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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 azocyclotin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos in or on certain products

(Text with EEA relevance)

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(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/EEC[1], and in particular Article 14(1), point (a), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

(1) For the active substances azocyclotin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, and profenofos, maximum residue levels ('MRLs') were set in Annex II and part B of Annex III to Regulation (EC) No 396/2005. For the active substance fenpropathrin, MRLs were set in part A of Annex III to Regulation (EC) No 396/2005.

(2) All these substances were never approved in the EU, or their approval was withdrawn before 2008, and therefore, they did not fall within the scope of the systematic review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005. The Commission requested the European Food Safety Authority ('the Authority') under Article 43 of Regulation (EC) No 396/2005 to review the existing MRLs for the above listed active substances, and to examine the available information in order to screen the quality of the toxicological reference values (TRVs).

(3) The Authority published the correspondent scientific opinions in 2023[2]. Following a first publication of these reasoned opinions in 2023, the Authority carried out a

[1] OJ L 70, 16.3.2005, p. 1.

[2] EFSA, Targeted review of maximum residue levels (MRLs) for azocyclotin and cyhexatin. EFSA Journal 2023; 21(6):8038. Available online : https://www.efsa.europa.eu/en/efsajournal/pub/8038.
EFSA, Targeted review of maximum residue levels (MRLs) for chlorfenapyr. EFSA Journal 2023; 21(12):8444. Available online : https://www.efsa.europa.eu/en/efsajournal/pub/8444.
EFSA, Targeted review of maximum residue levels (MRLs) for diazinon. EFSA Journal 2023; 21:8426. Available online :https://www.efsa.europa.eu/en/efsajournal/pub/8426.
EFSA, Targeted review of maximum residue levels (MRLs) for dicofol. EFSA Journal 2023; 21:8425. Available online :https://www.efsa.europa.eu/en/efsajournal/pub/8425.
EFSA, Targeted review of maximum residue levels (MRLs) for endosulfan 2023. EFSA Journal 2023; 21(7):8114. Available online : https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2023.8114.
EFSA, Targeted review of maximum residue levels (MRLs) for fenarimol 2023. EFSA Journal 2023; 21(7):8113. Available online :https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2023.8113.

stakeholder consultation[3] and the reasoned opinions were amended to reflect the outcome of this consultation[4].

(4) For the active substances azocyclotin and cyhexatin, MRLs exist on apples, oranges, and wine grapes. The Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs. It is therefore appropriate to delete the MRLs set out for these substances in Annex II and part B of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(5) For the active substance chlorfenapyr, MRLs in or on all food products are set at the LOQ, except for tea. The existing MRL and the calculated exposure assessment are affected by several uncertainties related to the data gaps identified in the assessment. It is therefore appropriate to delete this MRL set out for chlorfenapyr in Annex II and part B of Annex III to Regulation (EC) No 396/2005 and to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(6) For the active substance diazinon, for a number of plant commodities (almonds, cranberries, pineapples, radishes, onions, sweet pepper/bell peppers, sweet corn, Chinese cabbage/pe-tsai, kohlrabies, hops, seed spices, root and rhizomes spices, sugar beet roots). For these plant commodities, the Authority concluded that the MRLs are not substantiated, hence, they should be lowered to the LOQ. It should also be noted that the existing MRLs set for diazinon in livestock commodities (except poultry) are identical to the MRLs set for veterinary uses in Regulation (EU) 37/2010[5]. The Authority concluded that, lacking robust TRVs for diazinon, the risk assessment is only indicative. It is therefore appropriate to delete the MRLs set out for diazinon in Annex II and part B of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(7) For the active substance dicofol, for several food products (melons, cotton seeds, tea, hops, poultry (muscle, fat, liver, kidney and edible offals), milk and birds' eggs), the Authority concluded that the existing MRLs are not substantiated by sufficient toxicological data, hence, all MRLs are proposed to be lowered to the LOQ. It is therefore appropriate to delete the MRLs set out for dicofol in Annex II and part B of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

EFSA, Targeted review of maximum residue levels (MRLs) for fenpropathrin. EFSA Journal 2023; 21(6):8057. Available online :https://www.efsa.europa.eu/en/efsajournal/pub/8057.
EFSA, Targeted review of maximum residue levels (MRLs) for profenofos 2023. EFSA Journal 2023; 21:8445. Available online : https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8445.

