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COMMISSION REGULATION (EU) …/…

of XXX

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 cycloxydim, dichlorprop-P, flonicamid, flupyradifurone, methyl nonyl ketone, plant oils/citronella oil, potassium sorbate and potassium phosphonate, in or on certain products

(Text with EEA relevance)

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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 cycloxydim, dichlorprop-P, flonicamid, flupyradifurone, methyl nonyl ketone, plant oils/citronella oil, potassium sorbate and potassium phosphonate, 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), thereof,

Whereas:

(1) For the active substances dichlorprop-P, flonicamid, flupyradifurone and potassium phosphonate maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For the active substance cycloxydim, MRLs were set in Part A of Annex III to that Regulation. For the active substances methyl nonyl ketone and plant oils/citronella oil, MRLs were set in Annex IV to that Regulation. For the active substance potassium sorbate MRLs were set in Annex V to that Regulation.

(2) As regards cycloxydim, an application requesting a modification of the existing MRLs was submitted for pome fruits, apricots/peaches, peas (with pods), maize/corn, sugar beet roots and milk (sheep), pursuant to Article 6(1) of Regulation (EC) No 396/2005. As regards dichlorprop-P, such an application was submitted for barley, oat, rye and wheat grain. As regards flonicamid such an application was submitted for honey. As regards potassium phosphonate, such an application was submitted for globe artichokes, lamb's lettuce/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species, 'lettuces and salad plants, others', purslanes, chards/beet leaves, 'spinaches and similar leaves, others', watercress, poppy seeds, barley, oat and rye.

(3) In accordance with Articles 8 and 9 to Regulation (EC) No 396/2005, all those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission. The Commission forwarded the applications, the evaluation reports, and the supporting dossiers to the European Food Safety Authority (the 'Authority').

(4) The Authority assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned

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

opinions on the proposed MRLs[2]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(5) As regards cycloxydim in pome fruits, apricots/peaches, peas (with pods), maize/corn, sugar beet roots and milk (sheep), the Authority concluded that the data submitted in support of the request were found appropriate to derive or confirm the MRL proposal for the commodities under assessment. The Authority also concluded that the confirmatory data requirement as regards additional residue trials on maize/corn has been met. Therefore, it is appropriate to set the MRLs for the commodities at the levels recommended by the Authority and to delete the footnote of maize/corn referring to the unavailable residue trials.

(6) As regards dichlorprop-P in barley, oat, rye and wheat grain, the Authority concluded that the data submitted in support of the request were found appropriate to derive the MRL proposal for the commodities under assessment. Therefore, it is appropriate to set the MRL for these commodities at the levels recommended by the Authority.

(7) As regards flonicamid in honey, the Authority concluded that the data submitted in support of the request were not found appropriate to derive MRL proposal for the commodities under assessment. The Authority complemented the assessment by analysing the monitoring data available from the EU monitoring programmes conducted during 2009-2023 period. The Authority concluded that at the 99.5th percentile and at the 95th percentile of the data population at the 95% confidence level, residues in honey occur at levels ranging from 0.05 to 0.051 mg/kg, thus at the level of the existing EU MRL, for which the identified non-compliance rate was very low (≤0.2%). It is therefore, appropriate to propose setting the MRL at the level of 0.05 mg/kg. This MRL value covers the currently authorised uses for flonicamid according to the results of monitoring data. This MRL value (0.05 mg/kg) shall be revised if new uses on melliferous crops are authorised or in case new residue trials representative of existing uses of flonicamid on melliferous crops become available.

(8) As regards the MRLs for potassium phosphonate in globe artichokes, lamb's lettuce/corn salads, escaroles/broad-leaved endives, cresses and other sprouts and shoots, land cresses, roman rocket/rucola, red mustards, baby leaf crops (including brassica species), 'lettuces and salad plants, others', purslanes, chards/beet leaves, 'spinaches and similar leaves, others', watercress, poppy seeds, barley, oat, rye, the Authority concluded that the data submitted in support of the request were found to be sufficient to derive MRL proposals for the commodities under assessment. It concluded that the long-term intake of residues resulting from the new proposed uses of potassium phosphonates was unlikely to present a risk to consumer health and that considering the toxicological profile of the active substance, a short-term dietary risk

[2] EFSA scientific reports are available online: http://www.efsa.europa.eu.

Modification of the existing maximum residue levels for cycloxydim in various crops. EFSA Journal 2024;22(9): e8996. https://doi.org/10.2903/j.efsa.2024.8996.

