EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON FORMULAE) REGULATIONS 1998

ARRANGEMENT OF SECTIONS

S.I. No. 243 of 1998.

I, BRIAN COWEN, Minister for Health and Children in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972 (No. 27 of 1972) having regard to Council Directive 89/398/EEC1 of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses as amended by Directive 96/84/EC2 of the European Parliament and of the Council of 19 December 1996 and for the purposes of giving effect to Commission Directive 91/321/EEC3 of the 14th of May, 1991 and Council Directive 92/52/EEC4 of the 18th June, 1992 and Commission Directive 96/4/EC5 of the 16th February 1996, hereby make the following Regulations:—

(1)OJ No. L186 30.6.1989, p. 27.
(2)OJ No. L48 19.2.1997, p. 20.
(3)OJ No. L175 4.7.1991, p. 35.
(4)OJ No. L179 1.7.1992, p. 129.
(5)OJ No. L49/12 28.2.1996, p. 12.

REG 1

Title, Commencement and Interpretation
1. These Regulations may be cited as the European Communities (Infant Formulae and Follow-on Formulae) Regulations, 1998.

REG 2

2. (1) These Regulations shall come into operation on the 17th day of July, 1998.
(2) Trade in products which do not comply with these Regulations is prohibited with effect from 31 March 1999.

REG 3

3. (1) In these Regulations:
"advertising" means the making of any pronouncement in the course of a trade, business or profession for the purpose of promoting the supply of goods or services;
"authorised officer" means:
(a) an officer of the Minister for Health and Children who is authorised in writing by the Minister for Health and Children to be an authorised officer for the purposes of these Regulations; or
(b) an officer of a health board who is authorised in writing by the Chief Executive Officer of the health board to be an authorised officer for the purposes of these Regulations.
"export" means to market a product in a country outside the European Union;
"follow-on formulae" means foodstuffs intended for particular nutritional use by infants in good health aged over four months and constituting the principal liquid element in a progressively diversified diet of this category of persons;
"health board" means a health board established under Section 4(1) of the Health Act, 1970 (No. 1 of 1970);
"health care system" means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child-care institutions and health workers in private practice;
"infant formulae" means foodstuffs intended for particular nutritional use by infants in good health during the first four to six months of life and satisfying by themselves the nutritional requirements of this category of persons;
"infant milk" and "follow-on milk" means products within the meaning of these Regulations manufactured entirely from cows' milk proteins;
"infants" means children under the age of twelve months;
"labelling" means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a product and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such product;
"to market" includes to supply, whether or not for profit, offer, expose for sale and/or have in possession for sale and cognate words shall be construed accordingly;

"Minister" means the Minister for Health and Children;
"presentation" in relation to an infant formula or a follow-on formula, includes the shape, form, aspect, appearance or packaging of the product concerned, the packaging materials used, the way in which the product is arranged when it is exposed for sale and/or the setting in which the product is displayed with a view to sale, but does not include any form of labelling or advertising;
"product" means infant formulae and/or follow-on formulae as appropriate;
"young children" means children aged between one and three years.
(2) In these Regulations any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations or, as the case may be, to a Schedule thereto and any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article unless otherwise stated.
(3) A word or expression that is used in these Regulations and is also used in Council Directive 89/398/EEC, Directive 96/84/EC of the European Parliament and of the Council, Commission Directive 91/321/EEC, Council Directive 92/52/EEC and Commission Directive 96/4/EC has, unless the contrary intention appears, the meaning in these Regulations that it has in the Council, Commission and Parliament Directives.

REG 4

Conditions for the Marketing of Infant Formula and Follow-on Formula
4. (1) The name under which the products defined in Article 3(1) are marketed shall be, respectively, 'infant formula' and 'follow-on formula' and in the case of products manufactured entirely from cows' milk proteins, 'infant milk' and 'follow-on milk'.
(2) No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.
(3) No foodstuff other than infant formula may be marketed as suitable for infants aged under four months.
(4) It shall be an offence to market the products defined in Article 3(1) which do not comply with these Regulations.

REG 5

Composition of Infant Formula and Follow-on Formula
5. (1) Infant formulae shall be manufactured from protein sources defined in the Schedules to these Regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has, in the opinion of the Minister, been established by generally accepted scientific data.
(2) Follow-on formulae shall be manufactured from protein sources defined in the Schedules to these Regulations and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over four months has, in the opinion of the Minister, been established by generally accepted

scientific data.
(3) The use of food ingredients is subject to the prohibitions and limitations specified in Schedules I and II to these Regulations.
(4) The Minister may, when forming an opinion in accordance with sub-articles (1) and (2) of this Article, have regard to the views of such persons or authorities as he considers appropriate.

