



Brussels, XXX
PLAN/2024/307_Rev1
[...] (2024) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

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 zoxamide in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

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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 zoxamide 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/EEC¹, and in particular Article 14(1), point (a), and Article 49(2) thereof,

Whereas:

- (1) For the active substance zoxamide, maximum residue levels ('MRLs') were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.
- (2) The European Food Safety Authority ('the Authority') submitted a reasoned opinion on the review of the existing MRLs for zoxamide in accordance with Article 12(1) of Regulation (EC) No 396/2005 and on the setting of an import tolerance for onions, garlic and shallots².
- (3) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005, an application for import tolerance was submitted for zoxamide in onions, garlic and shallots.
- (4) In accordance with Article 8 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and in accordance with Article 9 of that Regulation, the evaluation report was forwarded to the Commission.
- (5) The Authority assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals and forwarded its reasoned opinion to the applicant, the Commission and the Member States, and made it available to the public.
- (6) The Authority concluded that all data requirements were met and that the modification to the MRLs requested by the applicant was acceptable on the basis of a consumer exposure assessment showing that the short-term and long-term intake of residues resulting from the use of zoxamide according to the agricultural practices on onions, garlic and shallots is unlikely to present a risk to consumer health.

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

² European Food Safety Authority; Review of the existing maximum residue levels for zoxamide according to Article 12 of Regulation (EC) No 396/2005 and setting of an import tolerance for onions, garlic and shallots; EFSA Journal 2023; 21(12):e8427. <https://doi.org/10.2903/j.efsa.2023.8427>.

- (7) The Authority recommended setting MRLs for potatoes, tomatoes, cucumbers, gherkins, courgettes, melons, pumpkins and watermelons, for which sufficient supporting data on good agricultural practices were submitted and assessed. As there is no risk for consumers, it is appropriate to set the MRLs for those products in Annex II to Regulation (EC) No 396/2005 at the level identified by the Authority.
- (8) The Authority concluded that concerning the MRLs for table grapes, wine grapes, spring onions/green onions and Welsh onions, aubergines/eggplants, chive, honey and other apiculture products some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for those products should be maintained in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (9) For all other products, it is appropriate to set the MRLs to the product specific LOD in accordance with Article 14(1), point (a), of Regulation (EC) No 396/2005, in conjunction with Article 17 of that Regulation.
- (10) The Commission consulted the European Union reference laboratories for residues of zoxamide as regards the need to adapt certain LODs. Those laboratories proposed product-specific LODs that are analytically achievable for all products.
- (11) 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.
- (12) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (13) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced placed on the market before the new MRLs for zoxamide become applicable and for which a high level of consumer protection is maintained. This is the case for all products.
- (14) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been before the new MRLs for cypermethrin become applicable and for which a high level of consumer protection is maintained.
- (15) 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.
- (16) 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 III 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 ... [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 ... [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
Ursula VON DER LEYEN