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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	28 February 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	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 prothioconazole in or on certain products

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Delegations will find attached document D093665/3.

Encl.: D093665/3



Brussels, **XXX**  
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[...](2024) **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 prothioconazole 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 prothioconazole 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<sup>1</sup>, and in particular Article 14(1), point (a), thereof,

Whereas:

- (1) For the active substance prothioconazole, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.
- (2) An application requesting a modification of the existing MRLs for prothioconazole in sugar beet roots and chicory roots was submitted to the Member State concerned pursuant to Article 6(1) of Regulation (EC) No 396/2005.
- (3) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission. The Commission forwarded the application, the evaluation report, and the supporting dossier to the European Food Safety Authority (the 'Authority').
- (4) The Authority assessed the application and the evaluation report. It examined in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs<sup>2</sup>. It forwarded its reasoned opinion to the applicant, the Commission and the Member States and made it available to the public.
- (5) As regards the modifications to the MRLs for prothioconazole in sugar beet roots and chicory roots requested by the applicant, the Authority concluded that all the data requirements had been met and that the modifications to the MRLs requested by the applicant were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of prothioconazole. Neither the long-term exposure to that substance via consumption of all food products that may contain it nor the short-term exposure due to high

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

<sup>2</sup> EFSA 2023. Reasoned Opinion on the modification of the existing maximum residue levels for prothioconazole in sugar beet and chicory roots. EFSA Journal, 21(8), 1–49. <https://doi.org/10.2903/j.efsa.2023.8198>.

consumption of relevant products show a risk that the acceptable daily intake or the acute reference dose is exceeded.

- (6) Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the proposed modifications to the MRLs fulfil the requirements of that Article.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) 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*