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To:	General Secretariat of the Council
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Subject:	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

Delegations will find attached document D088849/02.

Encl.: D088849/02



Brussels, **XXX**
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D088849/02
[...] (2023) **XXX** draft

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)

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/EEC¹, and in particular Article 14(1), point (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 0,6 mg/kg was lowered by Commission Regulation (EU) 2023/377² to 0,5 mg/kg based on monitoring data which demonstrated that such a lower level is achievable. This level is to be further lowered to 0,4 mg/kg after 22 February 2026 unless modified further in light of new information provided by 30 June 2025. As the European Food Safety Authority ('the Authority') had identified unacceptable risks for consumers from the existing MRL for teas³, Regulation (EU) 2023/377 did not provide for transitional arrangements for teas 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 this new information, the Authority performed a new acute (short-term) dietary risk assessment for nicotine in teas, excluding the previously considered Irish consumption data, and concluded that the current MRL of 0,6 mg/kg for nicotine in teas is safe for consumers⁴. Therefore, in order to allow for the normal marketing, processing and consumption of products, it is appropriate to provide for a transitional arrangement for

¹ OJ L 70, 16.3.2005, p. 1.

² 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).

³ European Food Safety Authority. Statement on the short- term (acute) dietary risk assessment for the temporary maximum residue levels for nicotine in rose hips, teas and capers. EFSA Journal 2022;20(9):7566.

⁴ European Food Safety Authority. Statement on the revised targeted risk assessment for certain maximum residue levels for nicotine. EFSA Journal 2023;21(3):7883.

teas that have been produced before the lowering of the MRL for nicotine in teas to 0,5 mg/kg, provided by Regulation (EU) 2023/377, as a high level of consumer protection is maintained.

- (4) As regards nicotine in rose hips, for which the temporary MRL was lowered by Regulation (EU) 2023/377 from 0,3 mg/kg to 0,2 mg/kg, the Authority confirmed the previously identified unacceptable risks for consumers resulting from the existing MRL of 0,3 mg/kg. Therefore, no transitional arrangement can be allowed for rose hips which have been produced before the lowering of the MRL.
- (5) As regards nicotine in seed spices and fruit spices, temporary MRLs were set at 0,02 mg/kg by Regulation (EU) 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 fruit spices. Therefore, it is appropriate to establish the MRLs for these products at the LOD of 0,05 mg/kg. Those MRLs will be reviewed; the review will take into account the information available by 22 February 2030.
- (6) As regards nicotine in cinnamon, a temporary MRL was set at 0,07 mg/kg by Regulation (EU) 2023/377, based on a combined data set for bark spices, root and rhizome spices, bud spices, flower pistil spices and aril spices. Recently, specific monitoring data on cinnamon were submitted to the Commission, indicating that residues may occur in this product at higher levels than the temporary MRL established by Regulation (EU) 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. That MRL will be reviewed; the review will take into account additional monitoring data available by 22 February 2030.
- (7) Based on the relevant risk assessments of the Authority⁵ and taking into account the factors relevant to the matter under consideration, the proposed modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (8) For technical reasons, the amendments to the MRLs for seed spices, fruit spices and cinnamon should apply later than those of Regulation (EU) 2023/377, while the transitional provision for the new MRLs for teas as laid down in Regulation (EU) 2023/377 should apply at the same time as Regulation (EU) 2023/377, to prevent a gap in the transitional arrangement.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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.

⁵ European Food Safety Authority. 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.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by Regulation (EU) 2023/377 shall continue to apply to teas which were produced in the Union or imported into the Union before 14 September 2023.

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 15 September 2023.

However, Article 2 shall apply from 14 September 2023.

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