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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 dithiocarbamates
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 dithiocarbamates 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 dithiocarbamates, maximum residue levels ('MRLs') were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. MRLs are expressed as carbon disulfide (CS₂) since the analytical method used to quantify substances belonging to the group of dithiocarbamates such as maneb, mancozeb, metiram, propineb, thiram and ziram, is based on the conversion of those substances into CS₂.
- (2) For dithiocarbamates 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.
- (3) Naturally occurring compounds in certain plant products mimic the presence of residues resulting from the use of those substances as pesticides. Therefore, the Authority, in its reasoned opinion also considered monitoring data from organic products, reflecting content of CS₂ which is not related to the use of dithiocarbamates as pesticides.
- (4) In this reasoned opinion the Authority proposed to change the residue definition to "dithiocarbamates (including maneb, mancozeb, metiram, propineb, thiram and ziram) determined and expressed as CS₂". However, risk managers decided to simplify this residue definition to "dithiocarbamates (dithiocarbamates determined and expressed as CS₂)" since the proposed list of dithiocarbamates is not comprehensive and the existing analytical methods for dithiocarbamates are based on determining their CS₂ common moiety without being able to determine the individual substance that was used. Ongoing research for analytical methods could enable future determination of the individual substances used as pesticide.

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 existing maximum residue levels for dithiocarbamates according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2023;21(5):7987.

- (5) The current MRLs for wine grapes, cranberries, bananas, peanuts/groundnuts, wheat and ginseng are based on Codex MRLs ('CXLs'), which were included in Annex II to Regulation (EC) No 396/2005. The Authority concluded that those MRLs are safe for consumers, but as some information was not available, further consideration from risk managers was required. Therefore, as there is no risk for consumers those MRLs should be maintained at the level of the CXLs in Annex II to Regulation (EC) No 396/2005. Those MRLs will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.
- (6) The current MRLs for oranges, mandarins, almonds, pecans, carrots, garlic, onions, tomatoes, sweet peppers/bell peppers, cucumbers, courgettes, melons, watermelons, sweet corn, asparagus, leeks, barley, hops, cumin and sugar beet roots were based on uses in the Union which are no longer authorised. However, CXLs exist for those products and the Authority concluded that they are safe for consumers. Therefore, as there is no risk for consumers, those MRLs should be lowered to those CXLs in Annex II to Regulation (EC) No 396/2005. Nevertheless, the Authority identified some information as unavailable for certain products and further consideration from risk managers was required. Therefore, while the MRLs for those products are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.

The current MRLs for 'pome fruits' are based on CXLs which were included in Annex II to Regulation (EC) No 396/2005. The Authority concluded that a risk for consumers concerning the existing MRLs cannot be excluded. The current MRLs in and on cherries (sweet) and plums were based on uses in the Union which are no longer authorised. The Authority concluded that a risk for consumers concerning the existing MRLs cannot be excluded. However, for 'pome fruits', cherries and plums, lower MRLs are available, based on authorised uses in the Union of ziram, which are safe for consumers. Therefore, as there is no risk for consumers, it is appropriate to set new lower MRLs for those products in Annex II to Regulation (EC) No 396/2005. Nevertheless, for those lower MRLs based on uses of ziram, the Authority identified some information as unavailable and further consideration from risk managers was required. Therefore, while the MRLs are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.

- (7) The current MRLs for apricots, peaches, strawberries, currants (black, red and white), papayas and potatoes were based on uses in the Union which are no longer authorised. The Authority concluded that a risk for consumers concerning the existing MRLs cannot be excluded. However, for those products, the Authority identified lower naturally occurring levels of CS₂, which are safe for consumers, in the monitoring data from organic products. Therefore, the MRLs for those products should be lowered to those naturally occurring levels in Annex II to Regulation (EC) No 396/2005.
- (8) The current MRLs for table grapes and mangoes are based on CXLs which were included in Annex II to Regulation (EC) No 396/2005. The Authority concluded concerning the existing MRLs that they are not safe for consumers. However, lower MRLs are available, based on import tolerances for mancozeb, which are safe for consumers. Therefore, as there is no risk for consumers, it is appropriate to set new lower MRLs for those products in Annex II to Regulation (EC) No 396/2005. Nevertheless, for those MRLs, the Authority identified some information as unavailable and further consideration from risk managers was required. Therefore, while the MRLs are considered safe, they will be reviewed. The review will take into

account the information available within two years from the publication of this Regulation.

