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

ANNEX

The Annexes to Directive 91/321/EEC are amended as follows:

1. Annex I is amended as follows:

(a) The introductory wording of Section 2 and Sections 2.1 and 2.2 are replaced by the following:

'2. **Protein**

(Protein content = nitrogen content × 6,38) for cows' milk proteins.

(Protein content = nitrogen content × 6,25) for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.1. *Formulae manufactured from cows' milk proteins*

Minimum	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

2.2. *Formulae manufactured from protein partial hydrolysates*

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilization (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 µmoles/100 kJ (42 µmoles/100 kcal) and the L-carnitine content shall be equal to at least 1,8 µmoles/100 kJ (7,5 µmoles/100 kcal).'

(b) The minimum content for lipids in Section 3 is modified as follows:

'Minimum
1,05 g/100 kJ
(4,4 g/100 kcal)'

(c) The third indent of Section 3.1 is deleted.

(d) The following shall be added to Section 3.

'3.5. The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

3.6. The trans fatty acid content shall not exceed 4 % of the total fat content.

3.7. The erucic acid content shall not exceed 1 % of the total fat content.

3.8. Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

1 % of the total fat content for n-3 LCP and

2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid)

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.'

(e) The following shall be added in Section 5.1:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
'Selenium (2) (μg)	—	0,7	—	3

(2) Limit applicable to formulae with added selenium.'

(f) In Section 6 of Annex I, the reference to nicotinamide is replaced by the following:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
'Niacin (mg-NE)	0,2	—	0,8	—'

2. Annex II is amended as follows:

(a) In Section 2, first paragraph following the numerical values, add the words: '... or breast milk ...' after the word 'casein',

and at the end of Section 2, add the following paragraph:

'For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Annex V.'

(b) The third indent of Section 3.1 is deleted.

(c) The following shall be inserted in Section 3:

'3.5. The trans fatty acid content shall not exceed 4 % of the total fat content.

3.6. The erucic acid content shall not exceed 1 % of the total fat content.'

3. The following is added as Section 7 to both Annex I and Annex II:

'7. The following nucleotides may be added:

	Maximum (1)	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0,60	2,50
uridine 5'-monophosphate	0,42	1,75
adenosine 5'-monophosphate	0,36	1,50
guanosine 5'-monophosphate	0,12	0,50
inosine 5'-monophosphate	0,24	1,00

(1) The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).'

4. Annex III is amended as follows:

(a) The following shall be added to Section 2:

Mineral substances	Permitted salts
'selenium	sodium selenate sodium selenite'

(b) The following substances shall be added to Section 3:

'cytidine 5'-monophosphate and its sodium salt
uridine 5'-monophosphate and its sodium salt
adenosine 5'-monophosphate and its sodium salt
guanosine 5'-monophosphate and its sodium salt
inosine 5'-monophosphate and its sodium salt'.

5. The following shall be added to Annex IV:

Claims related to	Conditions warranting the claim
'7. Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen of reduced antigen properties.	(a) The formulae shall satisfy the provisions laid down in Secion 2.2 of Annex I and the amount of immunoreactive protein measured with methods generally acceptable as approrpiate shall be less than 1 % of nitrogen containing substances in the formulae; (b) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is made; (c) The formulae administered orally should not induce sensitization, in animals, to the intact proteins from which the formulae are derived; (d) Objective and scientifically verified data as proof to the claimed properties must be available.'

6. The following is added as Annex VIII:

'ANNEX VIII

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient	Labelling reference value
Vitamin A	(µg) 400
Vitamin D	(µg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,8
Niacin equivalents	(mg) 9
Vitamin B6	(mg) 0,7
Folate	(µg) 100
Vitamin B12	(µg) 0,7
Calcium	(mg) 400
Iron	(mg) 6
Zinc	(mg) 4
Iodine	(µg) 70
Selenium	(µg) 10
Copper	(mg) 0,4'