

COMMISSION DIRECTIVE 1999/50/EC

of 25 May 1999

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 for particular nutritional uses ⁽¹⁾, as amended by Directive 96/84/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 4(1) thereof,

After consulting the Scientific Committee for Food,

- (1) Whereas Article 6 of Commission Directive 91/321/EEC ⁽³⁾, as last amended by Directive 96/4/EC ⁽⁴⁾, provides 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 and that necessary maximum levels for such substances shall be established without delay;
- (2) Whereas different regulations on the maximum levels of pesticide residues in such products cause trade barriers between certain Member States;
- (3) Whereas 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 ⁽⁵⁾, as last amended by Directive 97/41/EC ⁽⁶⁾, 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals ⁽⁷⁾, as last amended by Commission Directive 98/82/EC ⁽⁸⁾, 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin ⁽⁹⁾, as last amended by Directive 98/82/EC, and 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 ⁽¹⁰⁾, as last amended by Directive 98/82/EC, are without prejudice to specific provisions applicable to infant formulae and follow-on formulae;

- (4) Whereas, 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;
- (5) Whereas 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) for the protection of the health of infants and young children; whereas the doubts expressed concern not only pesticides and pesticide residues, but also dangerous chemical substances, and consequently the Commission will examine the possibility of fixing, as soon as possible, maximum levels for heavy metals in foods intended for infants and young children;
- (6) Whereas, therefore, as far as foods 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;
- (7) Whereas this very low common limit should be fixed at 0,01 mg/kg which is in practice the minimum detectable level;
- (8) Whereas severe limitations on pesticide residues should be required; whereas, with careful selection of raw materials, and given that infant formulae and follow-on formulae undergo extensive

⁽¹⁾ OJ L 186, 30.6.1989, p. 27.

⁽²⁾ OJ L 48, 19.2.1997, p. 20.

⁽³⁾ OJ L 175, 4.7.1991, p. 35.

⁽⁴⁾ OJ L 49, 28.2.1996, p. 12.

⁽⁵⁾ OJ L 340, 9.12.1976, p. 26.

⁽⁶⁾ OJ L 184, 12.7.1997, p. 33.

⁽⁷⁾ OJ L 221, 7.8.1986, p. 37.

⁽⁸⁾ OJ L 290, 29.10.1998, p. 25.

⁽⁹⁾ OJ L 221, 7.8.1986, p. 43.

⁽¹⁰⁾ OJ L 350, 14.12.1990, p. 71.

processing during their manufacture, it is feasible to produce products containing very low levels of pesticide residues;

- (9) Whereas, however, for a small number of pesticides even such low levels might allow the possibility that under worst-case intake conditions the ADI of these pesticides is exceeded; whereas, therefore, infant formulae and follow-on formulae should be free of those particular pesticides and should be produced without the use of such pesticides;
- (10) Whereas this Directive reflects current knowledge about these substances; whereas any amendment, based on scientific or technical progress, will be decided by the procedure laid down in Article 13 of Directive 89/398/EEC;
- (11) Whereas Directive 91/321/EEC should be amended accordingly;
- (12) Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

ready for consumption or as reconstituted according to the instructions of the manufacturer.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

3. Those pesticides listed in Annex IX shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

4. Microbiological criteria shall be established as necessary.;

3. the following is added as Annex IX:

ANNEX IX

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

Chemical name of the substance

...'

HAS ADOPTED THIS DIRECTIVE:

Article 2

Article 1

Directive 91/321/EEC is hereby amended as follows:

1. the following point (e) is added to Article 1(2):

(e) "pesticide residue" means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Council Directive 91/414/EEC (*), including its metabolites and products resulting from its degradation or reaction;

(*) OJ L 230, 19.8.1991, p. 1.;

2. Article 6 is replaced by the following:

Article 6

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 shall be established without delay.

2. Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg of the product as proposed

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 June 2000. They shall forthwith inform the Commission thereof.

Those laws, regulations and administrative provisions shall be applied in such a way as to:

- (a) permit trade in products conforming to this Directive no later than 30 June 2000,
- (b) prohibit trade in products which do not comply with this Directive, with effect from 1 July 2002.

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 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 May 1999.

For the Commission
Martin BANGEMANN
Member of the Commission
