EUROPEAN
COMMISSION

Brussels, XXX
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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 beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) …/…

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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 beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad 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)(a) and Article 49(2) thereof,

Whereas:

(1) For beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin and penthiopyrad maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For metobromuron, no MRLs were set in Regulation (EC) No 396/2005, and as that active substance is not included in Annex IV to that Regulation, the default value of 0.01 mg/kg laid down in Article 18(1)(b) of Regulation (EC) No 396/2005 applies

(2) For beta-cyfluthrin and cyfluthrin 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 396/2005[2]. Although these active substances are no longer authorised for use on edible crops within the European Union, MRLs were established by the Codex Alimentarius Commission (Codex Maximum Residue Limits (CXLs)) and import tolerances were reported by Member States, including the supporting residues data. EFSA assessed the CXLs and import tolerances requested, and a consumer risk assessment was carried out. The Authority recommended lowering the MRLs for apples, pears, potatoes, sweet peppers/bell peppers, head cabbages, "fruit spices", "root and rhizome spices", swine (muscle, liver, kidney), bovine (muscle, liver, kidney), sheep (muscle, liver, kidney), goat (muscle, liver, kidney), equine (muscle, liver, kidney), horse milk and birds' eggs. 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 cauliflower, the Authority identified a possible acute risk to consumers if the CXL for cauliflower was set, therefore the existing MRL based on the EU uses will be lowered to the default MRL. The Authority further

[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 beta-cyfluthrin and cyfluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(9):6837.

concluded that concerning the MRLs for barley and wheat 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 cycloxydim the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[3]. The Authority recommended lowering the MRLs for apples, pears, apricots, peaches, table and wine grapes, celeriacs/turnip rooted celeries, peas (fresh, with pods), Florence fennels, globe artichokes, rapeseeds/canola seeds, sugar beet roots and poultry (muscle, fat, liver). 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 spring onions/green onions and Welsh onions, lamb's lettuces/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, maize/corn and herbal infusions from roots 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 cyflumetofen, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. It proposed to change the residue definition in animal commodities to 2-(trifluoromethyl) benzoic acid (metabolite B-1), expressed as cyflumetofen. 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. The Authority further concluded that concerning the MRLs for 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), 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.

(5) For metobromuron, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[5]. It proposed to change the residue definition to sum of metobromuron and 4-bromophenylurea,

[3] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for cycloxydim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5962.

[4] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for cyflumetofen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6812.

[5] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for metobromuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(9):6841.

expressed as metobromuron. 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, strawberries, potatoes, carrots, parsnips, lamb's lettuces/corn salads, spinaches, watercresses, celery leaves, parsley, sage, thyme, basil and edible flowers, beans (with pods), beans (without pods), asparagus, Florence fennels, beans, peas, sunflower seeds, soyabeans, 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), 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.

(6) For penthiopyrad, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[6]. The Authority recommended lowering the MRLs for peaches and oats. 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 Spring onions/green onions and Welsh onions, lamb's lettuces/corn salads, lettuces, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards, spinaches purslanes, chards/beet leaves, chervil, chives, cardoons, celeries, Florence fennels, leeks, rhubarbs, cotton seeds, barley and sorghum 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.

(7) Existing Codex maximum residue limits (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.

(8) As regards products on which the use of the plant protection product concerned is not authorised in the EU, and for which no import tolerances or CXLs exist, MRLs should be set at the specific LOD or the default MRL should apply, as provided for in Article 18(1)(b) of Regulation (EC) No 396/2005.

(9) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LOD. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific LOD.

(10) 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.

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[6] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for penthiopyrad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021; 19(9):6810.

(11) 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.

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

(13) 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.

(14) 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.

(15) 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 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