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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 difenoconazole in or on certain products

(Text with EEA relevance)

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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 difenoconazole 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 the active substance difenoconazole, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In 2024, the European Food Safety Authority (the 'Authority') submitted a reasoned opinion² on the review of the MRLs for difenoconazole in accordance with Article 12 of Regulation (EC) No 396/2005.
- (3) The Authority proposed a new residue definition for enforcement applicable to animal products as 'difenoconazole – alcohol (CGA205375), expressed as difenoconazole' based on the results of the metabolism studies on difenoconazole residues in livestock.
- (4) The Authority recommended lowering MRLs for potatoes, sweet potatoes, aubergines, chards, cardoons and celeries. It further recommended keeping the existing MRLs for escaroles, fennel and rhubarbs, for which sufficient supporting data on good agricultural practices ('GAPs') were submitted and assessed by the Authority. As there is no risk for consumers, it is appropriate to set the MRLs for those products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (5) The Authority concluded that concerning the MRLs for 'pome fruits', 'stone fruits', 'grapes', strawberries, blackberries, raspberries (red and yellow), table olives, kaki/Japanese persimmons, bananas, cassava roots/manioc, yams, arrowroots, beetroots, carrots, celeriacs/turnip rooted celeries, horseradishes, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, radishes, salsifies, swedes/rutabagas, turnips, garlic, onion, shallots, spring onions/green onions and Welsh onions, tomatoes, sweet peppers/bell peppers, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, broccoli, cauliflowers, Brussels sprouts, head cabbages, Chinese cabbages/pe-tsai, kales, kohlrabies, lamb's lettuces/corn salads, lettuces,

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

² EFSA 2024. Review of the existing maximum residue levels for difenoconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal. 2024;22:e8987, <https://doi.org/10.2903/j.efsa.2024.8987>.

cresses and other sprouts and shoots, land cresses, Roman rocket/rucola, red mustard, baby leaf crops (including brassica species), spinaches, purslanes, witloofs/Belgian endives, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves, tarragon, beans (with pods), beans (without pods), peas (with pods), peas (without pods), lentils, asparagus, globe artichokes, leeks, beans, lentils, lupins/lupini beans, linseeds, poppy seeds, sunflower seeds, rapeseeds/canola seeds, mustard seeds, cotton seeds, safflower seeds, borage seeds, gold of pleasure seeds, olives for oil production, barley, buckwheat and other pseudocereals, maize/corn, common millet/proso millet, oat, rice, Sorghum, herbal infusion from 'flowers', 'leaves and herbs', 'roots', 'seed spices, subgroup of', 'fruit spices, subgroup of', liquorice, turmeric/curcuma, sugar beet roots, chicory roots, poultry meat, poultry fat, poultry liver, poultry kidney, poultry edible offals and eggs, some information was not available and that further consideration by risk managers was required. For lettuces, kales, escaroles, witloofs and celeries, the Authority nevertheless derived safe MRLs based on fall-back GAPs. Member States should review the GAPs of these crops to ensure consumer safety. As there is no risk for consumers, it is appropriate to set the MRLs for all these products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority. While these MRLs are considered safe, they will be reviewed taking into account the information available within two years from the publication of this Regulation.

- (6) The Authority further concluded that concerning the MRLs for cranberries, prickly pear (cactus fruit), avocados, guava, sweet corn, peanuts, tee, coffee beans, animal (swine, bovine, sheep, horse and other farm animals) products from tissues (fat, muscle, liver and kidney) and milk, which are based on maximum residue levels set by the Codex Alimentarius ('CXLs'), some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, it is appropriate to set the MRLs for these products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (7) The Authority also concluded that concerning the MRLs for bark spices, bud spices, flower pistil spice and aril spices, some information was not available and that further consideration by risk managers was required. As no MRL nor risk assessment values could be derived, it is appropriate to lower the MRLs for those products to the limit of determination ('LOD') in Annex II to Regulation (EC) No 396/2005.
- (8) The Authority assessed the existing CXLs in its reasoned opinion. When setting the MRLs, the Commission has taken into account those CXLs that are considered safe for consumers in the Union.
- (9) An application pursuant to Article 6(4) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs was submitted for citrus fruits, tree nuts, mangoes, papayas, dry peas and soyabeans. The Authority assessed the submitted information and concluded³ that risk for consumers is unlikely. The Authority further concluded that data gaps identified in the MRL review according to Article 12 of Regulation (EC) No 396/2005 are addressed for these products. It is therefore appropriate to set the MRLs for these products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (10) 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, it is appropriate to set

³ EFSA 2025. Setting of import tolerances for difenoconazole in various crops. EFSA Journal. 2025; 23:e9472. <https://doi.org/10.2903/j.efsa.2025.9472>.

the MRLs at the product-specific LOD or to apply the default MRL as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.

- (11) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products technical developments permit the setting of lower LODs.
- (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 not apply to products placed on the market in the Union before the new MRLs become applicable and for which 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 adapt themselves to the requirements which 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 the products which were placed on the market in the Union before [OP: *please insert date = 6 months after 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 [OP: *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