Brussels, XXX
PLAN/2026/1190 v1
[…](2026) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dicloran, fenazaquin, fluopyram and tebufenozide in or on certain products

(Text with EEA relevance)

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COMMISSION REGULATION (EU) …/…

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amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for dicloran, fenazaquin, fluopyram and tebufenozide 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 dicloran, fenazaquin, fluopyram and tebufenozide, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) The European Food Safety Authority ('the Authority') assessed the MRLs for dicloran in accordance with Article 12 of Regulation (EC) No 396/2005 in 2013[2] and identified some information gaps on residue trials on onions considering metabolite 4-amino-3,5-dichlorophenol. The available information was nevertheless sufficient for the Authority to propose a tentative MRL for onoins based on an existing Codex maximum residue limit ('CXL'). Since this MRL was safe for consumers, it was set in Annex II to Regulation (EC) No 396/2005[3], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRL.

(3) No confirmatory data on residue trials were submitted to support the proposed MRL for onions. The Authority concluded that the MRL is not sufficiently supported by data[4] and noted that the CXL, on which it was based, has been withdrawn in 2021[5].

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

2 European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for dicloran according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2013; 11(6):3274, 30 pp. doi:10.2903/j.efsa.2013.3274.

3 Commission Regulation (EU) No 1126/2014 of 17 October 2014 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 asulam, cyanamide, dicloran, flumioxazin, flupyrsulfuron-methyl, picolinafen and propisochlor in or on certain products (OJ L 305, 24.10.2014, pp. 3–46, ELI: http://data.europa.eu/eli/reg/2014/1126/oj).

4 European Food Safety Authority, 2026. Lack of confirmatory data following Article 12 MRL reviews for dicloran, fenazaquin and tebufenozide. *EFSA Journal*, 24(4), e10064. https://doi.org/10.2903/j.efsa.2026.10064.

5 CAC (Codex Alimentarius Commission). (2021). Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Forty-fourth Session, Virtual, 8–15, 17–18 November and 14 December 2021.

(4) The Authority recommended lowering the MRL for dicloran in onions to the current limit of determination ('LOD'), since dicloran is not approved in the Union and no import tolerances have been requested for dicloran on onions. Moreover, the MRLs for dicloran on all other products are currently set at the product-specific LODs. It is, therefore, appropriate to lower the MRLs currently set for dicloran in Annex II to Regulation (EC) No 396/2005 and to set MRLs for dicloran on all products at the product-specific LODs in Annex V to that Regulation.

(5) The Authority assessed the MRLs for fenazaquin in accordance with Article 12 of Regulation (EC) No 396/2005 in 2020[6] and identified some information as unavailable for certain products. The Authority identified some information gaps on residue trials supporting the import tolerance uses on pome fruits and strawberries. The available information was nevertheless sufficient for the Authority to propose tentative MRLs safe for consumers, which were set in Annex II to Regulation (EC) No 396/2005[7], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(6) No confirmatory data on residue trials were submitted to support the proposed MRLs for the case of pome fruits and strawberries. The Authority concluded that the MRL for pome fruits is not sufficiently supported by data[8] and recommended lowering it to the LOD. For strawberries, no confirmatory data have been submitted to support the most critical Good Agricultural Practice ('GAP') assessed during the MRL review. Therefore, the currently established MRL on strawberries is not supported by data.

(7) Subsequently, the applicant submitted a request to modify the existing MRL for fenazaquin in strawberries in accordance with Article 6 of Regulation (EC) No 396/2005. The Authority concluded[9] that the submitted information was sufficient to derive an MRL for strawberries. It is, therefore, appropriate to set the MRLs for fenazaquin in strawberries in Annex II to Regulation (EC) No 396/2005 at the level recommended by the Authority, at which it identified no risk for consumers.

(8) The Authority assessed the MRLs for tebufenozide in accordance with Article 12 of Regulation (EC) No 396/2005 in 2018[10] and identified some information as unavailable for certain products. The Authority identified some information gaps on residue trials on cherries and rice and on confirmatory analytical methods for animal matrices. The available information was nevertheless sufficient for the Authority to propose tentative MRLs safe for consumers, which were set in Annex II to Regulation

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6 European Food Safety Authority, 2020. Reasoned Opinion on the review of the existing maximum residue levels for fenazaquin according to article 12 of regulation (EC) No 396/2005. *EFSA Journal*, 18(1), 5955. https://doi.org/10.2903/j.efsa.2020.5955.

