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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	12 March 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	D108180/05
Subject:	COMMISSION REGULATION (EU) .../... 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 1,4-dimethylnaphthalene, chlormequat, metribuzin, metribuzin-desamino-diketo (metribuzin-DADK), terbuthylazine and triclopyr in or on certain products

Delegations will find attached document D108180/05.

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COMMISSION

Brussels, XXX
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[…](2026) 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 1,4-dimethylnaphthalene, chlormequat, metribuzin, metribuzin-desamino-diketo (metribuzin-DADK), terbuthylazine and triclopyr in or on certain products

(Text with EEA relevance)

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 1,4-dimethylnaphthalene, chlormequat, metribuzin, metribuzin-desamino-diketo (metribuzin-DADK), terbuthylazine and triclopyr 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), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

(1) For 1,4-dimethylnaphthalene, terbuthylazine and triclopyr, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For chlormequat and metribuzin, MRLs were set in Part A of Annex III to that Regulation.

(2) For 1,4-dimethylnaphthalene, temporary MRLs were set by Commission Regulation (EU) 2022/1346[2] for products of plant origin (except for potatoes) at 0,05 mg/kg. Those temporary MRLs were set based on monitoring data showing that 1,4-dimethylnaphthalene could naturally occur in some plant compounds. They were set until 2 August 2024, pending the submission of monitoring data on the occurrence of that substance in the concerned products.

(3) The European Food Safety Authority (the 'Authority') and food business operators submitted recent monitoring data showing that residues of 1,4-dimethylnaphthalene in products of plant origin (except for potatoes) occur at levels higher than the limit of determination ('LOD'). Based on these more specific data, temporary MRLs should be set at a level of 0,03 mg/kg for products of plant origin (except for potatoes). This level corresponds to the 99th percentile of all the sample results. Those temporary MRLs should be reviewed after seven years from the publication of this Regulation.

(4) As regards terbuthylazine**,** the Authority submitted a reasoned opinion[3] on the review of its MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 in 2019. The Authority had identified some information as unavailable for certain products.

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

2 Commission Regulation (EU) 2022/1346 of 1 August 2022 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate in or on certain products (OJ L 202, 2.8.2022, p. 31, ELI: http://data.europa.eu/eli/reg/2022/1346/oj).

3 Review of the existing maximum residue levels for terbuthylazine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020; 18(1): e05980, https://doi.org/10.2903/j.efsa.2020.5980.

The available information was nevertheless sufficient for the Authority to propose MRLs that are safe for consumers. In 2021, the Commission set new MRLs for terbuthylazine[4] in Annex II to Regulation (EC) No 396/2005 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.

(5) In 2023, the applicant submitted the requested confirmatory data concerning terbuthylazine in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. The Authority evaluated the submitted confirmatory data and published a reasoned opinion[5]. The Authority concluded that the data gaps identified during the MRL review for sweet corn and sunflower seed were addressed. For muscle, fat, liver, kidney and milk from bovine and from equine, the Authority concluded that a significant transfer of residues is not expected and therefore, the data gap identified is addressed. It is, therefore, appropriate to maintain the existing MRLs and delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005 for sweet corn, sunflower seeds and bovine and equine tissues. By contrast, the Authority concluded that data gaps identified during the MRL review for the MRL for lupins/lupins beans and for cotton seeds were not addressed. Therefore, for lupins/lupins beans and for cotton seeds, it is appropriate to set the MRLs for terbuthylazine at the product-specific LOD and delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(6) As regards triclopyr, the Authority submitted a reasoned opinion[6] on the review of its MRLs in accordance with Article 12 of Regulation (EC) No 396/2005 in 2017. The Authority had identified some information as unavailable for certain products. The available information was nevertheless sufficient for the Authority to propose MRLs that are safe for consumers. In 2018, the Commission set new MRLs for triclopyr[7] in Annex II to Regulation (EC) No 396/2005 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.