REG 6

6. (1) Infant formulae shall comply with the compositional criteria specified in Schedule I.
(2) Follow-on formulae shall comply with the compositional criteria specified in Schedule II.
(3) For the purpose of making infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.
(4) No substance other than a substance specified in Schedule III may be used in the manufacture of infant formulae and follow-on formulae for the purposes of satisfying the requirements on:
— mineral substances,
— vitamins,
— amino acids and other nitrogen compounds,
— other substances having a particular nutritional purpose.
(5) Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

REG 7

7. (1) The Minister may, by order, stipulate the maximum levels of any substance included in infant formulae or follow-on formulae.
(2) The Minister may by order establish such microbiological criteria as he considers appropriate.

REG 8

Labelling, Advertising and Presentation of Infant Formula and Follow-on Formula
8. (1) The labelling of infant formulae shall bear the following particulars in addition to general EU and national labelling requirements:
(a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed;
(b) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources;
(c) the available energy value, expressed in kJ and kcal expressed in numerical form, per 100 ml of the product ready for use;
(d) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(e) the average quantity of each mineral substance and of each vitamin mentioned in Schedule I, expressed in numerical form, per 100 ml of the product ready for use;
(f) where applicable, the average quantity of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;
(g) instructions for appropriate preparation of the product;
(h) a warning against the health hazards of inappropriate preparation.
(2) The labelling of infant formulae may bear the average quantity of nutrients mentioned in Schedule III when such declaration is not covered by the provisions of paragraphs (e) and (f) of sub-article (1) of this Article, expressed in numerical form, per 100 ml of the product ready for use.
(3) Without prejudice to sub-article (1) the labelling of infant formulae shall also fulfil the following requirements:
(a) it shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding;
(b) the use of the terms "humanised", "maternalised" or similar terms shall be prohibited;
(c) the term "adapted" may only be used in conformity with sub-article (4) paragraph (b) of this Article and Schedule IV, point 1;
(d) the label shall include the following particulars, preceded by the words "Important Notice" or their equivalent:
(i) a statement concerning the superiority of breast-feeding,
(ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, midwives, public health nurses, general practitioners or other professionals responsible for maternal and child care;
(e) the label shall not include:
(i) pictures of infants,
(ii) other pictures or text which may idealise the use of the product.
(4) The labelling of infant formulae may:
(a) have graphic representations for easy identification of the product and for illustrating methods of preparation;
(b) bear claims concerning the special composition of an infant formula only in the cases listed in Schedule IV and in accordance with the conditions laid down therein.
(5) The requirements, prohibitions and restrictions referred to in sub-articles (3) and (4) shall also apply in respect of the products concerned in relation to:
(i) advertising
(ii) presentation.

REG 9

9. (1) The labelling of follow-on formulae shall bear the following particulars in addition to general EU and national labelling requirements:
(a) a statement which specifies the minimum age of the infant for whom the product is suitable and such minimum age so specified shall be not less than four months;
(b) that it should form only part of a diversified diet;
(c) that it is not to be used as a substitute for breast milk during the first four months of life;
(d) the available energy value, expressed in kJ and kcal, expressed in numerical form, per 100 ml of the product ready for use;
(e) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;
(f) the average quantity of each mineral substance and of each vitamin mentioned in Schedule II, expressed in numerical form, per 100 ml of the product ready for use;
(g) where applicable, the average quantity of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use;
(h) instructions for appropriate preparation of the product;
(i) a warning against the health hazards of inappropriate preparation.
(j) in addition to numerical information, information on vitamins and minerals included in Schedule 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.
(2) The labelling of follow-on formulae may bear the average quantity of nutrients mentioned in Schedule III when such declaration is not covered by the provisions of Paragraphs (f) and (g) of sub-article (1) of this Article, expressed in numerical form, per 100 ml of the product ready for use.
(3) Without prejudice to sub-article (1) the labelling of follow-on formulae shall also fulfil the following requirements:
(a) it shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding;
(b) the use of the terms "humanised", "maternalised" or similar terms shall be prohibited;
(c) the packaging at the point of sale shall, to the satisfaction of the Minister, ensure a clear distinction is made between infant formulae and follow-on formulae.
(4) The requirements, prohibitions and restrictions referred to in sub-article (3) shall also apply in respect of the products concerned in relation to:
(i) advertising.
(ii) presentation.

