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COMMISSION REGULATION (EU) …/…

of XXX

Commission Regulation (EU) 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 carbofuran, imazalil, mandipropamid, propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl in or on certain products

(Text with EEA relevance)

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Commission Regulation (EU) 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 carbofuran, imazalil, mandipropamid, propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl 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/EEC[1], and in particular Article 14(1), point (a), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

(1) For imazalil, mandipropamid, propaquizafop, quizalofop-P-ethyl and quizalofop-P-tefuryl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For carbofuran, MRLs were set in Annex II and Part B of Annex III to that Regulation.

(2) On 30 November 2024, the Codex Alimentarius Commission revoked some Codex maximum residue limits ('CXLs') for the active substance carbofuran. For the only one of those revoked CXLs that was implemented in the Union, concerning cotton seeds, the European Food Safety Authority ('the Authority') evaluated alternative authorised good agricultural practices ('GAPs') to identify a fall-back MRL proposal and published a scientific report[2].

(3) In its report, the Authority recommended lowering the MRL for carbofuran in cotton seeds at the current limit of determination ('LOD'), since carbofuran is not approved in the Union and no import tolerances have been requested for carbofuran on cotton seeds. Moreover, the MRLs for carbofuran on all other products are currently set at the product-specific LODs. It is, therefore, appropriate to delete the MRLs currently set for carbofuran in Annex II and Part B of Annex III to Regulation (EC) No 396/2005 and to set MRLs for carbofuran on all products at the product-specific LODs in Annex V to that Regulation.

(4) The Authority assessed the MRLs for imazalil in accordance with Article 12 of Regulation (EC) No 396/2005 in 2017[3] but identified some information as unavailable

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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 (2025). Assessment of fall-back MRLs for revoked CXLs previously implemented in the EU legislation. EFSA Journal, 23(3), e9299. https://doi.org/10.2903/j.efsa.2025.9299.

3 EFSA (2017). Reasoned opinion on the review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal;15(9):4977, 66 pp. https://doi.org/10.2903/j.efsa.2017.4977.

for certain products. In 2018, it updated its reasoned opinion[4] following new information submitted by the applicant related to the toxicological profiles of metabolites R014821, FK-722 and FK-284. The Authority identified some information gaps on: residue trials for peppers, courgettes and melons; toxicological data on metabolites R014821, FK-722 and FK-284; and storage stability data. The available information was nevertheless sufficient for the Authority to propose tentative MRLs. Since those MRLs were safe for consumers, they were set in Annex II to Regulation (EC) No 396/2005[5], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(5) Subsequently, the applicant submitted information to address part of the data gaps identified and in parallel submitted a request to modify the existing MRLs for imazalil in citrus fruits in accordance with Article 6 of Regulation (EC) No 396/2005.

(6) The Authority assessed the application and the further information submitted and concluded in its reasoned opinion[6] that the data gap concerning the toxicological profile of metabolites R014821, FK-772 and FK-284 was addressed. The data gap on storage stability was addressed.

(7) The data gaps on residue trials were not addressed in the case of melons. The Authority concluded that the EU critical GAP on melons submitted in the MRL review is not sufficiently supported by data and noted that the alternative Codex MRL of 2 mg/kg has been withdrawn in 2019. No import tolerances have been requested for imazalil on melons. Therefore, the MRLs laid down in Annex II to Regulation (EC) No 396/2005 for imazalil on melons should be lowered to the LOD. The data gaps on residue trials were not addressed either in the case of peppers. Therefore, the MRLs laid down in Annex II to Regulation (EC) No 396/2005 for imazalil on peppers should stay at the LOD.

(8) As regards the application concerning citrus fruits, the Authority concluded that the submitted information was sufficient to derive an MRL for the whole group of citrus fruits. It is, therefore, appropriate to set the MRLs for imazalil on citrus fruits in Annex II to Regulation (EC) No 396/2005 at the level recommended by the Authority, at which it identified no risk for consumers.