(7) For triclopyr, no application supporting the confirmatory data following the MRL review was submitted by any interested party within the established deadline. Nevertheless, some information identified as unavailable in the MRL review has been made available to the Authority in the context of other applications submitted under different regulatory processes, initiated after the MRL review. The Authority

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4 Commission Regulation (EU) 2021/618 of 15 April 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products (OJ L 131, 16.4.2021, ELI: http://data.europa.eu/eli/reg/2021/618/oj).

5 Evaluation of confirmatory data following the Article 12 MRL review for terbuthylazine, EFSA Journal 2025; 23 (2): e9231, https://doi.org/10.2903/j.efsa.2025.9231.

6 Review of the existing maximum residue levels for triclopyr according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2017; 15(3): e04735, https://doi.org/10.2903/j.efsa.2017.4735.

7 Commission Regulation (EU) 2018/686 of 4 May 2018 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorpyrifos, chlorpyrifos-methyl and triclopyr in or on certain products (OJ L 121, 16.5.2018, p. 30, ELI: http://data.europa.eu/eli/reg/2018/686/oj).

evaluated the available information and published a statement[8]. The Authority concluded that the data gaps identified during the MRL review for triclopyr under Article 12 of Regulation (EC) No 396/2005 were addressed for apples, pears and peaches. Therefore, for those products, it is appropriate to maintain the existing MRLs and delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005. By contrast, the Authority concluded that the data gaps identified for triclopyr in or on grapefruits, oranges, lemons, mandarins, apricots and rice were not addressed. For oranges, lemons and mandarins, EFSA proposed a MRL based on a post-harvest use which was assessed in a previous EFSA opinion and concluded to be fully supported by data[9]. It is considered appropriate to set the MRL for these commodities at the level recommended by the Authority. For rice, the applicant recently provided the supporting confirmatory data which currently is being assessed. It is considered appropriate to maintain the current temporary MRL for triclopyr in rice until the assessment is concluded keeping the respective footnote. For apricots, considering extrapolation from peaches, it is appropriate to maintain the current MRL level. Since for grapefruits no fall-back good agricultural practices were available, it is appropriate to set the MRLs for triclopyr in grapefruits at the product-specific LOD and delete the respective footnote requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(8) In 2021, an application was submitted requesting a modification of the existing MRLs for triclopyr in muscle, fat, liver, kidney, edible offal other than liver and kidney from swine, bovine, sheep and goat and for milk from cattle, sheep and goat, pursuant to Article 6(1) of Regulation (EC) No 396/2005. In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Commission forwarded the application, the evaluation report and the supporting dossiers to the Authority.

(9) The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinion on the proposed MRLs[10]. It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

(10) The Authority concluded that the submitted data were sufficient to derive or confirm the MRL proposals for the commodities under assessment. It is therefore appropriate to set the requested MRLs at the levels recommended by the Authority.

(11) For chlormequat, temporary MRLs were set by Commission Regulation (EU) 2022/1290[11] for oyster mushrooms, and by Commission Regulation (EU) 2017/693[12]

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8 Statement on the confirmatory data following the Article 12 MRL review for triclopyr. EFSA Journal 2024; 22 (12): e9176, https://doi.org/10.2903/j.efsa.2024.9176.

9 Reasoned Opinion on the modification of the existing maximum residue levels for triclopyr in oranges, lemons and mandarins. EFSA Journal 2022;20(8):7545, https://doi.org/10.2903/j.efsa.2022.7545.

10 Modification of the existing maximum residue levels for triclopyr in animal commodities. EFSA Journal 2023; 21(5): e08007, https://doi.org/10.2903/j.efsa.2023.8007.