REG 10

10. (1) Advertising of infant formulae shall be subject to the conditions laid down in Article 8(3) and 8(4).
(2) Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications.
(3) The Minister may from time to time by order restrict or prohibit such forms of advertising or promotion, either directly or indirectly, of infant formulae as he considers necessary.
(4) Advertisements for infant formulae shall contain only information which is, in the opinion of the Minister, of a scientific and factual nature; such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.
(5) (a) There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formulae directly to the consumer at the retail level;
(b) Without prejudice to the generality of paragraph (a) of this sub-article the following are prohibited: special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.
(6) The provision of free or low-priced products, samples or any other promotional gifts to the general public, including, inter alia, pregnant women, mothers or members of their families, either directly or indirectly, via the health care system or health workers by manufacturers and distributors of infant formulae or their associates, is prohibited.

REG 11

Provison of Information and Education Regarding Infant and Young Child Feeding
11. (1) Information provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition shall be objective and consistent in its planning, provision, design and dissemination.
(2) Informational and educational materials including, inter alia, written and audiovisual materials, in relation to the feeding of infants and intended to reach pregnant women and mothers of infant and young children, shall include clear information on all of the following:
(a) the benefits and superiority of breast-feeding;
(b) the importance of maternal nutrition and the preparation for and maintenance of breast-feeding;
(c) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
(d) the difficulty of reversing the decision not to breast-feed;
(e) where needed, the proper use of infant formulae, whether manufactured industrially or home-prepared.
(3) Any material referred to in sub-article (1) shall not use any pictures which may idealise the use of infant formulae. Any such material containing information about the use of infant formulae shall include:
(a) the social and financial implications of its use;

(b) the health hazards of inappropriate foods or feeding methods;
(c) the health hazards of improper use of infant formulae.

REG 12

Donations of Low-Price Sales of Supplies of Infant Formula and Informational and Educational Equipment to Institutions
12. (1) Donations or low-price sales of supplies of infant formulae to institutions or organizations, whether for use in the institutions or for distribution outside them, shall ensure that those products may only be used by, or distributed for, infants who have to be fed on infant formulae and only for as long as required by such infants and may be made only in accordance with guidelines, if any, approved by the Minister.
(2) (a) Donations of informational or educational equipment or materials by manufacturers or distributors or by persons or indiviudals associated with manufacturers or distributors shall be made only on request of the intended recipient and within guidelines, if any, approved by the Minister.
(b) Such equipment or materials:
(i) may bear the donating company's name or logo;
(ii) shall not refer to a proprietary brand of infant formulae;
(iii) shall be distributed only through the health care system.

REG 13

Codes of Practice
13. (1) The Minister may by order approve of such codes of practice, including guidelines at Article 12 (1) and (2) which he may consider will assist industry and other affected organisations to comply with the provisions of these Regulations and codes so ordered shall form part of these Regulations.
(2) The Minister may withdraw any approval referred to in sub-article (1) as he sees fit.

REG 14

Export of Infant Formula and Follow-on Formula
14. (1) Infant formulae and follow-on formulae intended for export shall comply with:
(a) (i) the requirements of Articles 5, 6 and 7 of these Regulations or
(ii) a relevant applicable world standard established by Codex Alimentarius;
(b) the provisions of Articles 8(1) to 8(4) and 9(1) to 9(3) of these Regulations;
(c) the provisions of Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which the product belongs;
unless otherwise requested or stipulated by provisions established by the importing country.
(2) The labelling of infant formulae and follow-on formulae intended

for export shall be in an appropriate language and ensure that a clear distinction is made between infant formulae and follow-on formulae.
(3) The stipulations, prohibitions and restrictions laid down in Articles 8(1) to 8(4) and 9(1) to 9(3) of these Regulations shall also apply to the presentation of the products concerned intended for export and in particular their form, aspect or packaging and the packaging materials used.
(4) No product other than infant formula may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

REG 15

Enforcement
15. These Regulations shall be enforced and executed by each health board in respect of its functional area through its authorised officers and/or the officers of the Minister for Health and Children who are authorised officers for the purposes of these Regulations.

REG 16

16. For the purposes of ensuring compliance with these Regulations, the provisions of the European Communities (Official Control of Food) Regulations, 1998 (S.I. No. 85 of 1998) shall apply.

