EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenbuconazole and penconazole in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fenbuconazole and penconazole 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) and Article 49(2) thereof,

Whereas:

(1) For the active substances fenbuconazole and penconazole maximum residue levels ('MRLs') were set in Annexes II and III to Regulation (EC) No 396/2005.

(2) In 2017 and 2018, respectively, the European Food Safety Authority (the 'Authority') submitted reasoned opinions[2][3] on the review of the MRLs for penconazole and fenbuconazole in accordance with Article 12 of Regulation (EC) No 396/2005. The Authority had identified some information as unavailable for certain products. The available information was sufficient for the Authority to propose MRLs that are safe for consumers.

(3) In 2019, the Commission set new MRLs for fenbuconazole and penconazole in Annex II to Regulation (EC) No 396/2005, either maintaining them at the existing level or setting them at the level identified by the Authority. Data gaps were indicated in Annex II to that Regulation specifying the date by which the missing information was to be submitted to the Authority by the applicant in support of the proposed MRLs.

(4) As fenbuconazole is no longer approved in the Union, the applicant submitted additional trial information addressing a data gap on Triazole Derivative Metabolites (TDMs) identified by the Authority[4] that had also been assessed by the Joint WHO/FAO Expert Meeting on pesticides residues supporting the existing Codex

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

[2] EFSA 2017. Reasoned opinion on the review of the existing maximum residue levels for penconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017;15(6):4853, 56 pp. https://doi.org/10.2903/j.efsa.2017.4853.

[3] EFSA 2018. Reasoned Opinion on the review of the existing maximum residue levels for fenbuconazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5399, 51 pp. https://doi.org/10.2903/j.efsa.2018.5399.

[4] EFSA 2023. Evaluation of confirmatory data following the Article 12 MRL review for fenbuconazole. EFSA Journal, 21(8), 1–44. https://doi.org/10.2903/j.efsa.2023.8205.

maximum residue limits ('CXLs')[5]. The data gap was not addressed for trials originally submitted for the establishment of the existing tentative MRLs, higher than the CXL, for some crops. The data gap on TDMs regarding trials was addressed for grapefruits, oranges, lemons, limes, pome fruits, cherries, peaches, blueberries by the trials submitted in support of the CXLs. The data gap on TDMs for mandarins were addressed by extrapolation from residue data of lemons.

(5) Therefore, the existing MRL should be lowered to the level of CXLs for grapefruits, oranges and peaches and maintained at the current MRLs (already at the CXLs level) for lemons, limes, mandarins, pome fruits, cherries and blueberries.

(6) The data gap on occurrence of TDMs was not addressed for fenbuconazole in the case of tree nuts, table and wine grapes, cranberries, bananas, sweet/bell peppers, sunflower seeds, peanuts/groundnuts, rapeseeds/canola seeds, barley, rye and wheat. Therefore, the MRLs laid down in Annex II to Regulation (EC) No 396/2005 for these products should be lowered to the limit of determination ('LOD'), except for tree nuts, which are already at the LOD.

(7) Data regarding both trials and occurrence of TDMs in the case of fenbuconazole were not submitted for apricots, plums and cucurbits with edible and inedible peel. Therefore, the MRLs laid down in Annex II to Regulation (EC) No 396/2005 for these products should be lowered to the LOD.

(8) For fenbuconazole, in the case of animal products, the calculated livestock dietary burden showed that the threshold was not exceeded considering TDM residues via apple pomace and citrus-dried pulp. The Authority assessed the new information provided and identified no consumer intake concerns. Therefore, MRLs for liver, kidney and edible offals of swine, bovine, sheep, goat, equine and other farmed terrestrial animals should be maintained. For milk, based on the assessment of the European Union reference laboratory, the LOD of 0,05 mg/kg laid down in Annex II to Regulation (EC) No 396/2005, should be lowered to 0,01 mg/kg.

(9) For penconazole, the missing information on a representative study on primary crop metabolism, additional residue trials, and storage stability of the relevant metabolites were submitted for blackberries and raspberries. As those data gaps were addressed, the new residue trials point to the need for a higher MRL and the Authority confirmed[6] that the higher MRL is safe for consumers, the existing MRL should be raised.

(10) Data gaps for penconazole were also addressed for pumpkins and watermelons, confirming the existing MRL which should be maintained.

(11) Trial data for penconazole had been submitted for pome fruits and plums from which higher MRLs could in principle be derived. Although the missing data on residue trials analysing simultaneously for the residue definitions for monitoring and risk assessment were not provided, the Authority was able to use a conversion factor to take into account the difference in residue definitions. As the Authority did not indicate a risk for consumers, based on the new data the MRLs should be raised.

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5 FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

6 EFSA 2023. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for penconazole. EFSA Journal 2023;21(3):7889, 52 pp., https://doi.org/10.2903/j.efsa.2023.7889.

(12) For penconazole, sufficient trial data had been submitted for apricots, peaches, table and wine grapes from which lower MRLs can be derived, and for cherries, gooseberries, tomatoes and aubergines/eggplants to support the existing MRLs. Although the missing residue trials analysing simultaneously for the residue definitions for monitoring and risk assessment were not provided, the Authority was able to use a conversion factor to take into account the difference in residue definitions. As the Authority did not indicate a risk for consumers the MRLs should therefore be lowered to levels identified by the Authority for apricots, peaches and table and wine grapes, and the existing MRLs maintained for cherries, gooseberries, tomatoes and aubergines/eggplant.

(13) All footnotes requiring the submission of additional information should be deleted from Annex II to Regulation (EC) No 396/2005 for fenbuconazole and penconazole.

(14) In addition, on 6 February 2023[7], the Codex Alimentarius Commission adopted a new CXL for fenbuconazole in tea green, black (fermented and dried).

(15) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[8], where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of Union food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of 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 that CXL pose to consumers and published a scientific report[9]. In cases where the Authority did not identify risks for consumers in the Union, and for which the Union therefore did not present a reservation[10] to the Codex Committee on Pesticides Residues, the CXLs can be considered safe. This is the case for the CXL for fenbuconazole in tea green, black (fermented and dried), therefore it should be included in Regulation (EC) No 396/2005.

(17) 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.

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7 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-fifth Session. FAO headquarters, Rome, Italy. 21-25 November 2022, 12-13 December 2022, and 19 December 2022-6 February 2023. fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-45%252FFinal%2BReport%2BCAC45%252FCompiled%2BREP22_CAC.pdf.

8 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).

9 EFSA (European Food Safety Authority), 2022. Scientific support for preparing an EU position in the 53rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2022;20(9):7521, 310 pp. https://doi.org/10.2903/j.efsa.2022.7521

10 https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-53%252FCRDs%252Fpr53_crd13revx.pdf.

Feltkode ændret

(18) 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.

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

(20) In order 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 in the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(21) 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.

(22) 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

Annex II to Regulation (EC) N 396/2005 is 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 … [*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 … [*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