(9) An application requesting a modification of the existing MRLs for imazalil in cucumbers, courgettes and gherkins was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005.

(10) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Commission forwarded the application, the evaluation report and the supporting dossier to the Authority.

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4 EFSA (2018). Reasoned Opinion on the updated review of the existing maximum residue levels for imazalil according to Article 12 of Regulation (EC) No 396/2005 following new toxicological information. EFSA Journal; 16(10):5453, 52 pp. https://doi.org/10.2903/j.efsa.2018.5453.

5 Commission Regulation (EU) 2019/1582 of 25 September 2019 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 imazalil in or on certain products (OJ L 246, 26.9.2019, pp. 1–14, ELI: http://data.europa.eu/eli/reg/2019/1582/oj).

6 EFSA (2025). Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels in citrus fruits for imazalil. EFSA Journal; 23(8):9614, 37 pp. https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2025.9614.

(11) The Authority assessed the application and the evaluation report and gave a reasoned opinion on the proposed MRLs[7]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(12) The Authority concluded that the data submitted in support of the application were found appropriate to derive or confirm the MRL proposal for cucumbers, courgettes and gherkins. The Authority also concluded that the confirmatory data requirement as regards additional residue trials on courgettes has been met. The data gap on the toxicological information for the metabolites has been addressed. The Codex MRL for cucumbers and gherkins has been revoked in 2019. Therefore, it is appropriate to set the MRLs for these commodities in Annex II of Regulation (EC) No 396/2005 at the levels recommended by the Authority.

(13) In light of the review carried out for the MRLs for imazalil and of the outcomes of the applications for MRLs concerning imazalil in certain commodities, the respective footnotes requiring the submission of additional information on imazalil should be deleted from Annex II to Regulation (EC) No 396/2005.

(14) On 2 December 2023, the Codex Alimentarius Commission adopted new CXLs for the active substance mandipropamid[8].

(15) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[9], where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts thereof would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of the Union food law, or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Union. Moreover, in accordance with Article 13, point (e), of that Regulation, the Union is to promote consistency between international technical standards and Union food law while ensuring that the high level of protection adopted in the Union is not reduced.

(16) The Authority assessed the risks that those new CXLs pose to consumers and published a scientific report[10]. The CXLs for which the Authority did not identify risks to consumers in the Union, and for which the Union therefore did not present a reservation to the Codex Committee on Pesticides Residues or the Codex Alimentarius Commission, can be considered safe. Several CXLs have already been implemented in Regulation (EC) No 396/2005[11]. For the CXL for mandipropamid in the group

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7 EFSA (2023). Reasoned Opinion on the modification of the existing maximum residue levels for imazalil in courgettes, cucumbers and gherkins. EFSA Journal; 21(4):7980, 33 pp. https://doi.org/10.2903/j.efsa.2023.7980.

8 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-sixth Session. FAO headquarters, Rome, Italy. 27 November to 2 December 2023. https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-46%252F%25E2%2598%2585Final%252520Report%252FREP23_CACe.pdf.

9 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

10 EFSA (2023). Scientific support for preparing an EU position for the 54th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal, 21(8), 1–303. https://doi.org/10.2903/j.efsa.2023.8111.

11 Commission Regulation (EU) 2024/2633 of 8 October 2024 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for

"cucurbits with inedible peel, others", the Authority did not identify any risks for consumers. This CXL should therefore also be included in Regulation (EC) No 396/2005.

(17) In accordance with Article 43 of Regulation (EC) 396/2005, the Authority was asked to propose fall-back MRLs for recently revoked Codex MRLs that have been previously implemented in the EU legislation[12].The Authority recommended to lower the existing MRLs for mandipropamid in or on sweet peppers and melons, which are confirmed as being safe for consumers, in line with the current CXLs and with a view to setting MRLs at levels as low as reasonably achievable. The MRLs for these products should therefore be set in Annex II to Regulation (EC) No 396/2005 at the levels identified by the Authority.