REG 17

Offences
17. (1) A person shall not manufacture, prepare, import, export, distribute, market, advertise and/or label any product or promotional material which does not comply with these Regulations.
(2) Any person who contravenes any article or sub-article of these Regulations shall be guilty of an offence.
(3) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000 or at the discretion of the Court, to imprisonment for a term not exceeding six months or to both.
(4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of or to be attributable to any neglect on the part of a director, secretary or other officer of the body corporate, the director, secretary or other officer or any person purporting to act in such capacity shall, as well as the body corporate, be guilty of an offence and shall be liable to be proceeded against and punished accordingly.
(5) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted within twelve months from the date of the offence or any time within twelve months from the date on which knowledge of the commission of the offence came to the attention of an authorised officer.

REG 18

18. (1) An offence under these Regulations shall be prosecuted by the Minister for Health and Children or, subject to the provisions of sub-article (2), by a health board in whose functional area the offence was committed.
(2) Legal proceedings arising from contraventions of any or all of Articles 8, 9, 10, 11 and 12 shall be initiated by the health board only with the consent of the Minister for Health and Children.

REG 19

19. (1) An authorised officer shall be furnished with a certificate of his appointment as an authorised officer and when exercising any power conferred on an authorised officer by these Regulations shall, if so requested by a person affected, produce the certificate for the inspection of the person.
(2) It shall be an offence for a person falsely to represent himself to be an authorised officer.

REG 20

20. A health board shall—
(a) forward to the Minister such information as he may request in respect of the exercise of the functions conferred on it by or under these Regulations;
(b) comply with any directions given by the Minister from time to time as to the exercise of its powers or the performance of its functions and duties under these Regulations.

REG 21

Revocation
21. (1) The European Communities (Infant Formulae) Regulations, 1994 (S.I. No. 459 of 1994) are hereby revoked.
(2) References in another instrument to any of the Regulations revoked under sub-article (1) shall be construed as references to these Regulations, as appropriate.

SCHEDULE I

ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER
NB: the values refer to the product ready for use
1. ENERGY

MinimumMaximum250 kJ315 kJ(60 kcal/100 ml)(75 kcal/100 ml)
2. PROTEIN
(protein content = nitrogen content x 6.38) for cows' milk proteins.
protein content = nitrogen content x 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

MinimumMaximum0.45 g/100 kJ0.7 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 Schedule V); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.
2.2. Formulae manufactured from protein partial hydrolysates

MinimumMaximum0.56 g/100 kJ0.7 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 Schedule 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).
2.3. Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

MinimumMaximum0.56 g/100 kJ0.7 g/100 kJ(2.56 g/100 kcal)(3 g/100 kcal)
Only soya protein isolates must be used in manufacturing these formulae.
The Chemical Index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule VI).
For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Schedule V).
The L-carnitine content shall be at least equal to 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal).
2.4. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.
3. LIPIDS

MinimumMaximum1.05 g/100 kJ1.5 g/100 kJ(4.4 g/100 kcal)(6.5 g/100 kcal)
3.1. The use of the following substances is prohibited:
— sesame seed oil,
— cotton seed oil.
3.2. Lauric Acid

MinimumMaximum—15% of the total fat content
3.3. Myristic Acid

MinimumMaximum—15% of the total fat content
3.4. Linoleic Acid (in the form of glycerides = linoleates)

MinimumMaximum70 mg/100 kJ285 mg/100 kJ(300 mg/100 kcal)(1 200 mg/100 kcal)
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.
4. CARBOHYDRATES

MinimumMaximum1.7 g/100 kJ3.4 g/100 kJ(7 g/100 kcal)(14 g/100 kcal)
4.1. Only the following carbohydrates may be used:
— lactose,
— maltose,
— sucrose,
— malto-dextrins,
— glucose syrup or dried glucose syrup,
— pre-cooked starch naturally free of gluten.
— gelatinized starch naturally free of gluten.
4.2. Lactose

MinimumMaximum0.85 g/100 kJ—(3.5 g/100 kcal)—
This provision does not apply to formulae in which soya proteins represent more than 50% of the total protein content.
4.3. Sucrose

MinimumMaximum—20% of the total carbohydrate content
4.4. Pre-cooked starch and/or gelatinized starch

MinimumMaximum—2 g/100 ml, and 30% of the total carbohydrate content
5. MINERAL SUBSTANCES
5.1. Formulae manufactured from cows' milk proteins

per 100 kJper 100 kcalMinimumMaximumMinimumMaximumsodium

(mg)5142060potassium (mg)153560145chloride (mg)122950125calcium (mg)12—50—phosphorus (mg)6222590magnesium (mg)1.23.6515iron (mg)10.120.360.51.5zinc (mg)0.120.360.51.5copper (µg)4.8192080iodine (µg)1.2—5—selenium (ag)2—0.7—3

1 limit applicable to formulae with added iron.

