Brussels, XXX
PLAN/2026/987 Rev.2
[…](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 bixlozone in or on certain products

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

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 bixlozone 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,

DRAFT

Whereas:

(1) In the context of the approval of the active substance bixlozone, a maximum residue level ('MRL') application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2]. The application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation.

(2) The European Food Safety Authority ('the Authority') assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance[3]. The Authority concluded that the data were appropriate to derive the MRL proposals for the commodities under assessment acknowledging that some information on metabolites was missing, which was found to be particularly relevant for rotational crops. It is, therefore, appropriate to set the requested MRLs for bixlozone for the representative uses (wheat, barley, oilseed rape and maize) and for honey at the levels recommended by the Authority. For the rotational crops (root and tuber vegetables, sugar beet roots, chicory roots, roots of herbal infusions and roots of spices, spinaches and similar leaves), it is appropriate to set the requested MRLs on a tentative basis and to insert the corresponding footnote for these commodities indicating the missing information and the deadline for its submission. As regards all other commodities, it is appropriate to set the MRLs at the product-specific limit of determination ('LOD') or to apply the default MRL as provided for in Article 18(1), point (b), of Regulation (EC) No 396/2005.

---

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

2 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, pp. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj).

3 EFSA (European Food Safety Authority), Álvarez, F., Arena, M., Auteri, D., Leite, S. B., Binaglia, M., Castoldi, A. F., Chiusolo, A., Colagiorgi, A., Colas, M., Crivellente, F., De Lentdecker, C., De Magistris, I., Egsmose, M., Fait, G., Ferilli, F., Santonja, G. G., Gouliarmou, V., Halling, K., … Villamar-Bouza, L. (2024). *Peer review of the pesticide risk assessment of the active substance bixlozone*. *EFSA Journal*, 22(10), e9054. https://doi.org/10.2903/j.efsa.2024.9054.

(3) The Authority proposed a residue definition for enforcement applicable to plant products as 'bixlozone' and a residue definition for enforcement applicable to animal products as '5-Hydroxy-F9600, free and conjugated, expressed as bixlozone'.

(4) The Commission consulted the European Union reference laboratories as regards the LODs. Those laboratories confirmed setting LODs according to the conclusion on the peer review by the Authority.

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

(6) 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

DRAFT