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COVER NOTE

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

date of receipt: 24 March 2025

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

No. Cion doc.: D105253/03

Subject: COMMISSION REGULATION (EU) .../...
of XXX
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 chlorpropham, fuberidazole, ipconazole, methoxyfenozide, S-metolachlor and triflusulfuron in or on certain products

Delegations will find attached document D105253/03.

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

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

of XXX

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 chlorpropham, fuberidazole, ipconazole, methoxyfenozide, S-metolachlor and triflusulfuron in or on certain products

(Text with EEA relevance)

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

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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 chlorpropham, fuberidazole, ipconazole, methoxyfenozide, S-metolachlor and triflusulfuron 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/EEC¹, and in particular Article 14(1), point (a), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

- (1) For fuberidazole, ipconazole, methoxyfenozide, S-metolachlor and triflusulfuron maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For chlorpropham, MRLs were set in Part A of Annex III to that Regulation.
- (2) The approval of the active substance chlorpropham expired on 28 February 2019². A temporary MRL for chlorpropham in potatoes was set by Commission Regulation (EU) 2021/155³ since monitoring data showed potential contamination of potatoes above the limit of determination ('LOD') when stored in facilities with a history of chlorpropham use. That Regulation also required potato trade organisations and manufacturers to develop and implement new and more efficient cleaning practices to reduce such contamination, and to submit to the Commission new monitoring data that would allow the Commission to review that temporary MRL.
- (3) The temporary MRL for chlorpropham in potatoes was reviewed based on monitoring data submitted to the Commission and the temporary MRL was subsequently lowered from 0,4 mg/kg to 0,35 mg/kg by Commission Regulation (EU) 2023/377⁴. This

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

² Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, 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 160, 18.6.2019, p. 11, ELI: http://data.europa.eu/eli/reg_impl/2019/989/oj).

³ Commission Regulation (EU) 2021/155 of 9 February 2021 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 carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products (OJ L 46, 10.2.2021, p. 5, ELI: <http://data.europa.eu/eli/reg/2021/155/oj>).

⁴ Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum

temporary MRL was to be reviewed based on monitoring data submitted to the Commission by 31 December of each year.

- (4) Recent monitoring data of chlorpropham in potatoes showed that a lower MRL of 0,2 mg/kg is currently achievable. It is therefore appropriate to lower the temporary MRL of chlorpropham in potatoes to the level of 0,2 mg/kg. The monitoring data should be submitted by food business operators every two years instead of each year and be accompanied by a report on the progress and implementation of cleaning practices in storage facilities with a history of chlorpropham use. The relevant footnote for potatoes in Annex III should be amended accordingly.
- (5) The approval of the active substance fuberidazole expired on 28 February 2019⁵, and no application for its renewal was submitted. All existing authorisations for plant protection products containing fuberidazole have been revoked. No Codex maximum residue limits ('CXLs') or import tolerances exist for that substance. The MRLs for fuberidazole on all products are currently set at the product-specific LODs. It is therefore appropriate to delete the MRLs for fuberidazole in Annex II to Regulation (EC) No 396/2005 and to set MRLs for fuberidazole on all products at the product-specific LODs in Annex V to that Regulation.
- (6) The approval of the active substance ipconazole expired on 31 May 2023⁶. The application for its approval was withdrawn and all existing authorisations for plant protection products containing ipconazole have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for ipconazole on all products are currently set at the product specific LODs. It is therefore appropriate to delete the MRLs for ipconazole in Annex II to Regulation (EC) No 396/2005 and to set MRLs for ipconazole on all products at the product-specific LODs in Annex V to that Regulation. The European Union reference laboratories recommended to change the residue definition of ipconazole for monitoring products to 'Ipconazole (sum of constituent isomers) (F)'. The Commission considers this new residue definition to be appropriate.
- (7) The approval of the active substance methoxyfenozide was restricted by Commission Implementing Regulation (EU) 2019/158⁷ to greenhouse uses only. The MRLs for methoxyfenozide in aubergines/eggplants are currently set at the level of 0,6 mg/kg by Commission Regulation (EU) 2023/1069⁸. During the assessment of the MRLs for

residue levels for benzalkonium chloride (BAC), chlorpropham, didecyltrimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (OJ L 55, 22.2.2023, p. 1, ELI: <http://data.europa.eu/eli/reg/2023/377/oj>).

⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

⁶ Commission Implementing Regulation (EU) 2023/939 of 10 May 2023 withdrawing the approval of the active substance ipconazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, amending Commission Implementing Regulation (EU) No 540/2011 and repealing Commission Implementing Regulation (EU) No 571/2014 (OJ L 125, 11.5.2023, p. 19, ELI: http://data.europa.eu/eli/reg_impl/2023/939/oj).

