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Delegations will find attached document D084206/03.

Encl.: D084206/03

EUROPEAN
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**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 cyantraniliprole 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 cyantraniliprole 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/EEC[1], and in particular Article 14(1), point (a), thereof,

Whereas:

(1) For cyantraniliprole, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) As regards cyantraniliprole, an application for import tolerances pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 was submitted for that substance used in Canada and in the United States on potatoes, 'tropical root and tuber vegetables', 'cucurbits with inedible peel', Chinese cabbages/ pe-tsai, other leafy brassica, 'lettuces and salad plants', 'spinaches and similar leaves' (except spinach), parsley and minor oilseeds (i.e. linseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans). The applicant provided data showing that the authorised uses of that substance on these crops in Canada and in the United States lead to residues exceeding the MRLs provided for in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops into the Union. A second application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs was submitted for apricots.

(3) In accordance with Article 8 of Regulation (EC) No 396/2005, both of those applications were evaluated by the Member State concerned and the evaluation reports were forwarded to the Commission.

(4) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and submitted a reasoned opinion on the proposed MRLs[2]. It forwarded this opinion to the applicants, the Commission and the Member States and made it available to the public.

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1 OJ L 70, 16.3.2005, p. 1.

2 Reasoned Opinion on the modification of the existing maximum residue level for apricots and setting of import tolerances for cyantraniliprole in various crops. EFSA Journal 2022;20(3):7219.

(5) As regards cyantraniliprole in apricots, potatoes, 'tropical root and tuber vegetables', 'cucurbits with inedible peel', Chinese cabbages/ pe-tsai, other leafy brassica, escaroles/broad-leaved endives, 'spinaches and similar leaves' (except spinach) and parsley, the Authority concluded that further consideration by risk managers was required as some information on the toxicity of cyantraniliprole degradation products in processed products was not available. Since the Authority concluded that the consumers' exposure to those degradation products is low and that the safety margin is wide, it is appropriate to propose setting the MRLs derived by the Authority for cyantraniliprole in all of those products.

(6) As regards cyantraniliprole in lettuces, the Authority concluded that further consideration by risk managers was required concerning the choice of the data set for deriving the MRLs. Based on the information provided by the Authority, it is appropriate to propose setting the MRL for cyantraniliprole in lettuces at 15 mg/kg based on the residue data on open leaf lettuces.

(7) As regards all other modifications to MRLs requested by the applicants for cyantraniliprole, the Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicants were acceptable concerning consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In its assessment the Authority took into account the most recent data on the toxicological properties of the substance. Neither the long-term 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 a risk that the acceptable daily intake or the acute reference dose is exceeded.

(8) 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, the proposed modifications to the MRLs fulfil the requirements of that article.

(9) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(10) 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*.

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*