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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 copper compounds in or on certain products

Delegations will find attached document D108179/04.

Encl.: D108179/04



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2025/350
(POOL/E4/2025/350/350-EN.docx)
D108179/04
[...](2025) **XXX**

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 copper compounds 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 copper compounds 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) thereof,

Whereas:

- (1) For copper compounds, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The group of copper compounds consists of Bordeaux mixture, copper hydroxide, copper oxychloride, copper oxide and tribasic copper sulphate, and is approved in the Union as active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council².
- (3) In 2018, the European Food Safety Authority ('the Authority') submitted a reasoned opinion on the review of the existing MRLs for copper compounds³ in accordance with Article 12(1) of Regulation (EC) No 396/2005.
- (4) In 2023, the Authority published a scientific opinion on the re-evaluation of the existing Health-Based Guidance Values for copper and exposure assessment from all sources⁴. The Authority established that there are no health risks below the copper retention threshold of an intake of 0.07 mg/kg body weight per day for the adult population and concluded that the current copper exposure presents no health risk for the population, including for children. It also concluded that plant protection products were not a major contributor to exposure to copper for the population.

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

² 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>).

³ European Food Safety Authority, Reasoned opinion on the review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3):5212, <https://doi.org/10.2903/j.efsa.2018.5212>.

⁴ European Food Safety Authority, Scientific Opinion on the re-evaluation of the existing Health-Based Guidance Values for copper and exposure assessment from all sources. EFSA Journal 2023;21(1):7728, <https://doi.org/10.2903/j.efsa.2023.7728>.

- (5) In 2025, the Authority published a statement updating the review of the existing MRLs for copper compounds⁵ in light of its scientific opinion on the re-evaluation of the Health-Based Guidance Values and exposure assessment from all sources. Due to copper being ubiquitous in the environment, the Authority considered data from residue trials supporting uses authorised in the Union as well as monitoring data, in order to derive appropriate MRLs.
- (6) The Authority concluded that the current MRLs for copper compounds in or on cashew nuts, coconuts, blackberries, dewberries, raspberries, dates, table olives, kumquats, carambolas, jambuls, cucumbers, gherkins, courgettes, celeries, Florence fennels, rhubarbs, poppy seeds, sesame seeds, cotton seeds, safflower seeds, borage seeds, gold of pleasure seeds, castor beans, olives for oil production, maize/corn, herbal infusions from strawberry leaves, sugar beet roots, bovine muscle, bovine fat, sheep muscle, sheep fat, goat fat, equine muscle, equine fat, poultry muscle, and fat of other farmed terrestrial animals reflect the current levels of copper in those products and pose no risk to consumers. They should therefore be maintained. The MRLs for these products should therefore remain at the existing levels and be included in Annex II to Regulation (EC) No 396/2005.
- (7) The Authority further concluded that the current MRLs for copper compounds in or on almonds, Brazil nuts, chestnuts, hazelnuts/cobnuts, macadamias, pecans, pine nut kernels, pistachios, walnuts, apples, pears, quinces, medlars, loquats/Japanese medlars, cherries, peaches, table grapes, wine grapes, strawberries, blueberries, cranberries, currants, gooseberries, rose hips, mulberries, azaroles/Mediterranean medlars, elderberries, kiwi fruits, potatoes, horseradishes, spring onions/green onions and Welsh onions, tomatoes, sweet peppers/bell peppers, aubergines/eggplants, 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, spinaches, purslanes, chards/beet leaves, grape leaves, watercresses, herbs and edible flowers, globe artichokes, leeks, buckwheat, sorghum, hops, swine liver, bovine liver, sheep liver, goat muscle, goat liver, liver of other farmed terrestrial animals, honey, and products from wild terrestrial animals should be raised to reflect the current levels of copper in those products. It is appropriate to set the MRLs for these products at the levels identified by the Authority in Annex II to Regulation (EC) No 396/2005, which pose no risk to consumers.
- (8) The Authority also concluded that the current MRLs for copper compounds in or on "citrus fruits", apricots, plums, figs, kaki/Japanese persimmons, litchis/lychees, passionfruits/maracujas, prickly pears/cactus fruits, star apples/cainitos, American persimmons/Virginia kaki, avocados, bananas, mangoes, papayas, granate apples/pomegranates, cherimoyas, guavas, pineapples, breadfruits, durians, soursops/guanabanas, cassava roots/manioc, sweet potatoes, yams, arrowroots, beetroots, carrots, celeriacs/turnip rooted celeries, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, garlic, onions, shallots, okra/lady's fingers, sweet corn, broccoli, cauliflowers, Brussels sprouts, head cabbages, kohlrabies, witloofs/Belgian endives, beans (with

⁵ European Food Safety Authority, Statement on the update of maximum residue levels (MRLs) for copper compounds in light of the EFSA scientific opinion on the re-evaluation of the Health-Based Guidance Values (HBGVs) and exposure assessment from all sources. EFSA Journal 2025;23e9271, <https://doi.org/10.2903%2Fj.efsa.2025.9271>.

pods), beans (without pods), peas (with pods), peas (without pods), lentils, asparagus, cardoons, bamboo shoots, palm hearts, cultivated fungi, wild fungi, mosses and lichens, algae and prokaryotes organisms, beans (dry), lentils (dry), peas (dry), lupins/lupini beans, linseeds, peanuts/groundnuts, sunflower seeds, rapeseeds/canola seeds, soyabeans, mustard seeds, pumpkin seeds, hemp seeds, oil palm kernel, oil palm fruits, kapok, barley, common millet/proso millet, oat, rice, rye, wheat, teas, coffee beans, “herbal infusions from flowers”, herbal infusions from rooibos, herbal infusions from mate/maté, “herbal infusions from roots”, herbal infusions from any other parts of the plant, cocoa beans, carob’s/Saint John’s breads, “spices”, sugar canes, chicory roots, swine muscle, swine fat, swine kidney, swine edible offals, bovine kidney, bovine edible offals, sheep kidney, sheep edible offals, goat kidney, goat edible offals, equine kidney, equine liver, equine edible offals, poultry fat, poultry kidney, poultry edible offals, muscle of other farmed terrestrial animals, kidney of other farmed terrestrial animals, edible offals of other farmed terrestrial animals, “milks”, and “bird eggs”, while they pose no risk to consumers, should be lowered to reflect the current levels of copper in those products with a view to setting MRLs at levels as low as reasonably achievable. However, several Member States and stakeholders raised concerns that the levels proposed by the Authority were too low and did not reflect adequately the current levels of copper in those products. They requested additional time to submit the relevant monitoring data. Since the Authority concluded that the current copper exposure presents no health risk for the population, these MRLs should be maintained at their current levels and set in Annex II to Regulation (EC) No 396/2005, allowing Member States and stakeholders additional time to submit monitoring data. The MRLs for these products will be reviewed. That review should take into account the information available by 30 June 2028 submitted via the chemical monitoring data collection exercises conducted on a yearly basis by the Authority⁶.

- (9) Additionally, since some information on the analytical methods for products of plant origin with high-oil content, dry products of plant origin, tea, coffee beans, cocoa beans, carobs, hops, herbal infusions, “spices”, and for products of animal origin, and information on the residue trials for kiwi fruits, cucurbits with inedible peel, watercress and hops was not available, the MRLs set out in this Regulation for these products should be reviewed. That review should take into account the information available by 30 June 2028.
- (10) The Authority proposed to change the residue definition to ‘total copper’. The Commission considers this new residue definition to be appropriate.
- (11) 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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:

⁶ Available online : <https://www.efsa.europa.eu/en/resources/data-collection-chemicals>.

Article 1

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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