EUROPEAN
COMMISSION

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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 oxamyl in or on certain products

(Text with EEA relevance)

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 oxamyl 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) and Article 18(1), point (b), thereof,

Whereas:

(1) For the active substance oxamyl, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) The approval of the active substance oxamyl expired on 1 May 2023[2]. All authorisations for plant protection products containing that active substance will have been revoked by 1 November 2023.

(3) In the context of the procedure for the renewal of the approval of that active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council[3], the European Food Safety Authority ('the Authority') published a conclusion on the peer review of the risk assessment of that active substance[4], establishing a lower acceptable daily intake (ADI) and a lower acute reference dose (ARfD).

(4) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion, assessing the risks that the current MRLs, including those based on Codex maximum residue limits (CXLs), for oxamyl, may pose to consumers in light of those lower ADI and ARfD.

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1 OJ L 70, 16.3.2005, p. 1.

2 Commission Implementing Regulation (EU) 2023/741 of 5 April 2023 concerning the non-renewal of approval of the active substance oxamyl, 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 98, 11.04.2023, p. 1).

3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council 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, p. 1).

4 European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance oxamyl. EFSA Journal 2022;20(5):7296.

(5) In its reasoned opinion[5], the Authority identified unacceptable chronic exposure risks for a wide range of diets, as well as acute exposure risks for a wide range of commodities, including for melons and watermelons for which MRLs are set on the basis of CXLs. Therefore, no MRL can be maintained and MRLs for oxamyl in all products should be set at the respective limits of determination (LOD), which should be set in Annex V to Regulation (EC) No 396/2005 in accordance with Article 18(1), point (b) of that Regulation. Additionally, the footnotes indicating lack of information on storage stability, crop metabolism and residue trials should be deleted.

(6) Additionally, the Authority identified that the default LOD value of 0.01* mg/kg does not provide a sufficient level of protection for consumers for most commodities, so that the LOD for these products should be set at lower, more protective levels.

(7) 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.

(8) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.

(9) Annex II and V to Regulation (EC) No 396/2005 should therefore be amended accordingly.

(10) 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 modification of the MRLs.

(11) 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

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 *3 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

[5] European Food Safety Authority; Statement on the risk assessment of maximum residue levels (MRLs) for oxamyl in view of consumer protection. EFSA Journal 2023;21(3):7823.

The President
Ursula VON DER LEYEN