⁷ Commission Implementing Regulation (EU) 2019/158 of 31 January 2019 renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, 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 31, 1.2.2019, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2019/158/oj).

⁸ Commission Regulation (EU) 2023/1069 of 1 June 2023 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for

methoxyfenozide in accordance with Article 12 of Regulation (EC) No 396/2005, the Authority identified some information on residue trials as unavailable for aubergines/eggplants⁹. The available information was nevertheless sufficient for the Authority to propose tentative MRLs that are safe for consumers and the data gaps were indicated in Annex II to Regulation (EU) 2023/1069, specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs. Subsequently, the applicant submitted information to address the data gaps, except the residue trials to support an indoor use of methoxyfenozide¹⁰. Information on residue trials for an indoor use for aubergines/eggplants was submitted later in an application from a Member State in accordance with Article 6 of Regulation (EC) No 396/2005. The Authority assessed the application and concluded that the available residue trials were sufficient to set a lower MRL for aubergines/eggplants¹¹.

- (8) It is appropriate to set the MRLs for aubergines/eggplants in Annex II to Regulation (EC) No 396/2005 at the level recommended by the Authority, at which it identified no risk for consumers. For the sake of clarity, the footnote indicating a lack of information concerning residue trials on aubergines/eggplants should be deleted from Annex II to Regulation (EC) No 396/2005.
- (9) The approval of the active substance S-metolachlor expired on 22 January 2024. The approval of this active substance was not renewed by Commission Implementing Regulation (EU) 2024/20¹² as the approval criteria as set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 were not satisfied. All existing authorisations for plant protection products containing S-metolachlor have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for S-metolachlor on all products are currently set at the product-specific LODs. It is therefore appropriate to delete the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 and to set MRLs for S-metolachlor on all products at the product-specific LODs in Annex V to that Regulation. Additionally, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.
- (10) The approval of the active substance triflurosulfuron (formerly triflurosulfuron-methyl) expired on 20 November 2023. The approval of this active substance was not renewed by Commission Implementing Regulation (EU) 2023/2513¹³ as the approval criteria as

bixafen, cyprodinil, fenhexamid, fenpicoxamid, fenpyroximate, flutianil, isoxaflutole, mandipropamid, methoxyfenozide, and spinetoram in or on certain products (OJ L 143, 2.6.2023, p. 40, ELI: <http://data.europa.eu/eli/reg/2023/1069/oj>).

⁹ EFSA 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for methoxyfenozide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal, 12 (1), 3509. <https://doi.org/10.2903/j.efsa.2014.3509>.

¹⁰ EFSA 2023. Lack of confirmatory data following Article 12 MRL reviews for 2,4-DB, iodosulfuron-methyl, mesotrione, methoxyfenozide and pyraflufen-ethyl. EFSA Journal, 21 (5), e08013. <https://doi.org/10.2903/j.efsa.2023.8013>.

¹¹ EFSA 2024. Modification of the existing maximum residue level for methoxyfenozide in aubergines. EFSA Journal, 22(7), e8922. <https://doi.org/10.2903/j.efsa.2024.8922>.

¹² Commission Implementing Regulation (EU) 2024/20 of 12 December 2023 concerning the non-renewal of the approval of the active substance S-metolachlor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2024/20, 3.1.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/20/oj).

¹³ Commission Implementing Regulation (EU) 2023/2513 of 16 November 2023 concerning the non-renewal of the approval of the active substance triflurosulfuron-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L, 2023/2513, 17.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2513/oj).

set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009 were not satisfied. All existing authorisations for plant protection products containing triflusal have been revoked. No CXLs or import tolerances exist for that substance. The MRLs for triflusal on all products are currently set at the product-specific LODs. It is therefore appropriate to delete the MRLs set out for this substance in Annex II to Regulation (EC) No 396/2005 and to set MRLs for triflusal on all products at the product-specific LODs in Annex V to that Regulation. The Commission consulted the European Union reference laboratories for residues of pesticides as regards the availability of analytical standards. Those laboratories confirmed the availability of analytical standards. The footnote referring to the commercial unavailability of the reference standard should therefore be deleted from Annex II to Regulation (EC) No 396/2005.

- (11) 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.
- (12) The trading partners of the Union were consulted through the World Trade Organization and their comments have been taken into account.
- (13) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (14) 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.
- (15) 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.
- (16) 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