(18) The Authority assessed the MRLs for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop in accordance with Article 12 of Regulation (EC) No 396/2005 in 2017 but identified data gaps[13] on residue trials for various commodities, validation data for analytical methods in various commodities and lack of storage stability data for certain commodities. The available information was nevertheless sufficient for the Authority to propose tentative MRLs that are safe for consumers. These MRLs were set in Annex II to Regulation (EC) No 396/2005[14], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(19) Subsequently, the applicant submitted information to address part of the data gaps identified and in parallel submitted a request to modify the existing MRLs for quizalofop-P-tefuryl in table grapes, sunflower seeds and soyabeans in accordance with Article 6 of Regulation (EC) No 396/2005.

(20) In accordance with Articles 8 and 9 to Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the Authority. The Authority concluded that the data submitted in support of the request were found appropriate to derive the MRL proposals for sunflower seeds and soyabeans. For table grapes, the submitted field trial data was not sufficient to support a change of MRL. Therefore, the MRLs for sunflower seeds and soyabeans should be established at the level proposed by the Authority.

(21) The Authority assessed the information submitted concerning the identified data gaps and concluded in its reasoned opinion[15] that the data gaps concerning the residue trials

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azoxystrobin, famoxadone, flutriafol, mandipropamid and mefentrifluconazole in or on certain products (OJ L, 2024/2633, 9.10.2024, ELI: http://data.europa.eu/eli/reg/2024/2633/oj).

12 EFSA (2024). Assessment of fall-back MRLs for revoked CXLs previously implemented in the EU legislation and review of the JMPR evaluation of the toxicological data related to pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole. EFSA Journal, 22(4), e8693. https://doi.org/10.2903/j.efsa.2024.8693.

13 EFSA (2017). Reasoned opinion on the review of the existing maximum residue levels for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop according to article 12 of regulation (EC) No 396/2005. EFSA Journal, 15(12), 5050. https://doi.org/10.2903/j.efsa.2017.5050.

14 Commission Regulation (EU) 2019/973 of 13 June 2019 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 bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop, tebufenozide in or on certain products (OJ L 157, 14.6.2019, pp. 3–27 ELI: http://data.europa.eu/eli/reg/2019/973/oj).

15 EFSA (2023) Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop and modification of the existing maximum residue levels for quizalofop-P-tefuryl. EFSA Journal, 22(2):8560. https://doi.org/10.2903/j.efsa.2024.8560.

for propaquizafop in lettuces and salad plants have not been addressed. However, the Authority identified a fall-back GAP and proposed a MRL for lettuces and salad plants fully supported by data on propaquizafop. The Authority identified a fall-back GAP for propaquizafop in spinaches and used the residue trials data on propaquizafop in lettuces and salad plants to derive a MRL for spinaches. Therefore, the MRLs for propaquizafop in lettuces and salad plants and for spinaches should be established at the level proposed by the Authority.

(22) The Authority concluded that the data gaps concerning the storage stability and information on analytical methods for quizalofop-P-ethyl in chards/beet leaves, herbal infusions from flowers and herbal infusions from herbs were not addressed. Therefore, the MRLs laid down in Annex II to Regulation (EC) No 396/2005 for these products should be lowered to the LOD.

(23) The Authority concluded that the data gap concerning the analytical method for quizalofop-P-ethyl in spinaches has not been addressed. Hence, the MRL for quizalofop-P-ethyl in spinaches is no longer supported by the available data.

(24) The Authority concluded that the provided information on analytical methods and hydrolysis in animal products was sufficient to address the identified data gaps for quizalofop-P-tefuryl and did not recommend modifying the corresponding MRLs. Therefore, it is appropriate to keep the MRLs at the current levels.

(25) For the sake of clarity, the respective footnotes requiring the submission of additional information on quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop should be deleted from Annex II to Regulation (EC) No 396/2005.

(26) 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.

(27) The trading partners of the Union were consulted through the World Trade Organization and their comments have been taken into account.

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

(29) The MRLs set out by this Regulation should not apply to products which have been placed on the market in the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(30) 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 amendments to the relevant MRLs.

(31) 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