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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 D091951/3.

Encl.: D091951/3



Brussels, **XXX**
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[...] (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) As regards nicotine in bark spices, root and rhizome, bud spices, flower pistil spices and aril spices, temporary MRLs were set by Commission Regulation (EU) 2023/377² at 0,07 mg/kg 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.
- (3) As regards nicotine in seed spices and fruit spices, temporary MRLs were set by Commission Regulation (EU) 2023/1536³ at 0,05 mg/kg 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. That Regulation also set a temporary MRL for nicotine in cinnamon at 0,2 mg/kg, until 22 February 2030, pending the submission of the same information.
- (4) Recently, food business operators submitted to the Commission specific monitoring data on spices, indicating that residues may occur in this product at higher levels than the temporary MRL established by Regulations (EU) 2023/377 and (EU) 2023/1536. Based on this more specific data, the Commission proposed the setting of temporary MRLs at a level of 0,3 mg/kg for all spices, corresponding to the 95th percentile of all the sample results.

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, didecyldimethylammonium 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 Commission Regulation (EU) 2023/1536 of 25 July 2023 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 (OJ L 187, 26.7.2023, p. 6).

- (5) Based on this new information, the European Food Safety Authority ('the Authority') performed a new acute (short-term) dietary risk assessment for nicotine in spices and a new chronic (long-term) exposure assessment for European consumers. The Authority examined the risks to consumers and, where relevant, to animals, and gave a statement on the proposed MRLs⁴. It concluded that the modifications to the MRLs for nicotine in spices were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of nicotine. Neither the long-term (chronic) exposure to that substance via consumption of all food products that may contain it nor the short-term (acute) exposure due to high consumption of relevant products show that there is any risk that the acceptable daily intake or the acute reference dose is exceeded.
- (6) Based on the relevant risk assessments of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, the proposed modifications to the MRLs are acceptable.
- (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*.

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

⁴ European Food Safety Authority, 2023. Targeted risk assessment for maximum residue levels for nicotine in spices. EFSA Journal, 21(10), 1–12. <https://doi.org/10.2903/j.efsa.2023.8372>.