11 Commission Regulation (EU) 2022/1290 of 22 July 2022 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 ametoctradin, chlormequat, dodine, nicotine, profenofos and Spodoptera exigua multicapsid nucleopolyhedrovirus (SeMNPV) isolate BV-0004 in or on certain products (OJ L 196, 25.7.2022, p. 74, ELI: http://data.europa.eu/eli/reg/2022/1290/oj).

for cultivated fungi at 6 mg/kg and 0,9 mg/kg, respectively. Those temporary MRLs were set based on monitoring data showing that residues occurred on untreated cultivated fungi at a level higher than the LOD due to cross-contamination of cultivated fungi with straw treated with chlormequat. They were set until 25 July 2023, pending the submission of monitoring data on the occurrence of that substance in the concerned products.

(12) The Authority and food business operators submitted recent monitoring data showing that residues of chlormequat still occur in oyster mushrooms and cultivated fungi at levels higher than the LOD. Based on this more specific data, temporary MRLs should be set at a level of 2 mg/kg for oyster mushrooms and 0,6 mg/kg for cultivated fungi. These levels correspond to the 95th percentile and the 97,5th percentile of all the sample results respectively. Those temporary MRLs should be revised after seven years from the publication of this Regulation.

(13) Since chlormequat is used on food products that can be used as feed, a potential carry-over of chlormequat residues into food of animal origin was assessed by the Authority[13,14] in the context of a recent MRL application and the assessment of fall-back MRLs for revoked Codex maximum residue limits ('CXLs'). The Authority confirmed that for all animal commodities (except for sheep and goat muscle and kidney), a lower MRL would be sufficient and recommended specific MRLs for products of animal origin. For milk (cattle, horse and other animals) and for poultry muscle and fat, the existing MRL is based on a currently revoked CXL, for which the Authority identified a lower fall-back MRL which was safe for consumers. It is, therefore, appropriate to lower these MRL values to the levels recommended by the Authority.

(14) The approval of the active substance metribuzin was non-renewed[15] on 31 October 2024, taking effect on 24 November 2024. In the conclusion of the peer review assessment of metribuzin[16] two separate residue definitions were proposed, one for 'metribuzin' and another for its metabolite 'metribuzin-desamino-diketo (metribuzin-DADK)' for products of plant origin, in order to cover the presence of the metabolite metribuzin-DADK from the use of metribuzin in products of plant origin. It is, therefore, appropriate to amend the residue definition accordingly. No CXLs or import tolerances exist for that substance. It is, therefore, appropriate to lower the MRLs set out for metribuzin in Annex III to Regulation (EC) No 396/2005 to the current

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12 Commission Regulation (EU) 2017/693 of 7 April 2017 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 bitertanol, chlormequat and tebufenpyrad in or on certain products (OJ L 101, 13.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/693/oj).

13 Assessment of fall-back MRLs for revoked CXLs previously implemented in the EU legislation and review of the JMPR evaluation of the toxicological data related to pyrasulfotole, pyraziflumid, spiropidion and tetraniliprole. EFSA Journal 2024;22(4), 8693, https://doi.org/10.2903/j.efsa.2024.8693.

14 Modification of the existing maximum residue level for chlormequat in oat. EFSA Journal 2025;23(4): e9385, https://doi.org/10.2903/j.efsa.2025.9385.

15 Commission Implementing Regulation (EU) 2024/2806 of 31 October 2024 concerning the non-renewal of the approval of the active substance metribuzin, 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 and Commission Implementing Regulation (EU) 2015/408 (OJ L, 2024/2806, 4.11.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2806/oj).

16 Peer review of the pesticide risk assessment of the active substance metribuzin. EFSA Journal 2023; 21(8):e08140, https://doi.org/10.2903/j.efsa.2023.8140.

product-specific LODs in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof, and list them in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b), of that Regulation.

(15) 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.

(16) The trading partners of the Union were consulted through the World Trade Organization and their comments have been taken into account.

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

(18) 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 modified MRLs become applicable and for which information shows that a high level of consumer protection is maintained. 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 amendements to the relevant MRLs.

(19) 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