



Maximum residue levels for nicotine

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EU to reinstate MRLs for nicotine on spices

Commission Regulation (EU) <u>2024/451</u> of 5 February 2024 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

Commission Regulation (EU) <u>2023/1536</u> 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

Commission Regulation (EU) <u>2023/377</u> 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

Update

Following the submission of additional data and a new risk assessment by the European Food Safety Authority (EFSA), the EU has reinstated the MRLs for nicotine in spices to 0.03 mg/kg (the level that applied before 15 September 2023 to seed/fruit spices). Earlier in 2023, the EU also amended MRLs on rose hips, herbs and edible flowers, wild fungi, teas, and herbal infusions.

Impacted products

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

What is changing?

After new data were made available, a targeted risk assessment of maximum residue levels for nicotine was carried out by <u>EFSA (2023)</u>. EFSA concluded that for spices (seed, fruit, root, bark, bud, flower pistil, and aril spices) a nicotine MRL of 0.3 mg/kg is safe for consumers. The European Commission has therefore reinstated **for all spices** the MRL of **0.3 mg/kg** (which applied before 15 September 2023 to seed/fruit spices).





THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

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 limit of determination (LOD, the lowest level that can be detected using the most modern and reliable analytical methods).

Why?

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

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 EFSA (2023) 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 MRLs for nicotine approved in 2023 apply from 15 September 2023.

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

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.

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.





THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

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 (EFSA 2009; EFSA 2011). 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.

Sources

Commission Regulation (EU) 2024/451





THE LATEST ON EU AGRI-FOOD POLICIES IMPACTING LOW-INCOME & MIDDLE-INCOME COUNTRIES

Commission Regulation (EU) 2023/1536

Commission Regulation (EU) 2023/377

Table & Figures

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
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

Source: Regulation (EU) <u>2023/377</u>; <u>2023/1536</u>; <u>2024/451</u>

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