COMMISSION DIRECTIVE 96/4/EC

of 16 February 1996

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], and in particular Article 4 thereof,

Whereas given the nature of infant formulae and follow-on formulae the detailed rules as to nutrient declaration on the labelling need to be clarified in order to avoid any problems which may arise from the application of other relevant Community legislation;

Whereas new scientific data justify certain modifications to the mandatory essential composition of infant formulae and follow-on formulae specified in Annexes I and II to Commission Directive 91/321/EEC [2], as amended by the Act of Accession of Austria, Finland and Sweden;

Whereas nucleotides, being the natural constituents of human milk, have been used to supplement infant formulae and follow-on formulae for many years in Member States and third countries without any negative effects; whereas therefore there is no justification for prohibiting their use in the manufacture of these products;

Whereas technological progress has resulted in the production of infant formulae, based on protein partial hydrolysates, which due to their low levels of immunoreactive proteins may be useful; whereas for this reason a claim as to these particular characteristics should be permitted; whereas these products are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions, which are not covered by this Directive;

Whereas Directive 91/321/EEC should be amended accordingly;

Whereas the Scientific Committee for Food, in accordance with Article 4 of Directive 89/398/EEC, has been consulted on the provisions liable to affect public health;

Whereas the measures provided in this Directive are in accordance with the opinion of the Standing Committee on Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 91/321/EEC is amended as follows:

1. Article 6 is replaced by the following:

   'Article 6

   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.

   Microbiological criteria shall also be established as necessary.'

2. Article 7 is amended as follows:

   (a) Points (d) and (e) of paragraph 2 are replaced by the following:

   '(d) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

   (e) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;'

   (b) The following is inserted as paragraph 2a:

   '2a. The labelling may bear:

   (a) the average quantity of nutrients mentioned in Annex III when such declaration is not covered by the provisions of paragraph 2 (e) of this Article, expressed in numerical form, per 100 ml of the product ready for use;

[1] OJ No L 186, 30. 6. 1989, p. 27.
[2] OJ No L 175, 4. 7. 1991, p. 35.

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in Annex VIII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values;'

3. The Annexes are amended as shown in the Annex hereto.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 March 1997. They shall forthwith inform the Commission thereof. Those laws, regulations and administrative provisions shall be applied in such a way as to:

— permit trade in products conforming to this Directive no later than 1 April 1997,

— prohibit trade in products which do not comply with this Directive, with effect from 31 March 1999.

When Member States adopt these provisions, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.

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, 16 February 1996.

For the Commission

Martin BANGEMANN

Member of the Commission