

## Maximum residue levels for nicotine

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#### EU amends MRLs for nicotine on coffee

Commission Regulation (EU) <u>2025/115</u> of 21 January 2025 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 fluxapyroxad, lambda-cyhalothrin, metalaxyl, and nicotine in or on certain products

### **Update**

The EU has amended the limit of determination (LOD) for nicotine on coffee from 0.01 to 0.05 mg/kg. (The LOD is the lowest level that can be detected using the most modern and reliable analytical methods.)

### Impacted products

Rose hips, herbs, edible flowers, wild fungi, teas, herbal infusions, spices, coffee

# What is changing?

The European Union (EU) has amended the LOD for nicotine on coffee from 0.01 to 0.05 mg/kg.

Previously, a targeted risk assessment of maximum residue levels (MRLs) for nicotine carried out by <u>EFSA (2023)</u> concluded that a nicotine MRL of 0.3 mg/kg on spices (seed, fruit, root, bark, bud, flower pistil, and aril spices) is safe for consumers. So for all spices the European Commission has reinstated the MRL of 0.3 mg/kg that applied before 15 September 2023.

Other nicotine MRL changes introduced in 2023 are set out in Table 1. The MRLs for all other products not listed in Table 1 are set to the LOD.

## Why?

The MRL for nicotine in coffee beans has been changed to a temporary level of 0.05 mg/kg, based on monitoring data and a recommendation from the EU Reference Laboratory to account for residues from non-pesticide sources.





Following a review of the temporary MRLs in place since 2011, new Regulations were introduced in 2023 to lower the EU MRLs for nicotine (Regulations 2023/377 and 2023/1536).

In the case of capers, there were concerns that the temporary MRL of 4 mg/kg could pose an acute risk to consumers (according to calculations performed with EFSA's Pesticide Residue Intake Model, PRIMo rev. 3.1).

A potential acute risk for consumers was also identified for the temporary MRLs for nicotine in rose hips and teas, taking into account recent food consumption data for these products representative for European consumers.

In the case of spices (seed, fruit, root, bark, bud, flower pistil, and aril spices), new monitoring data were provided by non-EU exporting countries and food business operators, and a review was requested. A risk assessment carried out by <a href="EFSA (2023">EFSA (2023)</a> concluded that the original nicotine MRL is safe for consumers, and the European Commission subsequently reinstated for all spices the MRL of 0.3 mg/kg.

#### Timeline

The new MRL for nicotine on coffee applies from 11 February 2025.

The revised MRL for nicotine on spices entered into force on 26 February 2024.

The MRLs for nicotine approved in 2023 have applied since 15 September 2023.

### **Recommended Actions**

Suppliers to the EU market of rose hips, herbs and edible flowers, wild fungi, teas, herbal infusions, and spices should maintain, and where necessary increase, systematic monitoring of nicotine residues.

Monitoring data for nicotine residues on rose hips, herbs, edible flowers, teas, herbal infusions, and spices must be submitted to the EU by **22 February 2030** to be considered during the MRL review process. For fresh wild fungi, the deadline for submitting monitoring data is **30 June 2025**, and for dried wild mushrooms, it is **25 July 2029**.

<u>EFSA (2024)</u> gives detailed guidance on how to submit data to the European Food Safety Authority.

It is also important to note that nicotine is not approved for use as an insecticide in the EU, and should not be applied to crops that are intended for export to the EU due to the likelihood of exceeding permitted residue levels.





### **Background**

In 2009, the EU authorisation for the use of nicotine as an active substance in plant protection products was withdrawn. No specific MRLs for nicotine were set, and the default MRL of 0.01 mg/kg was applied to all products.

In 2009 and 2011, the European Commission asked EFSA to provide advice on the setting of temporary MRLs for nicotine for a number of commodities in which residue levels greater than the default MRL were repeatedly identified during controls by food business operators and/or national competent authorities (<u>EFSA 2009</u>, <u>2011</u>). Based on the EFSA assessment, specific temporary MRLs were set in Annex IIIA of Regulation (EC) No 396/2005 for nicotine in wild fungi (Commission Regulation (EU) 765/2010); and for nicotine in rose hips, herbs and edible flowers, teas, herbal infusions, and spices (Commission Regulation (EU) 812/2011).

The source of residues in these commodities has not been established. Contamination during harvest, drying, storage, or transport is considered possible. Nicotine also occurs naturally as the main alkaloid in tobacco and related species, and is found in low concentrations in certain other crops. In the absence of scientific evidence on the source, the Commission decided to review the temporary MRLs after 10 years in order to take into account any new information available. On the basis of this review, two new draft Regulations were introduced in 2022 referencing recent monitoring and food consumption data (EFSA 2022).

MRLs are set in accordance with the rules set out in Regulation <u>396/2005</u>. For information on current MRLs for other substances, please consult the <u>EU Pesticide Residues database</u>.

#### Resources

EFSA (2009) <u>Statement on the potential risks for public health due to the presence of nicotine in wild mushrooms</u>. EFSA Journal, 7(5): 286.

EFSA (2011) Reasoned opinion on the setting of temporary MRLs for nicotine in tea, herbal infusions, spices, rose hips and fresh herbs. EFSA Journal, 9(3): 2098.

EFSA (2022) 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, 20(9): 7566.

EFSA (2023) <u>Targeted risk assessment of maximum residue levels for nicotine in spices</u>. EFSA Journal, 21(10): 8372.

EFSA (2024) Data collection. European Food Safety Authority.





### **Sources**

Commission Regulation (EU) <u>2024/451</u> as regards maximum residue levels for nicotine in or on certain products

Commission Regulation (EU) <u>2023/1536</u> as regards maximum residue levels for nicotine in or on certain products

Commission Regulation (EU) <u>2023/377</u> as regards didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products

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# **Table & Figures**

Table 1 Maximum residue levels for nicotine			
Food category	Products	Nicotine (mg/kg)	
		Old MRL	New MRL
Berries and small fruits	Rose hips	0.3	0.2
Herbs and edible flowers	Chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil and edible flowers, laurel/bay leaves, tarragon	0.4	0.1
Fungi, mosses and lichens	Wild fungi	0.04	0.02
Teas		0.6	0.5
Coffee		0.01*	0.05*
Herbal infusions	From flowers, from leaves and herbs, from roots, from any other parts of the plant	0.5	0.3
Spices	Seed spices, fruit spices	0.05*	0.3
	Root and rhizome spices, bud spices, flower pistil spices, aril spices	0.07	0.3
	Bark spices (cinnamon)	0.2	0.3
* Limit of determination.  **Jagrinfo www.agrinfo.eu			

Source: based on Regulations <u>2023/377</u>, <u>2023/1536</u>, <u>2024/451</u>, <u>2025/115</u>

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