

COMMISSION DIRECTIVE 2003/14/EC
of 10 February 2003
amending Directive 91/321/EEC on infant formulae and follow-on formulae
(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 Directive 91/321/EEC ⁽³⁾, as last amended by Directive 1999/50/EC ⁽⁴⁾, stipulates that infant formulae and follow-on formulae 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 91/321/EEC established a general maximum residue level of 0,01 mg/kg for any individual pesticide in infant formulae and follow-on formulae.
- (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 91/321/EEC establishes the principle of the prohibition of the use of these pesticides in the production of agricultural products intended for infant formulae and follow-on formulae. The pesticides in question should be listed in Annex IX to Directive 91/321/EEC. 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 infant formulae and follow-on formulae by state of the art analytical methods. However, some pesticides degrade slowly and still contaminate the environment. They might be present in infant formulae and follow-on formulae 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 91/321/EEC 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,

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 172, 8.7.1999, p. 38.

⁽³⁾ OJ L 175, 4.7.1991, p. 35.

⁽⁴⁾ OJ L 139, 2.6.1999, p. 29.

⁽⁵⁾ OJ L 230, 19.8.1991, p. 1.

⁽⁶⁾ OJ L 8, 14.1.2003, p. 7.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/321/EEC is amended as follows:

1. Article 6 is amended as follows:

— Paragraph 1 is replaced by the following:

‘1. Infant formulae and follow-on formulae 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.’

— Paragraph 3 is replaced by the following:

‘3. (a) Those pesticides listed in Annex IX shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae. However, for the purpose of control:

(i) pesticides listed in Table 1 of Annex IX 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 IX 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.

(b) By derogation of paragraph 2, for the pesticides listed in Annex X, the maximum residue levels specified therein shall apply.

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

(c) The levels referred to in subparagraphs (a) and (b) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.’

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

3. Annex II to this Directive is added as Annex X.

Article 2

1. The Member States shall authorise trade in products which comply with Article 6(3) of Directive 91/321/EEC 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 91/321/EEC 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 IX

Pesticides which shall not be used in agricultural production intended for the production of infant formulae and follow-on formulae

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
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
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'

ANNEX II

‘ANNEX X

Specific maximum residue levels of pesticides or metabolites of pesticides in infant formulae and follow-on formulae

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’