

**COMMISSION DIRECTIVE 2004/1/EC**  
**of 6 January 2004**  
**amending Directive 2002/72/EC as regards the suspension of the use of azodicarbonamide as**  
**blowing agent**  
**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs<sup>(1)</sup>, and in particular Article 3 thereof,

Whereas:

- (1) Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs<sup>(2)</sup> authorises the use of azodicarbonamide as a blowing agent in plastic materials and articles intended to come into contact with foodstuffs in accordance with the opinion of the Scientific Committee on Food (SCF).
- (2) Azodicarbonamide is used as blowing agent in the manufacture of plastic gaskets in metal lids used for the closure of glass jars. New findings have shown that azodicarbonamide decomposes into semicarbazide (SEM) when heated during production of the foamed gasket and during sterilisation of the sealed glass jar.
- (3) On 8 July 2003 the European Food Safety Authority (hereinafter called 'the Authority') was informed by industry that SEM had been found in a number of foods contained in glass jars. The levels of SEM in these foods were variable (up to 25 µg/kg), with the highest concentrations found in baby foods.
- (4) Based on the existing scientific data, including recent research commissioned by the Authority, the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (hereinafter called 'the Panel') concluded, in its statement of 1 October 2003, that SEM has a weak carcinogenic activity in laboratory animals and weak genotoxicity *in vitro* but that it was not possible according to the current scientific knowledge to conclude whether SEM poses a carcinogenic risk to humans.
- (5) An ad hoc expert group was specifically commissioned by the Authority to advise further on possible risks to infants, the consumer group for which potential expo-

sure to SEM per body weight is likely to be the highest. In evaluating the possible consequences of SEM in baby foods, the expert group reviewed toxicological aspects alongside microbiological and nutritional considerations.

- (6) On 9 October 2003 they advised that, taking into account the current available information on the levels of SEM in food, intake and toxicology, the risk to both infants and adults eating foods containing SEM was probably very small. However, the Panel stated that the presence of SEM in baby food was undesirable and recommended that it would be prudent to reduce exposure to SEM as swiftly as technological progress safely allows.
- (7) Considering the conclusions of the Panel and the ad hoc expert group and the remaining scientific uncertainties it is appropriate, in order to achieve the high level of health protection chosen in the Community, to suspend the use of azodicarbonamide in accordance with the precautionary principle referred to in Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(3)</sup> (Food law). The suspension of azodicarbonamide from the incomplete list of additives fully harmonised at Community level should apply while the Community seeks more complete information from any source, which could clarify the gaps in the present state of knowledge of SEM.
- (8) The Commission has been informed that alternatives for azodicarbonamide will become available in the near future. With respect to the possible replacement of azodicarbonamide in packaging materials for baby foods, it is critical that careful consideration and evaluation of seal integrity be carried out prior to their introduction in order not to compromise the microbiological safety of the food. It is therefore necessary to provide for a transitional period of 18 months to allow such evaluation to be carried out over a time period, which takes account of the minimum shelf-life for such packaged foods.
- (9) A transitional period should also be provided for in respect of materials and articles which are brought into contact with foodstuffs before the deadline for implementation of this Directive.

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 38. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 220, 15.8.2002, p. 18.

<sup>(3)</sup> OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

- (10) This transitional period should also take into account the requirements of Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs<sup>(1)</sup>.
- (11) Directive 2002/72/EC should therefore be amended accordingly.
- (12) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

*Article 1*

As regards the additive azodicarbonamide with reference number 36640 the text in column 4 of Section A of Annex III to Directive 2002/72/EC is replaced by the following:

'For use only as blowing agent. Use prohibited as from 2 August 2005.'

*Article 2*

1. Member States shall adopt and publish, by 2 August 2005 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

2. Member States shall apply the provisions referred to in paragraph 1 from 2 August 2005 in such a way as to prohibit the placing on the market and importation into the Community of plastic materials and articles intended to come into contact with foodstuffs and which do not comply with this Directive.

However, materials and articles filled before 2 August 2005 may continue to be placed on the market provided that the date of filling appears on the materials and articles. The date of filling may be replaced by another indication, provided that that indication permits the identification of the date of filling. Upon request the date of filling shall be made available to the competent authorities and any person enforcing the requirements of this Directive.

The first and second subparagraphs shall apply without prejudice to the requirements of Directive 2000/13/EC.

When Member States adopt the provisions referred to in paragraph 1, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

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

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 6 January 2004.

*For the Commission*

David BYRNE

*Member of the Commission*

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<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29. Directive as last amended by Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15.)