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Delegations will find attached document D070119/04.

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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 ametoctradin,
bixafen, fenazaquin, spinetoram, tefluthrin and thien carbazon-methyl 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 ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thien carbazon-methyl 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 ametoctradin, bixafen, fenazaquin, spinetoram and tefluthrin maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005. For thien carbazon-methyl no MRLs were set in Regulation (EC) No 396/2005, and as this 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 ametoctradin 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. It recommended lowering the MRLs for sweet peppers/bell peppers. 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. The Authority further concluded that concerning the MRLs for spring onions/green onions and Welsh onions, barley, oat, rye, wheat, hops, swine (muscle, fat, liver, kidney), bovine (muscle, fat, liver, kidney, milk), sheep (muscle, fat, liver, kidney, milk), goat (muscle, fat, liver, kidney, milk), equine (muscle, fat, liver, kidney, milk), poultry (muscle, fat, liver, kidney) and birds' eggs 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.

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 ametoctradin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5990.

- (3) For bixafen 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 linseeds, mustard seeds, barley and oat. For other products, it recommended raising or keeping the existing MRLs. Based on rotational crops studies and taking into account that the uptake of residues in succeeding crops cannot be fully avoided, specific MRLs reflecting uptake of residues from soil were derived for beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, herbal infusions from roots, sugar beet roots and chicory roots. 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.
- (4) For fenazaquin the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁴. It recommended lowering the MRLs for cucumbers, melons and watermelons. For other products, it recommended raising or keeping the existing MRLs. The Authority further concluded that concerning the MRLs for citrus fruits, pome fruits, strawberries, tomatoes and teas 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 spinetoram the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁵. It proposed to change the residue definition. It recommended lowering the MRLs for oranges, mandarins, plums, litchis/lychees, mangoes, potatoes, onions, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, sweet corn, broccoli, cauliflower, Brussels sprouts, head cabbages, lettuces, spinaches, beans (with pods), leeks and sugar beet roots. 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. Taking into account additional information on the good agricultural practice provided by Belgium and as there is no risk for consumers, the MRL for cresses and other sprouts and shoots and land cresses should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. The Authority further concluded that concerning the MRLs for tree nuts, pome fruits, apricots, table and wine grapes, blackberries, dewberries, cranberries, gooseberries (green, red and yellow), rose hips, mulberries (black and white), azaroles/Mediterranean medlars, elderberries, table olives, soyabeans, cotton seeds, olives for oil production, maize/corn, rice, bovine (fat, liver, kidney), equine (fat, liver, kidney), poultry (fat, liver) and birds' eggs some information was not available and

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for bixafen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5998.

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for fenazaquin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5955.

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for spinetoram according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(3): 5997.

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 tefluthrin the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁶. It recommended lowering the MRLs for witloofs/Belgian endives and chicory roots. 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. The Authority further concluded that concerning the MRLs for celeriacs/turnip rooted celeries, radishes, swedes/rutabagas, turnips, tomatoes, aubergines/eggplants, melons, watermelons, sweet corn, lamb's lettuces/corn salads, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), celeries, Florence fennels, rhubarbs, sunflower seeds, rapeseeds/canola seeds, soyabeans, cotton seeds, barley, maize/corn, common millet/proso millet, oat, rye, sorghum, wheat, poultry (muscle, fat, liver, kidney, edible offals) and birds' eggs 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) For thiencarbazon-methyl the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005⁷. It recommended setting MRLs at the Limit of Determination ('LOD'). Those MRLs should be set in Annex II to Regulation (EC) No 396/2005.
- (8) 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.
- (9) As regards products on which the use of the plant protection product concerned is not authorised, 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.
- (10) 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 concerned by this Regulation, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (11) 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.

⁶ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for tefluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5995.

⁷ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for thiencarbazon-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): 5957.

- (12) 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.
- (13) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) 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.
- (15) 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.
- (16) 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 Publications please insert 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*].

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