

Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Text with EEA relevance) (Codified version)

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(Codified version)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses⁽¹⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) Commission Directive 96/5/EC of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children⁽²⁾ has been substantially amended several times⁽³⁾. In the interests of clarity and rationality the said Directive should be codified.
- (2) Processed cereal-based foods and baby foods for infants and young children are used as part of a diversified diet and do not constitute the sole source of nourishment of infants and young children.
- (3) There is a great variety of the products in question reflecting the widely varied diet of infants being weaned and young children owing to social and cultural circumstances existing in the Community.
- (4) The essential composition of the products in question must be appropriate for the nutritional requirements of infants and young children in good health as established by generally accepted scientific data, account being taken of the abovementioned factors.
- (5) The essential nutritional requirements for the composition of the two broad categories of these products, namely processed cereal-based foods and baby foods, should be laid down.
- (6) Although, because of the nature of such products, a number of mandatory requirements and other restrictions as to the level of vitamins, minerals and other nutrients should be imposed, it should be allowed that such nutrients are added voluntarily by manufacturers, provided that they use exclusively certain substances to be specified by this Directive.

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- (7) The use of the products to which such nutrients have been voluntarily added at levels currently observed in the Community do not appear to result in excessive intakes of those nutrients by infants and young children. Attention should be paid to any future developments of the situation, and if necessary, appropriate measures should be taken.
- (8) Different rules on the maximum levels of pesticide residues in processed cereal-based foods and baby foods cause trade barriers between certain Member States.
- (9) Maximum levels for pesticide residues stipulated in Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables⁽⁴⁾, in Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals⁽⁵⁾, in Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin⁽⁶⁾, and in Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables⁽⁷⁾, are without prejudice to specific provisions applicable to processed cereal-based foods and baby foods.
- (10) Taking into account the Community's international obligations, in cases where the relevant scientific evidence is insufficient, the precautionary principle allows the Community to provisionally adopt measures on the basis of available pertinent information, pending an additional assessment of risk and a review of the measure within a reasonable period of time.
- (11) On the basis of the two opinions given by the Scientific Committee for Food on 19 September 1997 and 4 June 1998 there are at present doubts as to the adequacy of existing acceptable daily intake values (ADI) of pesticides and pesticide residues for the protection of the health of infants and young children. Therefore, as far as foodstuffs for particular nutritional uses intended for infants and young children are concerned, it is appropriate to adopt a very low common limit for all pesticides pending case-by-case scientific screening and evaluation of substances. This very low common limit should be fixed at 0,01 mg/kg which normally is in practice the minimum detectable level.
- (12) Severe limitations on pesticide residues should be required. With careful selection of raw materials, and given that processed cereal-based foods and baby foods undergo extensive processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues. However, in the case of a small number of pesticides or metabolites of pesticides even a maximum residue level of 0,01 mg/kg might, under worst-case intake conditions, allow infants and young children to exceed the ADI. This is the case for pesticides or metabolites of pesticides with an ADI lower than 0,0005 mg/kg body weight.
- (13) This Directive establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for processed cereal-based foods and baby foods. However, this prohibition does not necessarily guarantee that products are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned.

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- (14) The health of infants and young children can be better protected by applying additional requirements which can be enforced by analysis regardless of a product's origin.
- (15) Most of the pesticides which have ADI values lower than 0,0005 mg/kg body weight are already prohibited in the Community. The prohibited pesticides should not be detectable in processed cereal-based foods and baby foods by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in processed cereal-based foods and baby foods even if they have not been used. For the purposes of control, a harmonised approach should be followed.
- (16) Pending Commission Decisions on whether they satisfy the safety requirements of Article 5 of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁽⁸⁾, the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in this Directive. The latter should be set at levels ensuring that their respective ADI values are not exceeded by infants and young children under worst-case intake conditions.
- (17) The use of novel food ingredients should be dealt with horizontally for all foodstuffs in a separate measure.
- (18) This Directive reflects current knowledge about the products concerned. Any amendment, to allow for innovation based on scientific and technical progress, should be decided by the procedure referred to in Article 13(2) of Directive 89/398/EEC.
- (19) In view of the persons for whom the products are intended, the necessary microbiological criteria and maximum levels for contaminants should be laid down.
- (20) Pursuant to Article 7(1) of Directive 89/398/EEC, the products covered by this Directive are subject to the general rules laid down by 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⁽⁹⁾.
- (21) In this Directive the additions and exceptions to those general rules should be adopted and expanded upon, where appropriate.
- (22) In particular, the nature and destination of the products covered by this Directive require nutritional labelling showing the energy value and principal nutrients they contain. On the other hand, the method of use should be specified in accordance with point 9 of Article 3(1) and Article 11 of Directive 2000/13/EC, in order to prevent inappropriate uses liable to harm the health of infants.
- (23) Whilst claims not specifically prohibited may generally be made for the products in question in conformity with the rules applicable for all foodstuffs, such claims should, where appropriate, take into account the compositional criteria specified in this Directive.
- (24) On the provisions liable to affect public health, the consultation in accordance with Article 4 of Directive 89/398/EEC has taken place.

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- (25) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.
- (26) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex VIII, Part B,

HAS ADOPTED THIS DIRECTIVE:

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- (1) [OJ L 186, 30.6.1989, p. 27](#). Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council ([OJ L 284, 31.10.2003, p. 1](#)).
- (2) [OJ L 49, 28.2.1996, p. 17](#). Directive as last amended by Directive 2003/13/EC ([OJ L 41, 14.2.2003, p. 33](#)).
- (3) See Annex VIII, Part A.
- (4) [OJ L 340, 9.12.1976, p. 26](#). This Directive is repealed by Regulation (EC) No 396/2005 of the European Parliament and of the Council ([OJ L 70, 16.3.2005, p. 1](#)).
- (5) [OJ L 221, 7.8.1986, p. 37](#). This Directive is repealed by Regulation (EC) No 396/2005.
- (6) [OJ L 221, 7.8.1986, p. 43](#). This Directive is repealed by Regulation (EC) No 396/2005.
- (7) [OJ L 350, 14.12.1990, p. 71](#). This Directive is repealed by Regulation (EC) No 396/2005.
- (8) [OJ L 230, 19.8.1991, p. 1](#). Directive as last amended by Regulation (EC) No 396/2005.
- (9) [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](#)).