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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 21 March 2025

To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

No. Cion doc.: D105252/02

Subject: 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 amidosulfuron, azoxystrobin, hexythiazox, isoxaben, picloram, propamocarb, sodium silver thiosulfate and tefluthrin in or on certain products

Delegations will find attached document D105252/02.

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[...](2025) **XXX** draft

COMMISSION REGULATION (EU) .../...

of XXX

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(Text with EEA relevance)

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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/EEC¹, and in particular Article 5 (1) and Article 14(1), point (a), thereof,

Whereas:

- (1) For amidosulfuron, azoxystrobin, hexythiazox, isoxaben, propamocarb and tefluthrin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For picloram, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For sodium silver thiosulfate, 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 azoxystrobin, an application for an import tolerance was submitted for melons and watermelons based on uses in Brazil, pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005. As regards hexythiazox, such an import tolerance application was submitted for blackberries and raspberries based on uses in the United States.
- (3) As regards propamocarb, an application requesting a modification of the existing MRLs was submitted for small radish leaves and radishes, pursuant to Article 6(1) of Regulation (EC) No 396/2005. As regards picloram, such an application was submitted for swine fat and liver, bovine liver, sheep liver, goat liver, equine fat and liver, other farmed terrestrial animals' fat, liver and 'others', and 'honey and other apiculture products'.
- (4) 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').
- (5) The Authority assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned

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

opinions on the proposed MRLs². It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

- (6) As regards those applications, the Authority concluded that the data were appropriate to derive or confirm the MRL proposals for the commodities under assessment. For picloram, the Authority proposed a new residue definition for enforcement applicable to plant products and honey as ‘picloram, free and conjugated, expressed as picloram’ instead of ‘picloram’ only, based on the metabolic pattern identified in metabolism studies and the capabilities of enforcement analytical methods. For picloram, no change of the existing MRLs for livestock tissues is recommended by the Authority.
- (7) It is therefore appropriate to set the requested MRLs for azoxystrobin in melons and watermelons; for hexythiazox in blackberries and raspberries; for picloram in swine fat and liver, bovine liver, sheep liver, goat liver, equine fat and liver, other farmed terrestrial animals’ fat, liver and ‘others’, and ‘honey and other apiculture products’ at the level recommended by the Authority.
- (8) For propamocarb, according to Regulation (EU) 2024/3196 small radish leaves are included in Part B of Annex I to Regulation (EC) No 396/2005 to which the same MRLs as to Roman rocket/rucola in Part A of that Annex apply³. The Authority noted that the current MRL in Roman rocket/rucola is lower than the proposed MRL in small radish leaves. It concluded that consideration by risk managers is required to decide how to implement the proposed MRL for small radish leaves.
- (9) Given that the Authority concluded that the MRL value proposed for radish leaves is safe for consumers considering consumption data for Roman rocket/rucola, it is appropriate to set that MRL for propamocarb in Roman rocket/rucola and in radishes at the level recommended by the Authority.
- (10) As regards isoxaben, an application requesting a modification of the existing MRL in dry beans and dry peas was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005. As regards this application, a Member State made a request to use the fast-track procedure, provided for in the Technical Guidelines on the MRL setting procedure⁴, to set an MRL based on residue trials for beans (without pods).
- (11) The Authority assessed residue trials on beans (without pods) in the framework of the review of the existing MRLs for isoxaben and gave a reasoned opinion on the

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² EFSA scientific reports are available online: <http://www.efsa.europa.eu>.
Setting of import tolerances for azoxystrobin in melons and watermelons. EFSA Journal 2024;22(12): e9130, <https://doi.org/10.2903/j.efsa.2024.9130>

Setting of import tolerances for hexythiazox in blackberries and raspberries. EFSA Journal 2024;22(12): e9117, <https://doi.org/10.2903/j.efsa.2024.9117>

Modification of the existing maximum residue levels for picloram in animal commodities and honey. EFSA Journal 2024;22(10): e9067, <https://doi.org/10.2903/j.efsa.2024.9067>

Modification of the existing maximum residue levels for propamocarb in radishes (roots and small leaves). EFSA Journal 2024;22(11): e9092, <https://doi.org/10.2903/j.efsa.2024.9092>

Review of the existing maximum residue levels for tefluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1): e05995, <https://doi.org/10.2903/j.efsa.2020.5995>

³ Commission Regulation (EU) 2024/3196 of 18 December 2024 amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards radish leaves (OJ L, 2024/3196, 19.12.2024, ELI: <http://data.europa.eu/eli/reg/2024/3196/oj>)

⁴ Technical guidelines MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595 Rev. 6.1)

proposed MRL⁵. That opinion relies on the current scientific and technical knowledge on the subject. As it is appropriate to extrapolate from the residue trials on beans (without pods) to dry beans and dry peas, it is unnecessary to request the Authority to provide a reasoned opinion on beans and peas specifically.

