

**COMMISSION REGULATION (EC) No 242/2004**  
**of 12 February 2004**  
**amending Regulation (EC) No 466/2001 as regards inorganic tin in foods**  
**(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>, as last amended by Regulation (EC) No 2174/2003 <sup>(3)</sup>, sets maximum levels for certain contaminants in foodstuffs.
- (2) Commission Directive 91/321/EEC of 14 May 1991 on infant formula and follow-on formula <sup>(4)</sup> as last amended by Directive 2003/14/EC <sup>(5)</sup> provides that infant formulae and follow-on formulae must not contain any substance in such quantity as to endanger the health of infants and young children and that necessary maximum levels for such substances are to be established without delay.
- (3) Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children <sup>(6)</sup>, as last amended by Directive 2003/13/EC <sup>(7)</sup>, provides that processed cereal-based foods and baby foods must not contain any substance in such quantity as to endanger the health of infants and young children and that necessary maximum levels for such substances are to be established without delay.
- (4) Some Member States have adopted maximum levels for inorganic tin in foods. 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 whilst abiding by the principle of proportionality.
- (5) The Scientific Committee on Food concluded in its opinion of 12 December 2001 that levels of inorganic tin of 150 mg/kg in canned beverages and 250 mg/kg in other canned foods may cause gastric irritation in

some individuals. Information is not available to indicate whether or not infants and young children might be at greater risk.

- (6) To protect public health from this acute health risk it is necessary to set maximum levels for inorganic tin in canned foods and canned beverages. Until data becomes available on the sensitivity of infants and young children to inorganic tin in foods, it is necessary on a precautionary basis to protect the health of this vulnerable population group. Lower maximum levels are necessary, which are achievable through the strictly controlled manufacturing and packaging of infant formulae, follow-on formulae, baby foods and processed cereal-based foods for infants and young children.
- (7) Regulation (EC) No 466/2001 should be amended accordingly.
- (8) 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*

Annex I to Regulation (EC) No 466/2001 is amended as set out in the Annex to this Regulation.

*Article 2*

The Commission shall review the maximum levels for inorganic tin as set in points 1 and 2 of the Annex to this Regulation by 1 January 2006 taking into account the progress in scientific and technological knowledge.

*Article 3*

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

<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 326, 13.12.2003, p. 12.

<sup>(4)</sup> OJ L 175, 4.7.1991, p. 35.

<sup>(5)</sup> OJ L 41, 14.2.2003, p. 37.

<sup>(6)</sup> OJ L 49, 28.2.1996, p. 17.

<sup>(7)</sup> OJ L 41, 14.2.2003, p. 33.

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

Done at Brussels, 12 February 2004.

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

ANNEX

In Annex I to Regulation (EC) No 466/2001 the following Section 6 is added:

**'Section 6: Tin (inorganic)**

Product	Maximum level (mg/kg wet weight)	Performance criteria for sampling	Performance criteria for methods of analysis
1. Canned foods other than beverages	200	Commission Directive 2004/16/EC (*)	Directive 2004/16/EC
2. Canned beverages, including fruit juices and vegetable juices	100	Directive 2004/16/EC	Directive 2004/16/EC
3. Canned foods for infants and young children, excluding dried and powdered products:			
3.1. Canned baby foods and processed cereal-based foods for infants and young children <sup>(1)</sup>	50	Directive 2004/16/EC	Directive 2004/16/EC
3.2. Canned infant formulae and follow-on formulae, including infant milk and follow-on milk <sup>(2)</sup>	50	Directive 2004/16/EC	Directive 2004/16/EC
3.3. Canned dietary foods for special medical purposes <sup>(3)</sup> intended specifically for infants	50	Directive 2004/16/EC	Directive 2004/16/EC

(\*) See page 16 of this Official Journal.

<sup>(1)</sup> Baby foods and processed cereal-based foods for infants and young children as defined in Article 1 of Directive 96/5/EC. The maximum level refers to the product as sold.

<sup>(2)</sup> Infant formulae and follow-on formulae as defined in Article 1 of Directive 91/321/EEC. The maximum level refers to the product as sold.

<sup>(3)</sup> Dietary foods for special medical purposes as defined in Article 1(2) of Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29). The maximum level refers to the product as sold.'