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 [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. 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 [4]'.
4. Footnote 5 of point 2.3 Patulin of section 2 (Mycotoxins) of Annex I becomes footnote 4 and shall read:
   '[4] 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

[1] OJ L 37, 13.2.1993, p. 1.
[2] 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).