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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 alpha-cypermethrin and cypermethrin in or on certain products

(Text with EEA relevance)

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 alpha-cypermethrin and cypermethrin 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), point (a), and Article 49(2) thereof,

Whereas:

- (1) For cypermethrin, maximum residue levels ('MRLs') were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) The group of cypermethrins consists of various mixtures of isomers: cypermethrin, alpha-cypermethrin, beta-cypermethrin, and zeta-cypermethrin, under the residue definition 'cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers))'. The European Food Safety Authority ('the Authority') confirmed this residue definition as appropriate². In accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council³, cypermethrin⁴ is approved in the Union, while alpha-cypermethrin⁵, beta-cypermethrin⁶ and zeta-cypermethrin⁷ are not.

¹ OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

² European Food Safety Authority, Reasoned opinion on the Review of the residue definitions for risk assessment of pyrethroids forming common metabolites; EFSA Journal 2023;21(5):8022, <https://doi.org/10.2903/j.efsa.2023.8022>.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>).

⁴ Commission Implementing Regulation (EU) 2021/2049 of 24 November 2021 renewing the approval of the active substance cypermethrin as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 420, 25.11.2021, p. 6, ELI: <http://data.europa.eu/eli/reg/2021/2049/oj>).

⁵ Commission Implementing Regulation (EU) 2021/795 of 17 May 2021 withdrawing the approval of the active substance alpha-cypermethrin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 174, 18.5.2021, p. 2, ELI: <http://data.europa.eu/eli/reg/2021/795/oj>).

⁶ Commission Implementing Regulation (EU) 2017/1526 of 6 September 2017 concerning the non-approval of the active substance beta-cypermethrin in accordance with Regulation (EC) No 1107/2009

- (3) The Authority published a reasoned opinion on the review of the existing MRLs for cypermethrins in accordance with Article 12(1) of Regulation (EC) No 396/2005⁸. The Authority identified potential risks regarding the current MRLs for cypermethrins in or on oranges, quinces, table grapes, wine grapes, carambolas, potatoes, beetroots, carrots, celeriacs/turnip rooted celeries, parsnips, radishes, salsifies, swedes/rutabagas, turnips, onions, tomatoes, melons, broccoli, head cabbages, lamb's lettuces/corn salads, roman rocket/rucola, red mustards, watercresses, chervil, chives, parsley, sage, basil and edible flowers, beans (fresh, with pods), lentils (fresh), asparagus, celeries, rhubarbs, and rice, in case residues would consist of only alpha-cypermethrin, the more toxic compound. While a possible approach to ensure consumer protection would be to lower the MRLs for cypermethrin for those food products to the limits of determination ('LODs'), the Commission considers that a proportionate approach ensuring consumer protection is to set two sets of MRLs, one for cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) and the other for alpha-cypermethrin. Therefore, based on a request from the Commission, the Authority submitted a statement on MRLs for alpha-cypermethrin and screening of the existing EU MRLs for cypermethrin⁹.
- (4) As regards cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)), the Authority concluded that the current MRLs for cypermethrins in or on sweet corn, borage seeds, gold of pleasure seeds and hempseeds, based on the current Good Agricultural Practices ('GAPs') authorised in the Union, are confirmed as being safe for consumers. Those MRLs should therefore be maintained in Annex II to Regulation (EC) No 396/2005 at the existing levels.
- (5) The Authority also concluded that the current MRLs for cypermethrins in or on tree nuts, strawberries, carambolas, durians, okra/lady's fingers, beans (dry), lentils (dry), peas (dry), lupins/lupini beans (dry), peanuts/groundnuts, mustard seeds, safflower seeds, buckwheat, maize/corn, millet, cardamom, root and rhizome spices, sugar canes, sheep fat, goat fat, equine fat, poultry fat/liver/kidney/edible offals and sheep/goat/horse milk, based on the current Codex maximum residue levels ('CXLs'), are confirmed as being safe for consumers. Those MRLs should therefore be maintained in Annex II to Regulation (EC) No 396/2005 at the existing levels in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.
- (6) The Authority further derived MRLs based on the current GAPs authorised in the Union for cypermethrins in or on table olives, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley root, radishes, salsifies, swedes/rutabagas, turnips, onions, cresses, land cresses, roman rocket/rucola, red mustards, baby leaf crops, watercresses, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, bay leaves, tarragon and olives for oil

of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 231, 7.9.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/1526/oj>).

⁷ Commission Implementing Regulation (EU) 2020/1643 of 5 November 2020 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances calcium phosphide, denathionium benzoate, haloxypop-P, imidacloprid, pencycuron and zeta-cypermethrin (OJ L 370, 6.11.2020, p. 18, ELI: <http://data.europa.eu/eli/reg/2020/1643/oj>).

