

COMMISSION DIRECTIVE 2003/13/EC
of 10 February 2003
amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children
(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses ⁽¹⁾, as last amended by Directive 1999/41/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 4(1) thereof,

Having regard to the opinion of the Scientific Committee on Food,

Whereas:

- (1) Article 6 of Commission 96/5/EC ⁽³⁾, as last amended by Directive 1999/39/EC ⁽⁴⁾, stipulates that processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children.
- (2) On the basis of opinions given by the Scientific Committee on Food on 19 September 1997 and 4 June 1998, Directive 96/5/EC established a general maximum residue level of 0,01 mg/kg for any individual pesticide in processed cereal-based foods and baby foods.
- (3) 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 acceptable daily intake. This is the case for pesticides or metabolites of pesticides with an acceptable daily intake lower than 0,0005 mg/kg body weight.
- (4) Directive 96/5/EC 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. The pesticides in question should be listed in Annex VIII to Directive 96/5/EC. 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.
- (5) 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.

- (6) Most of the pesticides which have acceptable daily intake values lower than 0,0005 mg/kg body weight are already prohibited in the Community or will be prohibited by July 2003. 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 has to be followed.
- (7) 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 ⁽⁵⁾, as last amended by Commission Directive 2003/5/EC ⁽⁶⁾, the continued use of authorised pesticides should be permitted as long as their residues comply with the maximum residue levels established in the present Directive. The latter should be set at levels ensuring that their respective acceptable daily intake values are not exceeded by infants and young children under worst-case intake conditions.
- (8) Directive 96/5/EC should be amended accordingly.
- (9) 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

Directive 96/5/EC is amended as follows:

1. Article 6 is amended as follows:

— Paragraph 1 is replaced by the following:

‘1. Processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children. Necessary maximum levels for substances other than those referred to in paragraphs 2 and 3 shall be established without delay.’

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 172, 8.7.1999, p. 38.

⁽³⁾ OJ L 49, 28.2.1996, p. 17.

⁽⁴⁾ OJ L 124, 18.5.1999, p. 8.

⁽⁵⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁶⁾ OJ L 8, 14.1.2003, p. 7.

— Paragraph 3 is replaced by the following:

'3. (a) Those pesticides listed in Annex VIII shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods. However, for the purpose of control:

- (i) pesticides listed in Table 1 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level which is considered to be the limit of quantification of the analytical methods shall be kept under regular review in the light of technical progress;
- (ii) pesticides listed in Table 2 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

The levels referred to in (i) and (ii) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

- (b) For pesticides listed in Annex VII, where a decision concerning the non-inclusion of an active substance in Annex I to Directive 91/414/EEC is taken, Annex VII and Annex VIII to this Directive shall be amended accordingly.'

2. Annex VII is replaced by Annex I to this Directive.

3. Annex VIII is replaced by Annex II to this Directive.

Article 2

1. The Member States shall authorise trade in products which comply with Article 6(3) of Directive 96/5/EC by 6 March 2004 at the latest.

2. The Member States shall prohibit trade in products which do not comply with Article 6(3) of Directive 96/5/EC by 6 March 2005.

Article 3

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 6 March 2004 at the latest. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, 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.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 10 February 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

ANNEX VII

Specific maximum residue levels of pesticides or metabolites of pesticides in processed cereal-based foods and baby foods

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006'

ANNEX II

'ANNEX VIII

Pesticides which shall not be used in agricultural production intended for the production of processed cereal-based foods and baby foods

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin'