Brussels, XXX
PLAN/2026/701 Rev.0
[…](2026) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, cyflumetofen, diflufenican and milbemectin in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ametoctradin, cyflumetofen, diflufenican and milbemectin 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 ametoctradin, cyflumetofen, diflufenican and milbemectin, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) As regards cyflumetofen, an application requesting a modification of the existing MRLs was submitted for sweet peppers/bell peppers pursuant to Article 6(1) of Regulation (EC) No 396/2005. As regards milbemectin, such an application was submitted for cherries (sweet).

(3) The European Food Safety Authority ('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.

(4) As regards all those applications, 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 cyflumetofen in sweet peppers/bell peppers and for milbemectin in cherries (sweet) at the levels recommended by the Authority.

(5) As regards ametoctradin, Commission Regulation (EU) 2021/1110[3] reviewed its MRLs in accordance with Article 12 of Regulation (EC) No 396/2005, based on the

---

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

2 Modification of the existing maximum residue level for cyflumetofen in sweet peppers/bell peppers. EFSA Journal 2026; 24 (1): e9877, https://doi.org/10.2903/j.efsa.2026.9877.

Peer review of the pesticide risk assessment of the active substance milbemectin. EFSA Journal 2023; 21 (7): e08126, https://doi.org/10.2903/j.efsa.2023.8126.

3 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 as regards maximum residue levels

Authority reasoned opinion[4]. The Authority had identified missing information on analytical methods, residue trials on primary and rotational crops, storage stability and feeding studies, and proposed tentative MRLs for several commodities.

(6) In 2023, the applicant submitted the requested confirmatory data concerning ametoctradin 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 all commodities were addressed, that the existing tentative MRLs are confirmed and that for some livestock products the MRLs could be increased.

(7) It is, therefore, appropriate to maintain or increase the existing MRLs for barley, oat, rye, wheat, hops, bovine muscle, bovine fat, bovine liver, bovine kidney, equine muscle, equine fat, equine liver, equine kidney, swine muscle, swine fat, swine liver, swine kidney, sheep muscle, sheep fat, sheep liver, sheep kidney, goat muscle, goat fat, goat liver, goat kidney, poultry muscle, poultry fat, poultry liver, poultry kidney, milk cattle, milk sheep, milk goat, milk horse, chicken eggs, duck eggs, geese eggs and quail eggs and delete the respective footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

(8) As regards diflufenican, Commission Regulation (EU) 2015/603[6] reviewed its MRLs in accordance with Article 12 of Regulation (EC) No 396/2005, based on the Authority reasoned opinion[7]. The Authority had identified missing information on storage stability, residue trials, analytical methods and the northern outdoor Good Agricultural Practice and proposed tentative MRLs for several commodities.

(9) In 2018, the applicant submitted the requested confirmatory data concerning diflufenican 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[8]. The Authority concluded that the data gaps identified during the MRL review were only partly addressed and proposed no changes to the existing MRLs for wheat, rye, barley and products of animal origin.

(10) It is, therefore, appropriate to maintain the existing MRLs for wheat, rye, barley and products of animal origin, and delete the footnotes requiring the submission of additional information from Annex II to Regulation (EC) No 396/2005.

---

for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products (OJ L 239, 7.7.2021, pp. 4–21, ELI: http://data.europa.eu/eli/reg/2021/1110/oj).

4 Reasoned Opinion on the review of the existing maximum residue levels for ametoctradin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5990, https://doi.org/10.2903/j.efsa.2020.5990.

5 Evaluation of confirmatory data following the Article 12 MRL review for ametoctradin. EFSA Journal 2026;24 (1): e9829, https://doi.org/10.2903/j.efsa.2026.9829.

6 Commission Regulation (EU) 2015/603 of 13 April 2015 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 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in or on certain products (OJ L 100, 17.4.2015, pp. 10–59, ELI: http://data.europa.eu/eli/reg/2015/603/oj).

7 Reasoned opinion on the review of the existing maximum residue levels (MRLs) for diflufenican according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3281, https://doi.org/10.2903/j.efsa.2013.3281.

8 Peer review of the pesticide risk assessment of the active substance diflufenican. EFSA Journal 2026;24 (2): e9758, https://doi.org/10.2903/j.efsa.2026.9758.

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

(12) 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

Annex II to Regulation (EC) No 396/2005 is 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