

## I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 1425/2003**  
**of 11 August 2003**  
**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,

After consulting the Scientific Committee for Food (SCF),

Whereas:

- (1) Commission Regulation (EC) No 466/2001<sup>(2)</sup>, as last amended by Regulation (EC) No 563/2002<sup>(3)</sup>, sets maximum levels for certain contaminants in foodstuffs. Maximum levels have been established for nitrates, aflatoxins, ochratoxin A, lead, cadmium, mercury, 3-MCPD and dioxins.
- (2) Some Member States have adopted, or plan to adopt, maximum levels for patulin in fruit juices in particular apple juice, solid apple products such as apple compote and apple puree and in such products intended for infants and young children. In view of the disparities between Member States and the consequent risk of distortion of competition, Community measures are necessary in order to ensure market unity while abiding by the principle of proportionality.
- (3) Patulin is a mycotoxin produced by fungi belonging to several genera, including *Penicillium*, *Aspergillus*, and *Byssoschlamys* species. Although patulin can occur in many mouldy fruits, grains and other foods, the major sources of patulin contamination are apple products.
- (4) The Scientific Committee for Food endorsed in its meeting on 8 March 2000 the provisional maximum tolerable daily intake (PMTDI) of 0,4 µg/kg body weight (bw) for patulin.

- (5) In 2001, a specific task 'Assessment of the dietary intake of patulin by the population of EU Member States' 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<sup>(4)</sup> (SCOOP) has been performed. It can be concluded from the assessment that the average exposure seems to be quite below the PMTDI of 0,4 µg/kg bw. Nevertheless taking into consideration specific groups of consumers, especially small children, and assuming worst cases, the exposure to patulin is more significant but still below the PMTDI.
- (6) Regulation (EC) No 466/2001 should therefore be amended accordingly.
- (7) 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 5, the following paragraph is added:  
'4. The Commission shall review the maximum levels for patulin laid down in points 2.3.1 and 2.3.2 of section 2 of Annex I by 30 June 2005 at the latest with a view to reducing them to take account of the progress in scientific and technological knowledge and the implementation of the "Code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages".'
2. Annex I shall be amended as set out in the Annex to this Regulation.

*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*.

It shall apply from 1 November 2003.

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

<sup>(2)</sup> OJ L 77, 16.3.2001, p. 1.

<sup>(3)</sup> OJ L 86, 3.4.2002, p. 5.

<sup>(4)</sup> OJ L 52, 4.3.1993, p. 18.

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

Done at Brussels, 11 August 2003.

*For the Commission*  
David BYRNE  
*Member of the Commission*

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## ANNEX

In Section 2 (Mycotoxins) of Annex I, the following point 2.3 is inserted:

Products	Patulin: maximum levels (µg/kg or ppb)	Sampling method	Reference analysis method
<b>2.3. Patulin</b>			
2.3.1. — Fruit juices and fruit nectar, in particular apple juice, and fruit juice ingredients in other beverages <sup>(1)</sup> — Concentrated fruit juice <sup>(1)</sup> after reconstitution as instructed by the manufacturer	50,0	Directive 2003/78/EC	Directive 2003/78/EC
2.3.2. Spirit drinks <sup>(2)</sup> , cider and other fermented drinks derived from apples or containing apple juice	50,0	Directive 2003/78/EC	Directive 2003/78/EC
2.3.3. Solid apple products, including apple compote, apple puree intended for direct consumption	25,0	Directive 2003/78/EC	Directive 2003/78/EC
2.3.4. — Apple juice and solid apple products, including apple compote and apple puree, for infants and young children <sup>(3)</sup> and labelled and sold as intended for infants and young children — other baby food <sup>(5)</sup>	10,0 <sup>(4)</sup>	Directive 2003/78/EC	Directive 2003/78/EC

<sup>(1)</sup> Fruit juices, including fruit juices from concentrates, concentrated fruit juice and fruit nectar as defined in Annex 1 and 2 to Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption (OJ L 10, 12.1.2002, p. 58).

<sup>(2)</sup> Spirit drinks as defined in Article 1 of Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks (OJ L 160, 12.6.1989, p. 1), as last amended by Regulation (EC) No 3378/94 of the European Parliament and of the Council of 22 December 1994 (OJ L 366, 31.12.1994, p. 1).

<sup>(3)</sup> Infants and young children as defined in Article 1 of Commission Directive 91/321/EEC of 14 May 1991, on infant formulae and follow-on formulae (OJ L 175, 4.7.1991, p. 35), as last amended by Directive 2003/14/EC (OJ L 41, 14.2.2003, p. 37) and Article 1 of 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, 14.2.2003, p. 33).

<sup>(4)</sup> A method of analysis will be validated by an international collaborative ring trial which will 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 is no evidence by 1 November 2003 that the level of 10 µg/kg patulin can be reliably determined, the level of 25 µg/kg will apply.

<sup>(5)</sup> Baby food as defined in Article 1 of 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, 14.2.2003, p. 33).