- (12) It is therefore appropriate to set the MRL for isoxaben in dry beans and dry peas in Annex II to Regulation (EC) No 396/2005 at the same level as the MRL for beans (without pods).
- (13) As regards tefluthrin, an application requesting a modification of the existing MRL for tefluthrin in horseradishes, jerusalem artichokes, parsnips, salsifies and parsley roots was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005.
- (14) As regards that application, a Member State made a request to use the fast-track procedure, provided for in the Technical Guidelines on the MRL setting procedure, to set an MRL based on residue trials on carrots.
- (15) The Authority assessed residue trials on carrots in the framework of the review of the existing MRLs for tefluthrin and gave a reasoned opinion on the proposed MRL⁶. That opinion relied on the current scientific and technical knowledge on the subject. As it is appropriate to extrapolate from the residue trials on carrots to horseradishes, Jerusalem artichokes, parsnips, salsifies and parsley roots, as confirmed by the Union guidelines on extrapolation of MRLs⁷, it is unnecessary to request the Authority to provide a reasoned opinion on horseradishes, jerusalem artichokes, parsnips, salsifies and parsley roots specifically.
- (16) It is therefore appropriate to set the MRL for tefluthrin in horseradishes, jerusalem artichokes, parsnips, salsifies and parsley roots in Annex II to Regulation (EC) No 396/2005 at the same level as the MRL for carrots.
- (17) As regards amidosulfuron, additional information was submitted for the assessment of confirmatory data to address the data gaps identified following Article 12 of Regulation (EC) No 396/2005 for all representative commodities, including dry commodities (cereals). The applicant submitted information previously unavailable during the MRL review on analytical methods for dry commodities⁸. The Authority concluded that the confirmatory data requirement as regards analytical methods for enforcement in dry commodities, specifically on barley, oat, rye and wheat, is satisfactorily met⁹.
- (18) Therefore, it is appropriate to delete the footnotes for barley, oat, rye and wheat referring to the unavailability of analytical methods and to permanently set MRLs for amidosulfuron in barley, oat, rye and wheat in Annex II to Regulation (EC) No 396/2005.

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⁵ European Food Safety Authority. Reasoned opinion on the review of the existing maximum residue levels for isoxaben according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2022;20(1):7062. <https://doi.org/10.2903/j.efsa.2022.7062>

⁶ Review of the existing maximum residue levels for tefluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1): e05995. <https://doi.org/10.2903/j.efsa.2020.5995>

⁷ Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752 Rev 01 – 10 May 2023)

⁸ Reasoned opinion on the review of the existing maximum residue levels (MRLs) for amidosulfuron according to article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014, 12(3):3614. <https://doi.org/10.2903/j.efsa.2014.3614>

⁹ Peer review of the pesticide risk assessment of the active substance amidosulfuron. EFSA Journal 2024; 22(9):e8984. <https://doi.org/10.2903/j.efsa.2024.8984>

- (19) Sodium silver thiosulfate was approved by Commission Implementing Regulation (EU) No 1195/2013¹⁰, which provides that only indoor uses in non-edible crops may be authorised for that substance. The conditions of use of that substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. Additionally, residues of silver from the use of sodium silver thiosulfate cannot be distinguished from residues resulting from the presence of silver in the environment, which occurs at higher levels. Moreover, thiosulfate degrades rapidly in the environment to substances that are also naturally occurring. Given that the Authority did not identify any concerns related to the properties of the substance¹¹, it is appropriate to include sodium silver thiosulfate in Annex IV to Regulation (EC) No 396/2005.
- (20) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (21) 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 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

¹⁰ Commission Implementing Regulation (EU) No 1195/2013 of 22 November 2013 approving the active substance sodium silver thiosulfate, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 315, 26.11.2013, p. 27, ELI: http://data.europa.eu/eli/reg_impl/2013/1195/oj)

¹¹ Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2019, 17(2), e05591. <https://doi.org/10.2903/j.efsa.2019.5591>