[3] Available online :https://www.efsa.europa.eu/en/call/call-expressions-interest-submit-data-10-non-approved-active-substances-review-mrls.

[4] EFSA, Outcome of the stakeholder consultation on the reasoned opinions for azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos. EFSA supporting publication 2024:EN-9002. Available online : https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2024.EN-9002.

[5] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. (OJ L 015 20.1.2010, p. 1. ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).

(8) For the active substance endosulfan, the Authority concluded that the existing MRLs for endosulfan in soya beans and teas are not substantiated by sufficient toxicological data, hence, MRLs are proposed to be lowered to the LOQ. As regards endosulfan in or on cotton seeds, seed spices, fruit spices and root and rhizome spices, the Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs. It is therefore appropriate to delete the MRLs set out for endosulfan in Annex II and part B of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(9) For the active substance fenarimol, the Authority concluded that the existing MRLs are not substantiated by sufficient toxicological data for this active substance in or on apricots, cherries (sweet), peaches, table and wine grapes, strawberries, raspberries (red and yellow), currants (black, red and white), gooseberries (green, red and yellow), bananas, gherkins, courgettes, other cucurbit with edible peel, watermelons, other cucurbits with inedible peel and hops, hence, all these MRLs are proposed to be lowered to the LOQ. It is therefore appropriate to delete the MRLs set out for fenarimol in Annex II and part B of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(10) For the active substance fenpropathrin, the Authority concluded that the existing MRLs in citrus fruits, strawberries, melons and tea are not substantiated by sufficient toxicological data, hence, all these MRLs are proposed to be lowered to the LOQ. It is therefore appropriate to delete the MRLs set out for fenpropathrin in part A of Annex III to Regulation (EC) No 396/2005 as well as to set all MRLs at the product specific LOQs in Annex V to Regulation (EC) No 396/2005 in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(11) For profenofos, a temporary MRL was set by Regulation (EU) No 2023/377[6] for herbs and edible flowers, pending the submission of monitoring data on the occurrence of this active substance in these products. Likewise, a temporary MRL was set by Regulation (EU) 2022/1290[7] for rose petals, pending the submission of monitoring data on the occurrence of this substance in the concerned products. It is therefore appropriate to continue to monitor the levels of profenofos in herbs and edible flowers and rose petals to review these MRLs based on monitoring data. As regards MRLs of profenofos in or on mangoes, tomatoes, cotton seeds, coriander, cumin, fennel, fruit spices, cardamom, commodities from swine, bovine, sheep, goat, equine, poultry, and other farmed terrestrial animals (except for milk and eggs), the Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs. It is therefore appropriate to delete the MRLs set out for profenofos in the above listed

[6] Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products. (OJ L 55, 22.2.2023, pp. 1–84. ELI: http://data.europa.eu/eli/reg/2023/377/oj).

[7] Commission Regulation (EU) 2022/1290 of 22 July 2022 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, chlormequat, dodine, nicotine, profenofos and Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in or on certain products. (OJ L 196, 25.7.2022, pp. 74–114. ELI: http://data.europa.eu/eli/reg/2022/1290/oj).

commodities in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation. Additionally, temporary MRLs are maintained as proposed in Regulation (EU) 2023/377 and Regulation (EU) 2022/1290. Additionally, for the avoidance of doubt, for profenofos, the respective footnotes have been updated as regards dates.

(12) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LOQs. Those laboratories proposed product specific LOQs that are analytically achievable.

(13) 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.

(14) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(15) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products, which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(16) 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 themselves to the requirements which result from the modification of the MRLs.

(17) 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 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 products which were produced in the Union or imported into the Union before … [*Office of publications: please insert date = 6 months after the 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 … [*Office of publications: 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