⁸ European Food Safety Authority, Reasoned opinion on the review of the existing maximum residue levels for cypermethrins according to Article 12 of Regulation (EC) No 396/2005; EFSA Journal 2023;21(3):7800, <https://doi.org/10.2903/j.efsa.2023.7800>.

⁹ European Food Safety Authority, Statement on MRLs for alpha-cypermethrin and screening of the existing EU MRLs for cypermethrin; EFSA Journal. 2025;23:e9386, <https://doi.org/10.2903/j.efsa.2025.9386>.

production at levels that are higher than the current levels and are confirmed as being safe for consumers. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

- (7) In addition, the Authority derived MRLs based on the current CXLs for cypermethrins in or on kumquats, grape leaves, asparagus, soyabeans, herbal infusions from ginseng, allspice/pimento, sichuan pepper, caraway, juniper berry, peppercorn, vanilla and tamarind at levels that are higher than the current levels and are confirmed as being safe for consumers. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority in accordance with Article 14(2), point (e), of Regulation (EC) No 396/2005.
- (8) The Authority also derived a MRL based on the current GAP authorised in the United States for cypermethrins in or on sorghum, at a level that is higher than the current levels and is confirmed as being safe for consumers. The MRL for sorghum should therefore be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (9) The Authority recommended to lower the existing MRLs for cypermethrins in or on sweet potatoes, aubergines/eggplants, garlic, shallots, lamb's lettuces/corn salads, roman rocket/rucola, red mustards, and chicory roots, based on the current GAPs authorised in the Union which are confirmed as being safe for consumers, and with a view to setting MRLs at levels as low as reasonably achievable. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.
- (10) The Authority also recommended to lower the existing MRLs for cypermethrins in or on oranges, grapefruits, lemons, limes, mandarins, gherkins, pumpkins, watermelons, cassava roots/manioc, yams, arrowroots, globe artichokes, linseeds, poppy seeds, sesame seeds, sunflower seeds, rape seeds/canola seeds, coffee beans, sugar beet roots, swine liver/edible offals, bovine liver/kidney/edible offals, sheep muscle/liver/kidney/edible offals, goat muscle/liver/kidney/edible offals, equine muscle/liver/kidney/edible offals, poultry muscle, and birds' eggs, which are confirmed as being safe for consumers, in line with the current CXLs and with a view to setting MRLs at levels as low as reasonably achievable. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.
- (11) The Authority further recommended to lower the current MRL for cypermethrins on cotton seeds, which is confirmed as being safe for consumers, based on the current GAP authorised in the United States and with a view to setting MRLs at levels as low as reasonably achievable. The MRLs for cotton seeds should therefore be set in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (12) While CXLs exist for residues of some cypermethrin isomers in or on quinces, medlars, loquats/Japanese medlars, table grapes, wine grapes, potatoes, tomatoes, cucumbers, courgettes, melons, broccoli, head cabbages, cauliflowers, Brussels sprouts, Chinese cabbages/pe-tsai, kales, witloofs/Belgian endives, beans (fresh, with pods), beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods), barley, oat, rice, rye, wheat, swine muscle/fat, bovine muscle, bovine fat, and cattle milk, the Authority could not confirm these CXLs as safe for consumers. The Authority recommended to lower the existing MRLs for cypermethrins in or on these products to levels that are confirmed as being safe for consumers, based on the current GAPs authorised in the Union and with a view to setting MRLs at levels as low as

