Council of the European Union

**Brussels, 10 January 2025**
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**AGRILEG 3**
**PESTICIDE 1**

**COVER NOTE**

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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| date of receipt: | 8 January 2025 |
| To: | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union |
| No. Cion doc.: | D102305/02 |
| Subject: | COMMISSION REGULATION (EU) …/… of XXX amending Annexes II 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, flupyradifurone, methyl nonyl ketone, plant oils/citronella oil, potassium sorbate and potassium phosphonate in or on certain products |

Delegations will find attached document D102305/02.

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COMMISSION

Brussels, XXX
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[…](2024) XXX draft

**COMMISSION REGULATION (EU) …/…**

**of XXX**

**amending Annexes II 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, flupyradifurone, methyl nonyl ketone, plant oils/citronella oil, potassium sorbate and potassium phosphonate in or on certain products**

(Text with EEA relevance)

**COMMISSION REGULATION (EU) …/…**

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**amending Annexes II 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, 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 cycloxydim, dichlorprop-P, flupyradifurone and potassium phosphonate, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For the active substances methyl nonyl ketone and plant oils/citronella oil, it was concluded that no MRLs were required. These active substances were therefore included in Annex IV to that Regulation. For the active substance potassium sorbate, no specific MRLs were set. Therefore, for this active substance the default value of 0,01 mg/kg laid down in Article 18(1), point (b), of Regulation (EC) No 396/2005 applies.

(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 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 of 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').

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

(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 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 were 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 is met.

(6) Therefore, it is appropriate to set the MRLs for cycloxydim for those commodities at the levels recommended by the Authority and to delete the footnote of maize/corn referring to the unavailable residue trials.

(7) As regards dichlorprop-P in barley, oat, rye and wheat grain, the Authority concluded that the data were appropriate to derive the MRL proposal for the commodities under assessment.

(8) Therefore, it is appropriate to set the MRL for dichlorprop-P for those commodities at the levels recommended by the Authority.

(9) 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 were 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 is unlikely to present a risk to consumer health and that considering the toxicological profile of the active substance, a short-term dietary risk assessment is not required. For baby leaf crops, including brassica species, it concluded that 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.

(10) Due to the shorter growth period of baby leaf crops and the fact that the last application usually has the greatest impact on the expected residue, it is appropriate to set the MRL at 200 mg/kg, the same level as is established for the other products in the group 'lettuces and salad plants'.

(11) 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 proposed

[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 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.

modifications to the MRLs for cycloxydim, dichlorprop-P and potassium phosphonate for the commodities concerned are acceptable.

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

(13) 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.

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

(15) 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. This is the case for CXLs for flupyradifurone in pineapple and sunflower seeds.

(16) The CXLs for flupyradifurone in pineapple and sunflower seeds should therefore be included in Regulation (EC) No 396/2005, 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.

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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.

(17) The approval of methyl nonyl ketone expired on 26 May 2017[8]. The approval of methyl nonyl ketone was withdrawn due to the non-submission of required confirmatory data that were not related to residues or dietary exposure. However, 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 therefore appropriate to maintain this active substance in Annex IV to Regulation (EC) No 396/2005 and delete the footnote referring to its temporary inclusion.

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

(19) An application for the approval of 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 in accordance with Article 18(1), point (b), of Regulation (EC) No 396/2005 applies. However, potassium sorbate is authorised as a food additive. In 2019, the Authority reviewed the safety of sorbates, including potassium sorbate, used as food additives[10]. The Authority concluded that there are no health concerns related to the consumer exposure to sorbates based on a higher Acceptable Daily Intake.

(20) Therefore, it is appropriate to include potassium sorbate in Annex IV to Regulation (EC) No 396/2005.

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

(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*

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

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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 additives. EFSA Journal 2019;17(3):5625. https://doi.org/10.2903/j.efsa.2019.5625.

*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*