7 Commission Regulation (EU) 2021/1110 of 6 July 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council asregards maximum residue levels for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products (OJ L 239, 7.7.2021, pp.4–21 ELI: https://eur-lex.europa.eu/eli/reg/2021/1110/oj/eng/pdf).

8 European Food Safety Authority, 2026. Lack of confirmatory data following Article 12 MRL reviews for dicloran, fenazaquin and tebufenozide. *EFSA Journal*, 24(4), e10064. https://doi.org/10.2903/j.efsa.2026.10064.

9 European Food Safety Authority, 2025. Modification of the existing maximum residue levels for fenazaquin in strawberries, sweet peppers, tomatoes and aubergines. *EFSA Journal*, 23(7), e9604. https://doi.org/10.2903/j.efsa.2025.9604.

10 European Food Safety Authority, 2018. Reasoned Opinion on review of the existing maximum residue levels for tebufenozide according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2018;16(2):5190, 52 pp. https://doi.org/10.2903/j.efsa.2018.5190.

(EC) No 396/2005[11], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(9) No confirmatory data on residue trials were submitted to support the proposed MRLs in cherries and rice and no confirmatory analytical methods for animal matrices were submitted to address the data gaps. The Authority concluded that the currently established MRLs for those commodities are not supported by data[12] and recommended to keep the MRL for tebufenozide in cherries at the LOD. For the commodities of animal origin and rice, CXLs were adopted by the Codex Alimentarius Commission in 2025[13].

(10) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[14], 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.

(11) The Authority assessed the risks that those new CXLs for tebufenozide pose to consumers and published a 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 to the Codex Alimentarius Commission, can be considered safe. Those CXLs should therefore be included in Regulation (EC) No 396/2005, except where they relate to products which are not listed in Annex I to that Regulation or where they are at a lower level than the current MRLs for the pesticide/product combinations concerned.

(12) As regards tebufenozide, an application was submitted requesting a modification of the existing MRLs in Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamias, pecans, pine nut kernels, pistachios and ‘others’ tree nuts pursuant to Article 6 (1) of Regulation (EC) No 396/2005.

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11 Commission Regulation (EU) 2019/973 of 13 June 2019 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 bispyribac, denatonium benzoate, fenoxycarb, flurochloridone, quizalofop- P- ethyl, quizalofop- P-tefuryl, propaquizafop, tebufenozide in or on certain products (OJ L 157, 14.6.2019, pp. 3–27. ELI: http://data.europa.eu/eli/reg/2019/973/oj).

12 European Food Safety Authority, 2026. Lack of confirmatory data following Article 12 MRL reviews for dicloran, fenazaquin and tebufenozide. *EFSA Journal*, 24(4), e10064. https://doi.org/10.2903/j.efsa.2026.10064.

13 CAC (Codex Alimentarius Commission). (2025). Report on the joint FAO/WHO food standards programme. Codex Alimentarius Commission, Forty-eighth Session, Rome, 14–15 November 2025.

14 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).

15 European Food Safety Authority, 2025. Scientific support for preparing an EU position in the 56th session of the codex committee on pesticide residues (CCPR). *EFSA Journal*, 23(10), 9640. https://doi.org/10.2903/j.efsa.2025.9640.

(13) The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs[16]. It forwarded this opinion to the applicant, the Commission and the Member States and made it available to the public.

(14) As regards this application, the Authority concluded that the data were appropriate to derive or confirm the MRL proposals for the commodities under assessment. It is, therefore, appropriate to set the requested MRLs for tebufenozide in Brazil nuts, cashew nuts, chestnuts, coconuts, hazelnuts/cobnuts, macadamias, pecans, pine nut kernels, pistachios and 'others' tree nuts at the levels recommended by the Authority.

