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Delegations will find attached document D110097/05.

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Brussels, XXX
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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, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

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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, 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(2) As these active substances were never approved in the Union, or their approval was withdrawn before 2008, they did not fall within the scope of the systematic review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005.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 therefore requested the European Food Safety Authority ('the Authority'), under Article 43 of Regulation (EC) No 396/2005, to review the existing MRLs for these 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 corresponding scientific opinions in 2023. Following a first publication of these reasoned opinions in 2023, the Authority carried out a stakeholder consultation[2] and the reasoned opinions were amended to reflect the outcome of this consultation[3].

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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, 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.

3 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.

(4) For the active substances azocyclotin and cyhexatin, the European Union reference laboratories proposed to change the residue definition to '*sum of cyhexatin, azocyclotin and other salts of tricyclohexyltin determined and expressed as tricyclohexyltin cation [F]*'. It is, therefore, appropriate to amend the residue definition accordingly.

(5) MRLs for azocyclotin and cyhexatin 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 and to set all MRLs at the product-specific limits of quantification ('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 chlorfenapyr, no MRLs are set for animal commodities, while MRLs in or on plant commodities are set at the LOQ, except for tea. The existing MRL and the calculated exposure assessment are affected by several uncertainties related to data gaps identified in the assessment. It is therefore appropriate to delete all MRLs set out for chlorfenapyr in Annex II to Regulation (EC) No 396/2005 and to set all MRLs at the product-specific LOQ and to set MRLs for animal commodities at the product-specific LOQ 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, MRLs are set for melons, cotton seeds, tea, hops, poultry (muscle, fat, liver, kidney and edible offals), milk and birds' eggs. The Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs. In addition, the existing MRLs are not supported by data. 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 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.

(8) For the active substance endosulfan, MRLs are set for soyabeans, cotton seeds, teas, 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. In addition, the existing MRLs in soyabeans and teas are not supported by data. 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 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.

(9) For the active substance fenarimol, MRLs are set for pome fruits, apricots, cherries (sweet), peaches, table and wine grapes, strawberries, raspberries (red and yellow), currants (black, red and white), gooseberries (green, red and yellow), bananas, cucumbers, gherkins, courgettes, other cucurbits with edible peel, melons, pumpkins, watermelons, other cucurbits with inedible peel and hops. The Authority concluded

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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.
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.

that the risk assessment could not be finalised due to the lack of robust TRVs. In addition, the existing MRLs for 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 cucurbits with edible peel, watermelons, other cucurbits with inedible peel and hops are not supported by data. 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 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.

(10) For the active substance fenpropathrin, MRLs are set for citrus fruits, strawberries, melons and tea. The Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs. In addition, the existing MRLs are not supported by data. It is, therefore, appropriate to delete the MRLs set out for fenpropathrin in Part A 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.

(11) For profenofos, a temporary MRL was set by Commission Regulation (EU) 2023/377[4] 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 Commission Regulation (EU) 2022/1290[5] for rose petals, pending the submission of monitoring data on the occurrence of this substance in the concerned products. It is appropriate to maintain these temporary MRLs and to continue to monitor the levels of profenofos in herbs and edible flowers and rose petals to review these MRLs based on monitoring data.

(12) As regards MRLs for profenofos in or on mangoes, tomatoes, cotton seeds, coriander, cumin, fennel, fruit spices, 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 these commodities in Annex II to Regulation (EC) No 396/2005 and to set MRLs for these commodities at the product-specific LOQs in accordance with Article 14(1) in conjunction with Article 18(1), point (b), of that Regulation.

(13) 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.

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[4] 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).

[5] 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).

(14) 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.

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

(16) 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.

(17) 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.

(18) 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 placed on the market in 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