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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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 clethodim, dazomet, hexythiazox, metam and sethoxydim in or on certain products

Delegations will find attached document D070117/04.

Encl.: D070117/04



EUROPEAN
COMMISSION

XXX

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[...](2021) XXX draft

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

of XXX

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 clethodim, dazomet, hexythiazox, metam and sethoxydim in or on certain products

(Text with EEA relevance)

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

of **XXX**

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 clethodim, dazomet, hexythiazox, metam and sethoxydim 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 clethodim, dazomet, hexythiazox and metam, maximum residue levels (MRLs) were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) For clethodim, the European Food Safety Authority ("the Authority") submitted a reasoned opinion on the review of the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005². It proposed to change the current residue definition for clethodim, which also covers the non-approved substance sethoxydim and to list MRLs for clethodim and sethoxydim separately. It is appropriate to change the residue definition for clethodim accordingly and to insert a new entry for sethoxydim in Annex V. It concluded that, concerning MRLs for clethodim, some information was not available and the genotoxic potential of the clethodim metabolite 3-chloroallyl alcohol could not be concluded, no toxicological reference values could be derived for this metabolite and further consideration by risk managers was required. From a risk management perspective, it is appropriate to set MRLs for clethodim in Annex II to Regulation (EC) No 396/2005 at the specific limit of determination (LOD) and to include sethoxydim in Annex V to Regulation (EC) No 396/2005 at the specific LOD or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (3) For dazomet and metam, the Authority submitted reasoned opinions on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005^{3,4}. It proposed a revised residue definition based on methylisothiocyanate a common

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 clethodim according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(5):5706.

³ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for dazomet according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5562.

⁴ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for metam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5561.

metabolite for dazomet and metam. It is appropriate to change the residue definition accordingly. The Authority recommended lowering the MRLs for grapefruits, oranges, lemons, limes, mandarins, apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, table and wine grapes, blackberries, dewberries, raspberries (red and yellow), blueberries, cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, mulberries (black and white), azaroles/Mediterranean medlars, elderberries, figs, table olives, kumquats, kaki/Japanese persimmons, kiwi fruits (green, red, yellow), prickly pears/cactus fruits, avocados, mangoes and granate apples/pomegranates. 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 level identified by the Authority. The Authority concluded that concerning the MRLs for strawberries, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, okra/lady's fingers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, Chinese cabbages/pe-tsai, kales, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustards, baby leaf crops (including brassica species), spinaches, purslanes, chards/beet leaves, herbal infusions from roots and hops 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 also should be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. All of 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 hexythiazox, 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 grapefruits, oranges, lemons, limes, mandarins, almonds, brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamias, pecans, pine nut kernels, pistachios, walnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, peaches, blackberries, dewberries, raspberries (red and yellow), blueberries, cranberries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, mulberries (black and white), azaroles/Mediterranean medlars, elderberries, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, maize/corn and hops. 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 level identified by the Authority. The Authority also concluded that concerning the MRLs for apricots, cherries (sweet) plums, soyabeans and products of animal origin 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 level identified by the Authority. All of these MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

⁵ European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for hexythiazox according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019;17(1):5559.

- (5) 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.
- (6) 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.
- (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 LODs.
- (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,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annexes 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