(15) In light of the review carried out for the MRLs for fenazaquin and tebufenozide in certain commodities, the respective footnotes requiring the submission of additional information should be deleted from Annex II to Regulation (EC) No 396/2005.

(16) The Authority assessed the MRLs for fluopyram in accordance with Article 12 of Regulation (EC) No 396/2005 in 2020[17] and identified some information as unavailable for residue trials in chards/beet leaves, globe artichokes, leeks, lemons, mandarins, bananas, spring onions/green onions, tomatoes, melons, watermelons, Chinese cabbages/pe-tsai, escaroles/broad-leaved endives, land cresses, red mustards and spinaches. The available information was nevertheless sufficient for the Authority to propose a tentative MRLs safe for consumers, which were set in Annex II to Regulation (EC) No 396/2005[18], specifying the date by which the missing information was to be submitted to the Authority in support of the proposed MRLs.

(17) The data gaps on residue trials were not addressed in the case of globe artichokes, bananas, Chinese cabbages/pe-tsai, spinaches and chards/beet leaves. The Authority identified alternative GAPs for globe artichokes and bananas that are sufficiently supported by data and derived MRLs. For Chinese cabbages/pe-tsai, spinaches and chards/beet leaves, the Authority concluded that the MRLs are not sufficiently supported by data and should be lowered. Based on rotational crops studies and taking into account that the uptake of residues in succeeding crops cannot be fully avoided, specific MRLs reflecting uptake of residues from soil were proposed for Chinese cabbages/pe-tsai, spinaches and chards/beet leaves[19].

(18) The data gaps on residue trials were partially addressed in the case of melons and watermelons. The data provided were not sufficient to support the GAP assessed in

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16 European Food Safety Authority, 2026. Modification of the existing maximum residue level for tebufenozide in tree nuts. *EFSA Journal* 2026; 24 (1): e9819, https://doi.org/10.2903/j.efsa.2026.9819.

17 European Food Safety Authority, 2020. Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to article 12 of regulation (EC) No 396/2005. *EFSA Journal*,18(4), 6059. https://doi.org/10.2903/j.efsa.2020.6059.

18 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, pp. 55–71, ELI: http://data.europa.eu/eli/reg/2021/618/oj).

19 EFSA (2026). Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for fluopyram in limes. EFSA Journal, 24(8), e10279. https://doi.org/10.2903/j.efsa.2026.10279.

2020[20] but they were sufficient to support an alternative GAP and derive MRLs for these products[21].

(19) The data gaps on residue trials were addressed in the case of grapefruits, oranges, lemons, mandarins, tomatoes, spring onions/green onions, leeks, escaroles, land cresses and red mustards. The Authority concluded that the submitted information was sufficient to derive or confirm the MRLs for these products. It is, therefore, appropriate to set the MRLs for fluopyram for these commodities in Annex II to Regulation (EC) No 396/2005 at the level recommended by the Authority, at which it identified no risk for consumers[22].

(20) Four applications were submitted requesting a modification of the existing MRLs for fluopyram in kiwi, honey, cardoon, Florence fennel, rhubarb, bamboo shoots, palm hearts, seed spices, apples and soyabeans in accordance with Article 6(1), and in pome fruits, limes and peanuts pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005.

(21) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the 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 Authority.

(22) The Authority assessed the applications and the evaluation reports and gave a reasoned opinion on the proposed MRLs[23,24]. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

(23) The Authority concluded that the data submitted in support of the applications were found appropriate to derive or confirm the MRL proposals in kiwi, cardoon, Florence fennel, rhubarb, seed spices (except dill), soyabeans, pome fruits, limes and peanuts. It is, therefore, appropriate to set the MRLs for fluopyram in these commodities in Annex II to Regulation (EC) No 396/2005 at the level recommended by the Authority, at which it identified no risk for consumers[25,26].

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20 European Food Safety Authority, 2020. Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to article 12 of regulation (EC) No 396/2005. *EFSA Journal*,18(4), 6059. https://doi.org/10.2903/j.efsa.2020.6059.

21 European Food Safety Authority, 2026. Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for fluopyram in limes. *EFSA Journal*, 24(8), e10279. https://doi.org/10.2903/j.efsa.2026.10279.