reasonably achievable. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

- (13) The Authority identified unacceptable risks concerning the current MRLs and CXLs for cypermethrins for apples, pears, apricots, cherries, peaches, plums, blackberries, raspberries, litchis/lychees, mangoes, papayas, sweet peppers, kohlrabies, lettuces, escaroles/broad-leaves endives, spinaches, purslanes, chards/beet leaves, leeks, teas, and hops. The Authority consulted the Member States and requested them to report potential fall-back GAPs for these products, authorised in Member States or third countries and already evaluated at Member State level, which would not lead to an unacceptable risk for consumers. However, no fall-back GAPs were identified. Therefore, MRLs for cypermethrins for these products should be lowered to the product-specific LODs in Annex II to Regulation (EC) No 396/2005.
- (14) As the Authority identified that no residue trials were available to derive MRL values for cypermethrin in or on spring onions, lentils (fresh), cardoons, celeries, Florence fennels, rhubarbs, bamboo shoots, palm hearts, and herbal infusions from leaves and herbs, further consideration by risk managers was required. In addition, for lentils (fresh), the Authority concluded that the safety of the CXL could not be confirmed. In the absence of residue trials, which are necessary to derive a MRL value, the Commission considers appropriate to set the MRLs for those products at the product-specific LODs set out in Annex II to Regulation (EC) No 396/2005.
- (15) For dewberries, wild fungi, and commodities from other farmed terrestrial animals, for which the MRLs for cypermethrin were based on uses in the Union which are no longer authorised and for which there are neither CXLs nor import tolerances, it is appropriate to lower the MRLs for cypermethrin to the product-specific LODs in Annex II to Regulation (EC) No 396/2005 without seeking the opinion of the Authority in accordance with Article 17 of Regulation (EC) No 396/2005.
- (16) The Authority concluded that concerning the MRLs for Brussels sprouts, cresses, land cresses, and cotton seeds some information was not available and further consideration by risk manager was required. Since some information on the analytical methods for products of plant origin, on the residue trials for Brussels sprouts, cresses, and land cresses, and on the storage stability for cotton seeds required to assess potential risks from residues of cypermethrin in or on these products was not available, the new MRLs for these products should be reviewed. That review should take into account the information available within two years from the publication of this Regulation.
- (17) In addition, for tea, herbal infusions from flowers and herbal infusions from leaves and herbs, recent monitoring data show that residues of cypermethrins still occur. Further monitoring data is necessary to assess the evolution of the occurrence of cypermethrins and whether food business operators have taken effective measures to avoid cross contamination, e.g. avoiding cross contamination by spray drift. Therefore, the MRLs for these products should be reviewed. That review should take into account the information available within three years from the publication of this Regulation.
- (18) For alpha-cypermethrin, the Authority proposed MRLs based on levels of alpha-cypermethrin calculated by applying conversion factors to the uses of cypermethrins considered in the review of the existing MRLs for cypermethrins in accordance with Article 12(1) of Regulation (EC) No 396/2005. These MRLs should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

- (19) As regards residues of alpha-cypermethrin and cypermethrin in or on products for which no GAPs are authorised in the Union, and neither CXLs nor import tolerances exist, MRLs should be set at the product-specific LODs, or the default MRLs should apply, as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.
- (20) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. Those laboratories proposed product-specific LODs that are analytically achievable.
- (21) 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.
- (22) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (23) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been placed on the market in the Union before the new MRLs for alpha-cypermethrin and cypermethrins become applicable and for which a high level of consumer protection is ensured. This is the case for all products, except for grapefruits, oranges, lemons, limes, mandarins, apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, table grapes, wine grapes, blackberries, raspberries (red and yellow), kaki/Japanese persimmons, kiwi fruits (green, red, yellow), litchis/lychees, American persimmons/Virginia kaki, avocados, bananas, mangoes, papayas, granate apples/pomegranates, pineapples, yams, onions, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, courgettes, melons, pumpkins, watermelons, broccoli, cauliflowers, Brussels sprouts, head cabbages, Chinese cabbages/pe-tsai, kales, kohlrabies, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, roman rocket/rucola, red mustard, spinaches, purslanes, chards/beet leaves, witloofs/Belgian endives, beans (fresh, with pods and without pods), peas (fresh, with pods and without pods), lentils (fresh), celeries, globe artichokes, leeks, rhubarbs, wild fungi, barley, oat, rice, rye, wheat, teas, hops, swine muscle, swine fat, bovine muscle, bovine fat, bovine liver, bovine edible offals, and milks.
- (24) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt to the requirements which result from the modification of the MRLs for cypermethrins.
- (25) 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 the products which were placed on the market in the Union before ... *[Publication Office: please insert date = 6 months after the date of entry into force of this Regulation]*, except for grapefruits, oranges, lemons, limes, mandarins, apples, pears, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), peaches, plums, table grapes,

wine grapes, blackberries, raspberries (red and yellow), kaki/Japanese persimmons, kiwi fruits (green, red, yellow), litchis/lychees, American persimmons/Virginia kaki, avocados, bananas, mangoes, papayas, granate apples/pomegranates, pineapples, yams, onions, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, courgettes, melons, pumpkins, watermelons, broccoli, cauliflowers, Brussels sprouts, head cabbages, Chinese cabbages/petsai, kales, kohlrabies, lamb's lettuces/corn salads, lettuces, escaroles/broad-leaved endives, roman rocket/rucola, red mustard, spinaches, purslanes, chards/beet leaves, witloofs/Belgian endives, beans (fresh, with pods and without pods), peas (fresh, with pods and without pods), lentils (fresh), celeries, globe artichokes, leeks, rhubarbs, wild fungi, barley, oat, rice, rye, wheat, teas, hops, swine muscle, swine fat, bovine muscle, bovine fat, bovine liver, bovine edible offals, and milks.

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 ... [*Publication Office: please insert date = 6 months after the date of entry into force of this Regulation*].

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