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

**of XXX**

**amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for nicotine in or on certain products**

(Text with EEA relevance)

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

of **XXX**

## amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for nicotine 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)(a) thereof,

Whereas:

- (1) For nicotine, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The existing temporary MRL for nicotine in teas of currently 0.6 mg/kg was lowered by Commission Regulation (EU) No 2023/377<sup>2</sup> to 0.5 mg/kg based on monitoring data which demonstrated that such lower levels are achievable. This level will be further lowered to 0.4 mg/kg after 22 February 2026 unless modified by a Regulation in light of new information provided by 30 June 2025 at the latest. As the European Food Safety Authority ('the Authority') had identified unacceptable risks for consumers from the existing MRL<sup>3</sup> for teas, that same Regulation did not allow for transitional arrangement for teas which have been produced before the modification of the MRLs.
- (3) The Authority has received new information from Ireland pointing out that the Irish consumption data based on which the Authority identified unacceptable risks for consumers from the existing MRL for nicotine in teas did not accurately reflect exposure of Irish children and would lead to an overestimation of the risk. Based on the above, the Authority performed a new acute (short-term) dietary risk assessment for nicotine in teas, excluding the Irish consumption data, and concluded that the current MRL for nicotine in teas is safe for consumers<sup>4</sup>. Therefore, in order to allow for the normal marketing, processing and consumption of products, it is appropriate to provide for a transitional arrangement for teas that have been produced before the

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> Commission Regulation (EU) 2023/377 of 15 February 2023 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyltrimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products (OJ L 55, 22.2.2023, p. 1)

<sup>3</sup> EFSA 2023. Statement on the short-term (acute) dietary exposure assessment for the temporary maximum residue levels for nicotine in rose hips, teas and capers. EFSA Journal 2022;20(9):7566.

<sup>4</sup> EFSA, 2023. Statement on the revised target risk assessment for certain maximum residue levels for nicotine. EFSA Journal 2023;21(3):7883.

lowering of the MRL for nicotine in teas to 0.5 mg/kg provided by Regulation (EU) No 2023/377, as a high level of consumer protection is maintained.

- (4) For what concerns nicotine in ‘seed spices’ and ‘fruits spices’, temporary MRLs were set at 0.02 mg/kg by Regulation (EU) No 2023/377 until 22 February 2030, pending the submission and evaluation of new data and information on the natural occurrence or formation of nicotine in those products. The Commission has received new information from the European Union Reference Laboratories noting that a limit of determination (LOD) of 0.05 mg/kg may be more appropriate for ‘seed spices’ and ‘fruits spices’. Therefore, it is appropriate to establish the MRLs for these products at 0.05 mg/kg. Those MRLs will be reviewed; the review will take into account the information available within 22 February 2030.
- (5) For what concerns nicotine in cinnamon, a temporary MRL was set at 0.07 mg/kg by that same Regulation based on a combined data set for ‘bark spices’, ‘root and rhizome spices’, ‘bud spices’, ‘flower pistil spices’ and ‘aril spices’. Recently, some more specific monitoring data on cinnamon were submitted to the European Commission indicating that residues may occur in this product at higher levels than the temporary MRL established by Regulation (EU) No 2023/377. Based on those more specific data, the temporary MRL should be set at a level of 0.2 mg/kg, corresponding to the 95th percentile of all the sample results. Further monitoring data are needed to confirm this level. Therefore, the MRL will be reviewed; the review will take into account additional monitoring data that will become available by 22 February 2030.
- (6) Based on the relevant risk assessments<sup>5</sup> of the Authority and taking into account the factors relevant to the matter under consideration, the proposed modification to the MRL fulfils the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (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 III 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*.

It shall apply from 15 September 2023 as regards all proposed MRLs.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*The President*  
*Ursula VON DER LEYEN*

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<sup>5</sup> EFSA, 2011. Reasoned Opinion on the setting of temporary MRLs for nicotine in tea, herbal infusions, spices, rose hips and fresh herbs. EFSA Journal 2011;9(3):2098.