- (9) The current MRLs for “cane fruits”, rose hips, mulberries (black and white), azaroles/Mediterranean medlars, elderberries, figs, kumquats, kiwi fruits (green, red, yellow), American persimmons/Virginia kaki, “tropical root and tuber vegetables”, horseradishes, Jerusalem artichokes, radishes, swedes/rutabagas, turnips, broccoli, cauliflowers, Chinese cabbages/pe-tsai, kohlrabies, cresses and other sprouts and shoots, Roman rocket/rucola, spinaches, chards/beet leaves, grapes leaves and similar species, watercresses, chives, parsley, beans (without pods), peas (with pods), lentils, cardoons, celeries, Florence fennels, globe artichokes, cultivated fungi, wild fungi, “pulses”, linseeds, rapeseeds/canola seeds, mustard seeds, buckwheat and other pseudocereals, sorghum “herbal infusions from flowers, leaves and herbs and any other parts of the plant”, valerian roots, “seed spices other than cumin”, fruit spices, ginger, turmeric/curcuma, cloves, flower pistil spices, aril spices, and chicory roots were based on uses in the Union which are no longer authorised. However, for those products, the Authority identified equal or higher naturally occurring levels of CS₂, which are safe for consumers, in the monitoring data from organic products. Therefore, the MRLs for those products should be set to those naturally occurring levels in Annex II to Regulation (EC) No 396/2005.
- (10) The current MRLs for grapefruits, lemons, limes, Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamias, pine nut kernels, pistachios, walnuts, blueberries, gooseberries, table olives, kaki/Japanese persimmons, avocados, pumpkins, beetroots, celeriacs/turnip rooted celeries, parsnips, parsley roots/Hamburg roots parsley, salsifies, shallots, spring onions/green onions and Welsh onions, okra/lady’s fingers, gherkins, Brussels sprouts, lamb’s lettuces/corn salads, lettuces, escaroles/broad-leaved endives, land cresses, red mustards, baby leaf crops (including brassica species), purslanes, witloofs/Belgian endives, “herbs and edible flowers other than chives and parsley”, peas (without pods), rhubarbs, poppy seeds, sesame seeds, sunflower seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans, olives for oil production, oat and rye were based on uses in the Union which are no longer authorised. However, for those products, the Authority identified lower naturally occurring levels of CS₂, which are safe for consumers, in the monitoring data from organic products. Therefore, the MRLs for those products should be lowered to those naturally occurring levels in Annex II to Regulation (EC) No 396/2005.
- (11) For passion fruits/maracujas and pineapples, the Authority concluded that for the MRLs that were derived from import tolerances for metiram there is no risk for consumers. Therefore, those MRLs should be set in Annex II to Regulation (EC) No 396/2005. However, the Authority identified some information concerning fruits/maracujas and pineapples as unavailable and concluded that further consideration from risk managers was required. Therefore, while the MRLs for those products are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.
- (12) The current MRLs for aubergines/eggplants and beans and peas (with pods), soyabeans, cotton seeds, maize/corn and rice were based on uses in the Union which are no longer authorised. The Authority concluded that the MRLs based on an import tolerance for mancozeb for those products could be considered as safe. As there is no risk for consumers, those MRLs should be set in Annex II to Regulation (EC) No 396/2005. However, the Authority identified some information for those MRLs as

unavailable and concluded that further consideration from risk managers was required. Therefore, while the MRLs for those products are considered safe, they will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.

The current MRLs for head cabbages and kales were based on uses in the Union which are no longer authorised. For the existing CXLs, the Authority concluded that a consumer risk cannot be excluded. However, for those products, the Authority identified lower naturally occurring levels of CS₂, which are safe for consumers, in the monitoring data from organic products. Therefore, as there is no risk for consumers, the MRLs for those products should be set to those naturally occurring levels in Annex II to Regulation (EC) No 396/2005

- (13) For the MRLs for products of animal origin, the Authority concluded that the current CXLs, where available, cannot be considered to set MRLs due to missing detailed information on the dietary burden calculations and livestock feeding studies. Therefore, those MRLs should be set at the Limits of Determination ('LOD') specific to each product in Annex II to Regulation (EC) No 396/2005. Those MRLs will be reviewed. The review will take into account the information available within two years from the publication of this Regulation.
- (14) The Authority assessed the existing CXLs in its reasoned opinion. For setting the MRLs, the Commission has taken into account those CXLs that are considered safe for consumers in the Union.
- (15) As regards products on which the use of plant protection products containing the active substances belonging to the group of dithiocarbamates is not authorised, and for which no import tolerances or CXLs exist, it is appropriate to set the MRLs at the specific LODs, or the default MRL should apply as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.
- (16) The Commission consulted the European Union reference laboratories for residues of pesticides on the need to adapt certain LODs. For all the active substances covered by this Regulation, those laboratories proposed product specific LODs.
- (17) 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.
- (18) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (19) 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 before the new MRLs become applicable and for which a high level of consumer protection is maintained, except for "pome fruits" table grapes, mangoes, apricots, peaches, strawberries, currants (black, red and white), papayas, and potatoes for which an acute risk to consumers was identified.
- (20) 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 adapt themselves to the requirements which result from the modification of the MRLs.
- (21) 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 in and on all products which have been placed on the market in the Union before [*Office of Publications: please insert date 6 months after date of entry into force of this Regulation*], except for “pome fruits” table grapes, mangoes, apricots, peaches, strawberries, currants (black, red and white), papayas, and potatoes for which an acute risk to consumers was identified.

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 Publications: please insert date 6 months after 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