Modification of the existing maximum residue levels for dichlorprop-P in cereal grains. EFSA Journal 2024;22(10): e9003. https://doi.org/10.2903/j.efsa.2024.9003.

Modification of the existing maximum residue level for flonicamid in honey. EFSA Journal 2024;22(10): e9007. https://doi.org/10.2903/j.efsa.2024.9007.

Modification of the existing maximum residue levels in various plant commodities resulting from the use of potassium phosphonates. EFSA Journal 2024;22(6): e8842. https://doi.org/10.2903/j.efsa.2024.8842.

assessment was not required. For baby leaf crops, including brassica species, risk manager consideration is required to decide between setting an MRL of 200 mg/kg or an MRL of 150 mg/kg, both found to be safe for consumers. As the level of 200 mg/kg was based on overdosed residue trials, it is appropriate to establish the MRL at 150 mg/kg in line with the principle to establish MRLs at the lowest level that allows the desired effect to be obtained.

(9) Based on the scientific report of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the Commission has concluded that the proposed modifications to the MRLs are acceptable.

(10) As regards flupyradifurone, the Codex Alimentarius Commission adopted new Codex maximum residue limits ('CXLs') for this active substances[3] on 2 December 2023.

(11) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[4], 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.

(12) The Authority assessed the risks that those CXLs pose to consumers and published a scientific report[5]. The Union presented reservations,[4,6,7] to the Codex Committee on Pesticides Residues on the CXLs proposed for some pesticide/product combinations, for which the Authority had identified a potential consumer health risk in its scientific report.

(13) 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

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3 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-sixth Session. FAO headquarters, Rome, Italy. 27 November to 2 December 2023. 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.

4 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).

5 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.

6 European Union comments on Codex CX/PR 23/54/5-Add.1: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FWDs%252Fpr54_05_Add1x.pdf.

7 Report of the 54th session of the Codex Committee on Pesticide Residues REP23/PR54: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-54%252FREPORT%252FFINAL%252520REPORT%252520CORRIGENDUM%252FREP23_PR54e_CORR.pdf.

considered safe. This is the case for CXLs for flupyradifurone in pineapple and sunflower seeds. Those CXLs should therefore be included in Regulation (EC) No 396/2005.

(14) Based on the scientific report of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the Commission has concluded that the proposed modifications to the MRLs are acceptable.

(15) The approval of methyl nonyl ketone expired on 26 May 2017[8]. Methyl nonyl ketone was not approved because of the non-submission of confirmatory data required in the earlier approval that were not related to residues or dietary exposure. No consumer health concern was identified. Furthermore, the active substance is naturally present in foodstuff and is an approved flavouring substance which can be used in all types of flavoured foods. It is appropriate therefore, to keep this substance in Annex IV to Regulation (EC) No 396/2005 and delete the footnote referring to its temporary inclusion.

(16) The approval of the active substance plant oils/citronella oil expired on 31 August 2022 because no application for renewal had been submitted. Considering that various components of citronella oil may be naturally present in certain foodstuffs, it is considered justified to include it in Annex IV to Regulation (EC) No 396/2005 on a permanent basis and delete the footnote referring to its temporary inclusion.

(17) An application for potassium sorbate as a basic substance was made on 9 October 2015 and it was not approved in 2017[9] due to concerns about residues in food. Currently the default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005 applies. However, potassium sorbate is authorised as food additive. In 2019[10] EFSA has reviewed the safety of sorbates as food additives, including potassium sorbate, resulting in a higher Acceptable Daily Intake with not health concerns related to consumer exposure. It is considered appropriate to include potassium sorbate in Annex IV to Regulation (EC) No 396/2005.

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

(19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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8 Commission Implementing Regulation (EU) 2017/781 of 5 May 2017 withdrawing the approval of the active substance methyl nonyl ketone, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 118, 6.5.2017, p. 1, http://data.europa.eu/eli/reg_impl/2017/781/oj.

9 Commission Implementing Regulation (EU) 2017/2068 of 13 November 2017 concerning the non-approval of potassium sorbate as a basic substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 295, 14.11.2017, p. 49, http://data.europa.eu/eli/reg_impl/2017/2068/oj.

10 EFSA 2019. Opinion on the follow-up of the re-evaluation of sorbic acid (E200) and potassium sorbate (E202) as food additivies. EFSA Journal 2019;17(3): e05625. https://doi.org/10.2903/j.efsa.2019.5625.

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and IV to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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