Commission Regulation (EC) No 123/2005 of 26 January 2005 amending Regulation (EC) No 466/2001 as regards ochratoxin A (Text with EEA relevance)

COMMISSION REGULATION (EC) No 123/2005

of 26 January 2005

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food[(1)], and in particular Article 2(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 466/2001[(2)], sets maximum levels for certain contaminants in foodstuffs.

(2) According to Regulation (EC) No 466/2001, the Commission shall review the provisions as regards ochratoxin A (OTA) in dried vine fruit and with a view to including a maximum level for OTA in green and roasted coffee and coffee products, wine, beer, grape juice, cocoa and cocoa products and spices taking into account the investigations undertaken and the prevention measures applied to reduce the presence of OTA in these products.

(3) The 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. The Committee mentioned also that further studies are ongoing to elucidate the mechanisms involved in OTA carcinogenicity. It is anticipated that the European research project on the mechanisms of OTA induced carcinogenicity will be finished by the end of 2004. Once the comprehensive research results are available, the European Food Safety Authority (EFSA) will be requested by the Commission to update the scientific opinion from SCF in the light of these new research results.

(4) An assessment of the dietary intake of OTA by the population of the Community has been performed in the framework of Council Directive 1993/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food[(3)] (SCOOP). The main contributor to the OTA exposure is cereal and cereal products. Wine, coffee and beer were identified as significant contributors to the human OTA exposure. Dried vine fruit and grape juice contributed to a significant extent to the OTA-exposure for specific groups of vulnerable groups of consumers such as children.

(5) A maximum level for OTA has been established for cereal and cereal products and dried vine fruit by Regulation (EC) 466/2001. 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 has been established. The setting of a maximum level for OTA in beer is therefore not immediately necessary to protect public health, but should be considered in the frame of the foreseen review.

(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 already at this stage for these foodstuffs maximum levels to protect public health by preventing the distribution of unacceptably highly contaminated foodstuffs.

(7) OTA has also been observed in dried fruit other than dried vine fruit, cocoa and cocoa products, spices and liquorice. The appropriateness of setting a maximum level for OTA in these foodstuffs, including green coffee, as well a review of the existing maximum levels will be considered after the availability of the EFSA assessment of the research results on OTA toxicology.

(8) Regulation (EC) No 466/2001 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 466/2001 is amended as follows:

1. in Article 4(2) point (b), ‘and 2.2.2’ is replaced by ‘, 2.2.2, 2.2.3, 2.2.4 and 2.2.5’.

2. in Article 5, paragraph 2a is replaced by the following:

2a The Commission shall, based on an up-to-date risk assessment on ochratoxin A (OTA) performed by the EFSA and taking into account the prevention measures applied to reduce the OTA content, review the provisions under the heading 2.2 of section 2 of Annex I by 30 June 2006 at the latest. This review will concern in particular the maximum level for OTA in dried vine fruit and grape juice and the consideration of setting a maximum level for OTA in green coffee, dried fruit other than dried vine fruit, beer, cocoa and cocoa products, liqueur wines, meat and meat products, spices and liquorice.

For this purpose, Member States and interested parties shall communicate each year to the Commission the results of the investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by OTA. The Commission will make these results available to the Member States.

3. Annex I 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*.

It shall apply from 1 April 2005.

This Regulation shall not apply to products which were placed on the market before 1 April 2005 in conformity with the provisions applicable. The burden of proving when the products were placed on the market shall be borne by the food business operator.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 January 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission