

**GUIDELINES AS REGARDS MEASURES TO BE TAKEN CONCERNING  
THE PRESENCE OF NICOTINE IN WILD MUSHROOMS**

Communication from the European Communities

The following communication, received on 15 May 2009, is being circulated at the request of the Delegation of the European Communities.

**I. BACKGROUND**

1. The EC Commission has been informed by food business operators that dried wild mushrooms (mainly *Boletus edulis* hereafter called ceps, but also truffles and cantarelles) may contain levels of nicotine higher than 0.01 mg/kg<sup>1</sup> (default level as set by Article 18.1.b to Regulation (EC) No 396/2005. According to the information received, almost all wild mushrooms are affected, irrespective of their origin, although most of them originate from China. The data received show that 99 per cent of the 2008 production does not comply with the default limit of 0.01 mg/kg as set in Regulation (EC) No 396/2005. Residue levels found can be up to 9.9 mg/kg on the dried product.

2. Food business operators have been investigating the reason(s) of this unexpected presence of nicotine in dried mushrooms, but so far no clear causal link could be established. The nicotine residues found could be of various origins but also result from the combination of various factors, including pesticide use, cross-contamination and natural presence.

3. A monitoring and testing programme will be launched by food business operators at the start of the forthcoming 2009 harvest season. EC member States should also monitor the levels of nicotine in mushrooms as from the next harvest season, with a view to collect monitoring data and to have a clear understanding of the natural levels and unavoidable background presence that can be expected from various EC regions.

4. However, pending the submission of those data, urgent measures are needed to allow the placing on the market of dried mushrooms from the 2008 season, provided that they are safe.

5. Therefore, with a view to setting a temporary MRL under Reg. (EC) No 396/2005, the EC Commission asked the European Food Safety Authority (EFSA) on 27 April 2009 to deliver an opinion in relation to the risks for human health due to the presence of nicotine in wild mushrooms at concentrations up to 0.5 mg/kg.

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<sup>1</sup> Recalculated on the fresh mushroom, to which the default level applies. According to the available information the concentration factor as a consequence of drying is a factor of about nine.

6. In reply to this request, on 7 May 2009 the EFSA issued a statement concluding that a level of 0.5 mg/kg is not safe, because it would lead to an exceedance of the acute reference dose (ARfD).<sup>2</sup> The EFSA proposed alternative MRLs to be set on a temporary basis both for fresh (0.036 mg/kg) and for dried (1.17 mg/kg) wild mushrooms.

7. The EFSA also highlighted that the evaluation performed was affected by a number of uncertainties and limitations on the data available (consumption of wild mushrooms in Europe, and in particular on dried ones, contamination levels, actual unit-to-unit variability in fresh mushrooms).

8. As regards dried ceps, the EC Commission notes that one of the uncertainties highlighted by EFSA refers to the poor data as regards children's consumption of ceps. It would be therefore more appropriate to restrict the evaluation of a safe level of nicotine in ceps to the consumption data available for the adult population. Moreover, the EC Commission considers that, on a temporary basis and pending the submission of more detailed and reliable data, the 95<sup>th</sup> percentile of the data consumption should be used to estimate the acute exposure to nicotine in dried ceps.<sup>3</sup> As a consequence, for dried ceps, an acceptable level of 2.3 mg/kg could be derived.

## II. GUIDELINES

9. The Standing Committee on the Food Chain and Animal health (SCoFCAH) had an exchange of views on the available information and on the results of the risk assessment carried out by EFSA on the presence of nicotine in wild mushrooms.

10. Based on the statement from EFSA, the SCoFCAH has considered that the current default MRL for nicotine in mushrooms is not a health standard and that it is appropriate to take the following proportionate risk management measures on a temporary basis, ensuring a high level of consumer protection in the European Union:

- (a) Fresh wild mushrooms with a level of nicotine higher than 0.04 mg/kg and dried wild mushrooms other than ceps with a level of nicotine higher than 1.2 mg/kg should not be placed on the market and should be withdrawn from the market and safely disposed of.
- (b) Dried ceps with a level of nicotine higher than 2.3 mg/kg should not be placed on the market and should be withdrawn from the market and safely disposed of.
- (c) EC member States should put in place a monitoring programme for the 2009 season with a view to have a clear understanding of the natural levels and unavoidable background presence of nicotine in different wild mushroom species that can be expected from various origins. EC member States should, without any delay, communicate to the EC Commission and to EFSA the results of the monitoring programmes with a view to setting an MRL for nicotine in fresh and dried mushrooms under the provisions of Reg. (EC) No 396/2005.

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<sup>2</sup> Statement of EFSA on the risks for public health due to the presence of nicotine in wild mushrooms, issued on 7 May 2009. Available at:

[http://www.efsa.europa.eu/cs/BlobServer/Statement/Statement\\_nicotine\\_mushrooms\\_ej286\\_en.pdf?sbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Statement/Statement_nicotine_mushrooms_ej286_en.pdf?sbinary=true)

<sup>3</sup> Expressed as grams/kg body weight/day and calculated for the consuming days only (table 4-2 of the EFSA statement).

11. The management measures referred to in points A and B are to be applied on a temporary basis, awaiting the setting of an MRL for nicotine in fresh and dried mushrooms foreseen by the end of 2009, taking into account the results of the monitoring programme, referred to in paragraph 10(c) above.

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