005, p. 1.

² Commission Regulation (EU) 2019/1792 of 17 October 2019 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 amitrole, fipronil, flupyrsulfuron-methyl, imazosulfuron, isoproturon, orthosulfamuron and triasulfuron in or on certain products (OJ L 277, 29.10.2019, p. 66).

- (4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report. It examined in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs³. It forwarded its reasoned opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) In its reasoned opinion, the Authority concluded that the data submitted by the applicant concerning fipronil in potatoes was insufficient to set a new MRL. As regards the modification to the MRL for fipronil in sugar canes, bovine fat, sheep fat and goat fat requested by the applicant, the Authority concluded that all data requirements had been met and that such modifications were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. 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 show a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (6) Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the proposed modification to the MRL is acceptable.
- (7) Annexes II and V to 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

Annexes II and V to Regulation (EC) No 396/2005 are 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*.

³ Reasoned opinion on the setting of import tolerances for fipronil in potatoes, sugar canes and commodities of animal origin. EFSA Journal 2023;21(4):7931.

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