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

Delegations will find attached document D079214/03.

Encl.: D079214/03



Brussels, **XXX**
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[...](2022) **XXX** draft

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

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, chlorantraniliprole and emamectin in or on certain products

(Text with EEA relevance)

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

of **XXX**

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, chlorantraniliprole and emamectin 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 49(2) thereof,

Whereas:

- (1) For acequinocyl, chlorantraniliprole and emamectin, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For acequinocyl, the European Food Safety Authority ('the Authority') submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². For some products, the Authority recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for grapefruits, oranges, lemons, limes, mandarins, hazelnuts/cobnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, table and wine grapes, tomatoes, aubergines/eggplants, hops, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney, milk), equine (muscle, fat, liver, kidney, milk) some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (3) For chlorantraniliprole, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005³. It recommended lowering the MRLs for almonds, Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamias, pecans, pine nut kernels, pistachios,

¹ OJ L 070, 16.3.2005, p. 1.

² European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for acequinocyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5983.

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for chlorantraniliprole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(9): 6235.

walnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, sweet corn, cauliflowers, celeries, coffee beans and muscle (swine, bovine, sheep, goat and equine). For other products, it recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. For kales, the Authority recommended to keep the existing MRL of 20 mg/kg. However, the Member States requested to raise the MRL for kales to 40 mg/kg, which is the codex maximum residue limit (CXL) for radish leaves, because radish leaves are currently classified in Part B of Annex II to Regulation (EC) No 396/2005 under the subgroup “Kales”. In 2015 when the CXL for radish leaves was introduced in the Union legislation, radish leaves were not explicitly mentioned in the Union legislation. Hence, they were considered to belong to the subgroup “Baby leaf crops (including brassica species) and not to the subgroup “Kales”. The Member States requested to follow the current classification. The Authority further concluded that concerning the MRLs for sweet peppers/bell peppers, melons, watermelons, grape leaves and similar species, peanuts/groundnuts, sunflower seeds and rapeseeds/canola seeds some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (4) For emamectin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It proposed to change the residue definition to emamectin B1a and its salts, expressed as emamectin B1a (free base). It recommended lowering the MRLs for plums, potatoes, cucumbers, gherkins, courgettes, melons, watermelons, broccoli, cauliflowers, Brussels sprouts, head cabbages, lamb’s lettuces/ corn salads, lettuces, cresses and other sprouts and shoots, land cresses, Roman rocket/ rucola, red mustards, baby leaf crops (including brassica species), chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves, tarragon, peas (without pods) and globe artichokes. For other products, the Authority recommended raising or keeping the existing MRLs. The MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. The Authority further concluded that concerning the MRLs for oranges, lemons, mandarins, table and wine grapes, pumpkins, escarole/broad-leaved endives, cotton seeds, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney), sheep (muscle, fat, liver, kidney), goat (muscle, fat, liver, kidney), equine (muscle, fat, liver, kidney), other farmed terrestrial animals (muscle, fat, liver, kidney) and milk (cattle, sheep, goat, horse) some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. The Authority also concluded that concerning the MRL for apricots some information was not available. An application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for emamectin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(8):5803.

MRLs was submitted among other products also for apricots. The Authority in its opinion⁵ concluded that all requirements with respect to completeness of data submission were met, and that the modification to the MRL for apricots requested by the applicant was acceptable. This modification has been addressed in the Commission Regulation (EU) 2022/xxxx⁶ and therefore the additional information for apricots is not needed.

- (5) Existing CXLs were taken into account in the reasoned opinions of the Authority. CXLs, which are safe for consumers in the Union, were considered for MRL setting.
- (6) As regards products on which the use of the plant protection product concerned is not authorised in the Union, and for which no import tolerances or CXLs exist, MRLs should be set at the specific limit of determination or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (8) Based on the reasoned opinions of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (9) 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.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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.
- (12) 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.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁵ Reasoned opinion on the modification of the existing maximum residue levels for emamectin in various crops. EFSA Journal 2021;19(8):6824.

⁶ Reference to be added after publication of SANTE/11280/2021 (end of March 2022).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III 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 entry into force*].

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*].

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