22 European Food Safety Authority, 2026. Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for fluopyram in limes. *EFSA Journal*, 24(8), e10279. https://doi.org/10.2903/j.efsa.2026.10279.

23 European Food Safety Authority, 2023. Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for fluopyram in various crops. *EFSA Journal* 2023;21(6):8036, 58 pp. https://doi.org/10.2903/j.efsa.2023.8036.

24 European Food Safety Authority, 2026. Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for fluopyram in limes. *EFSA Journal*, 24(8), e10279. https://doi.org/10.2903/j.efsa.2026.10279.

25 European Food Safety Authority, 2023. Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for fluopyram in various crops. *EFSA Journal* 2023;21(6):8036, 58 pp. https://doi.org/10.2903/j.efsa.2023.8036.

26 European Food Safety Authority, 2026. Evaluation of confirmatory data following the Article 12 MRL review and setting of an import tolerance for fluopyram in limes. *EFSA Journal*, 24(8), e10279. https://doi.org/10.2903/j.efsa.2026.10279.

(24) The data was not sufficient to derive MRLs for bamboo shoots and palm hearts. It is therefore appropriate to keep the MRLs for fluopyram in these commodities in Annex II to Regulation (EC) No 396/2005 at the specific LOD level.

(25) The existing EU MRL for pome fruits was derived on the basis of an import tolerance application for uses in the USA in 2020[27]. The GAP used to derive the MRL is obsolete. The applicants submitted data on residue trials on apples to support the applications pursuant to Article 6(1) ,6(2) and 6(4). Based on these new residue trial data, the Authority derived a lower MRL for the whole group of pome fruits which is sufficient to support all currently authorised EU uses. Therefore, it is appropriate to set the MRL for this commodity in Annex II of Regulation (EC) No 396/2005 at the level recommended by the Authority[28].

(26) In November 2024, the Codex Alimentarius Commission adopted new CXLs for the active substance fluopyram [29].

(27) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[30], 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.

(28) The Authority assessed the risks that those new CXLs pose to consumers and published a scientific report[31]. 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. The Union presented a reservation to the progress of CXLs for cereals (barley, buckwheat, oats, rye, sorghum, triticale and wheat) due to the lack of the dietary burden calculations. The information on dietary burden calculations has been published in 2025[32] and the reservation for cereals can be

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27 European Food Safety Authority, 2020. Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2020;18(4):6059, 125 pp. https://doi.org/10.2903/j.efsa.2020.6059.

28 European Food Safety Authority, 2023. Reasoned Opinion on the modification of the existing maximum residue levels and setting of import tolerances for fluopyram in various crops. *EFSA Journal* 2023;21(6):8036, 58 pp. https://doi.org/10.2903/j.efsa.2023.8036.

29 Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission. Forty-seventh Session. FAO headquarters, Rome, Italy. 25-30 November 2024. fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-47%252FFINAL%252520REPORT%252FREP24_CACe.pdf.

30 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).

31 European Food Safety Authority, 2024. Scientific support for preparing an EU position in the 55th Session of the Codex Committee on Pesticide Residues (CCPR). *EFSA Journal*, 22(7), e8841. https://doi.org/10.2903/j.efsa.2024.8841.

32 FAO & WHO. 2025. Pesticide residues in food: Report 2024 – Joint FAO/WHO Meeting on Pesticide Residues. Rome. Annex 9, https://doi.org/10.4060/cd5918en.

lifted. The existing EU MRLs for wheat and sorghum were derived on the basis of import tolerance applications for uses in the USA in 2020[33]. The GAPs used to derive these MRLs are obsolete[34].

(29) The Authority did not identify any risks for consumers from the CXLs for fluopyram in barley, buckwheat, oats, rye, sorghum and wheat. These CXLs should therefore also be included in Regulation (EC) No 396/2005.

(30) 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.

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

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

(33) 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.

(34) 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.

(35) 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 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*].

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33 European Food Safety Authority, 2020. Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005. *EFSA Journal* 2020;18(4):6059, 125 pp., https://doi.org/10.2903/j.efsa.2020.6059.

34 https://www.federalregister.gov/documents/2022/02/18/2022-03385/fluopyram-pesticide-tolerances.

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

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