

**REPLY TO COMMENTS SUBMITTED BY COLOMBIA**

Submission by the European Communities

The following communication, dated 5 November 2004, is being circulated at the request of the Delegation of the European Communities.

The European Communities thanks Colombia for providing comments to the "Draft Commission Regulation amending Commission Regulation (EC) No. 466/2001 (Official Journal L77, 16/03/2001; pages 1-13) as regards ochratoxin A" (OTA) notified to the WTO in document G/SPS/N/EEC/247. The European Communities has examined the comments carefully and is providing hereby a response to the issues raised by Colombia.

**Comment by Colombia:**

**Cereals and cereal products are stated to be the main contributor of OTA to the European diet (50 per cent) and the studies cited show that the contribution of coffee to OTA intake is 8 per cent. We would therefore like to know the argument used to maintain, without any scientific justification whatsoever, that the OTA intake from coffee is considered significant enough to justify the levels established in the notified draft measure.**

Toxicology and the need for measures to reduce the presence of OTA in the food chain

1. The EU Scientific Committee on Food (SCF) concluded in its opinion on OTA, expressed on 17 September 1998, that OTA is a mycotoxin which possesses carcinogenic, nephrotoxic, teratogenic, immunotoxic and possibly neurotoxic properties. Therefore the Scientific Committee for Food considers *"it would be prudent to reduce exposure to ochratoxin A as much as possible"*.

2. Furthermore, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated ochratoxin A at its 56<sup>th</sup> meeting in 2001. JECFA concluded that *"efforts are needed to ensure that intakes of ochratoxin A do not exceed the PTWI [provisional tolerable weekly intake], and this could best be achieved by lowering overall contamination by appropriate agricultural, storage and processing practices"*.

3. The effective implementation of prevention measures is of major importance to reduce overall contamination. The adoption of achievable maximum levels does provide a strong incentive for the application of these preventive measures. They further provide a tool for the authorities to control the correct application by each actor in the chain of these prevention measures.

### Exposure assessment

4. An assessment of the dietary intake of OTA by the population of the European Communities has been performed in the framework of Council Directive 1993/5/EEC of 25 February 1993 on assistance to the Commission and co-operation by the member States in the scientific examination of questions relating to food (SCOOP).<sup>1</sup> The main contributor to the OTA exposure is cereal and cereal products. Wine, coffee and beer were identified as significant contributors to human OTA exposure. Dried vine fruit and grape juice contributed to a significant extent to the OTA-exposure for specific vulnerable groups of consumers such as children.

### The measures

5. A maximum level for OTA has been already established for cereal and cereal products and dried vine fruit by Regulation (EC) 466/2001 and has been applied since 5 April 2002. The level of OTA in beer is indirectly controlled as the OTA in beer originates from the presence of OTA in malt, for which a maximum level of 3 µg/kg has been established. The setting of a maximum level for OTA in beer is therefore not immediately necessary to protect public health as the level of OTA in beer is indirectly controlled by the maximum level of OTA in malt.

6. Given the significant contribution of wine and roasted coffee together with soluble coffee to the OTA human exposure and the significant contribution of grape juice to the OTA exposure of children, it is appropriate to set maximum levels for these foodstuffs, in addition to the existing maximum levels of OTA, to protect public health by preventing the distribution of unacceptably highly contaminated foodstuffs:

- |  |             |
|--|-------------|
| - roasted coffee beans and ground roasted coffee             | 5.0 µg /kg  |
| - soluble coffee   | 10.0 µg /kg |
| - wine and other wine and/or grape must based beverages      | 2.0 µg/kg   |
| - grape juice and grape juice ingredients in other beverages | 2.0 µg /kg  |

### **Comment by Colombia:**

#### **What method was established to determine the maximum OTA levels in roasted and soluble coffee?**

7. Commission Directive 2002/26/EC of 13 March 2002 laying down the sampling methods and the methods of analysis for the official control of the levels of ochratoxin A in foodstuffs fixes general criteria, with which the method of analysis has to comply in order to ensure that the laboratories in charge of the control use methods of analysis with comparable levels of performance. These performance criteria consist, *inter alia*, of the repeatability, the reproducibility and the recovery rate.

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<sup>1</sup> OJ L 52, 4.3.1993, p. 18.

Performance characteristics for ochratoxin A

Level µg/kg	Ochratoxin A		
	RSD <sub>r</sub> %	RSD <sub>R</sub> %	Recovery %
< 1	≤ 40	≤ 60	50 to 120
1 - 10	≤ 20	≤ 30	70 to 110

- The detection limits of the methods used are not stated as the precision values are given at the concentrations of interest
- The precision values are calculated from the Horwitz equation:  $RSD_R = 2^{(1-0.5\log C)}$

WHERE:

- RSD<sub>R</sub> is the relative standard deviation calculated from results generated under reproducibility conditions  $[(s_R / \bar{x}) \times 100]$
- C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)

This is a generalized precision equation, which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

8. The CEN method EN 14132 "Determination of ochratoxin A in barley and roasted coffee – HPLC method with immunoaffinity column clean-up" complies with the criteria set out in the legislation.

**Comment by Colombia:**

**If cereals and cereal products are the main sources of OTA exposure in the European diet, why are the maximum levels established for them the same as those for roasted coffee?**

9. The level established for cereal products for human consumption is not the same as the level proposed for roasted coffee. All products derived from cereals (including processed cereal products and cereal grains intended for direct human consumption) have to comply with the maximum level of 3 µg/kg, including also the cereals and cereal products used as an ingredient in foodstuffs. The maximum level proposed for roasted coffee beans and ground roasted coffee, with the exception of soluble coffee, is 5 µg/kg.

10. The raw cereal grains for which a maximum level of 5 µg/kg is established are not intended for direct consumption or direct use as an ingredient in foodstuffs but have to undergo a cleaning, sorting or other physical treatment to reduce the OTA content before their use as foodstuff or as an ingredient in foodstuffs (to be compared with "green coffee" which has first to undergo a treatment before use as foodstuff).

**Comment by Colombia:**

**If beer is indirectly controlled by means of the maximum OTA limits established for its main input, namely malt, why is soluble coffee controlled by maximum OTA limits when its main input, roasted coffee, is also controlled?**

11. The concentration factor of OTA in soluble coffee is about 2 in comparison with ground roasted coffee. In the absence of a specific maximum level of OTA in soluble coffee, there is the real

risk that control authorities would apply the same maximum level for OTA in soluble coffee as the level established for roasted coffee, which would create trade problems for soluble coffee. As the concentration factor is about two, the establishment of a maximum level of 10 µg/kg for soluble coffee, and the compliance with it, does not require additional efforts from the operator in case the soluble coffee is obtained from ground roasted coffee complying with the maximum level of 5 µg/kg OTA. On the other hand, it does provide a guarantee on the uniform enforcement of a harmonized maximum level across the European Communities.

**Comment by Colombia:**

**Why is there a need to protect public health in relation to soluble coffee and not in relation to beer?**

12. The answer to this question can be found in the answer on question 1 (exposure assessment) combined with the answer given on question 4.

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