

**COMMISSION REGULATION (EC) No 455/2004**  
**of 11 March 2004**  
**amending Regulation (EC) No 466/2001 as regards patulin**  
**(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 <sup>(1)</sup>, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 466/2001 <sup>(2)</sup>, sets maximum levels for certain contaminants in foodstuffs. Maximum levels have been established for amongst others patulin.
- (2) A maximum level of 10,0 µg/kg has been established for apple juice and solid apple products, including apple compote and apple puree, for infants and young children and other baby food on the condition that a method of analysis would have been validated by an international collaborative ring trial to be performed before 1 November 2003 in order to demonstrate that the level of 10 µg/kg patulin can be reliably determined. In case there was no evidence by 1 November 2003 that the level of 10 µg/kg could be reliably determined, the level of 25 µg/kg would apply.
- (3) A collaborative trial has been organised to provide the evidence that the level of 10,0 µg/kg can be reliably determined. A report indicating that a method can reliably determine levels of patulin in clear apple juice and fruit puree at 10 µg/kg and lower has been provided on 27 October 2003.
- (4) It is appropriate to adopt transitional arrangements for products manufactured and put on the market before the date of application.
- (5) Regulation (EC) No 466/2001 should therefore be amended accordingly.

- (6) 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 7, the following paragraph is added:  
'The maximum levels established in point 2.3. Patulin of section 2 (Mycotoxins) of Annex I shall not apply to products which have been lawfully placed on the Community market before 1 November 2003. The burden of proving when the products were placed on the market shall be borne by the food business operator.'
2. Footnote 4 of point 2.3 Patulin of section 2 (Mycotoxins) of Annex I is deleted.
3. The second indent of the point 2.3.4. of section 2 (Mycotoxins) of Annex I shall read:  
'— other baby foods other than processed cereal-based foods <sup>(4)</sup>'.
4. Footnote 5 of point 2.3 Patulin of section 2 (Mycotoxins) of Annex I becomes footnote 4 and shall read:  
'<sup>(4)</sup> Baby foods other than processed cereal-based foods as defined in Commission Directive 96/5/EC of 16 February 1996 on processed cereal based foods and baby foods for infants and young children (OJ L 49, 28.2.1996, p. 17) as last amended by Directive 2003/13/EC (OJ L 41, 14.02.2003, p. 33)'.

*Article 2*

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 11 March 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

<sup>(1)</sup> OJ L 37, 13.2.1993, p. 1.

<sup>(2)</sup> OJ L 77, 16.3.2001, p.1. Regulation as last amended by Regulation (EC) No 1425/2003 (OJ L 203, 12.8.2003, p. 1).