2 limit applicable to formulae with added selenium.

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

5.2. Formulae manufactured from soya proteins alone or in a mixture with cows' milk proteins

All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are as follows:

per 100 kJper 100 kcalMinimumMaximumMinimumMaximumiron (mg)0.250.512zinc (mg)0.180.60.752.4

6. VITAMINS

per 100 kJper 100 kcalMinimumMaximumMinimumMaximumVitamin A (µg-RE)1144360180Vitamin D (µg)20.250.6512.5Thiamin (µg)10—40—Riboflavin(µg)14—60—Niacin (mg-NE)3)0.2—0.8—Pantothenic acid (µg)70—300—Vitamin B6(µg)9—35—Biotin (µg)0.4—1.5—Folic acid (µg)1—4—Vitamin B12(µg)0.025—0.1—Vitamin C (µg)1.9—8—Vitamin K (µg)1—4—Vitamin E (mg a-TE)4(4)0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ—0.5/g of poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal—

(1) RE = all trans retinol equivalent.

(2) In the form of cholecalciferol, of which 10µg = 400 i.u. of vitamin D.

(3) NE = Niacin equivalent = mg nicotinic acid + mg tryptophan/60.

(4) a-TF = d-a-tocopherol equivalent

7. THE FOLLOWING NUCLEOTIDES MAY BE ADDED:

Maximum1(mg/100 kJ)(mg/100 kcal)cytidine 5"-monophosphate0.602.50uridine 5"-monophosphate0.421.75adenosine 5"-monophosphate0.361.50guanosine 5"-monophosphate0.120.50inosine 5"-monophosphate0.241.00

(1) The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

SCHEDULE II

ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

NB: the values refer to the product ready for use

1. ENERGY

MinimumMaximum250 kJ/100 ml335 kJ/100 ml(60 kcal/100 ml)(80 kcal/100 ml)

2. PROTEINS

(protein content = nitrogen content x 6.38) for cows' milk proteins.

(protein content = nitrogen content x 6.25) for soya protein isolates.

MinimumMaximum0.5 g/100 kJ1 g/100 kJ(2.25 g/100 kcal)(4.5 g/100 kcal)
The Chemical Index of the proteins present shall be at least equal to 80% of that of the reference protein (casein or breast milk as defined in Schedule VI).
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.
For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only proteins isolates from soya may be used.
Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.
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 Schedule V.
3. LIPIDS

MinimumMaximum0.8 g/100 kJ1.5 g/100 kJ(3.3 g/100 kcal)(6.5 g/100 kcal)
3.1. The use of the following substances is prohibited:
—sesame seed oil,
—cotton seed oil.
3.2 Lauric Acid

MinimumMaximum—15% of the total fat content
3.3 Myristic Acid

MinimumMaximum—15% of the total fat content
3.4 Linoleic Acid (in the form of glycerides = linoleates)

MinimumMaximum70 mg/100 kJ—(300 mg/100 kcal)this limit applies only to follow-on formulae containing vegetables oils
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.
4. CARBOHYDRATES

MinimumMaximum1.7 g/100 kJ3.4 g/100 kJ(7 g/100 kcal)(14 g/100 kcal)
4.1. Gluten
The use of ingredients containing gluten is prohibited.
4.2 Lactose

MinimumMaximum0.45 g/100 kJ—(1.8 g/100 kcal)—
This provision does not apply to follow-on formulae in which soya protein isolates represent more than 50% of the total protein content.
4.3. Sucrose, fructose, honey

MinimumMaximum—separately or as a whole:20% of the total carbohydrate content
5. MINERAL SUBSTANCES
5.1.

per 100 kJper 100 kcalMinimumMaximumMinimumMaximumiron

(mg)0.250.512iodine (µg)1.2—5—
5.2. Zinc
5.2.1 Follow-on formulae manufactured entirely from cows' milk

MinimumMaximum0.12 mg/100 kJ—(0.5 mg/100 kcal)—
5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk

MinimumMaximum0.18 mg/100 kJ—(0.75 mg/100 kcal)—
5.3. Other Mineral Substances
The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Schedule VII.
5.4. Calcium/Phosphorus Ratio
The calcium/phosphorus ratio shall not exceed 2.0.
6. VITAMINS

per 100 kJper 100 kcalMinimumMaximumMinimumMaximumvitamin A (µg-RE)(1)144360180vitamin D (µg)(2)0.250.7513vitamin C (µg)1.9—8—vitamin E (mg a-TE)(3)0.5/g poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ—0.5/g poly-unsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal—
(1)RE = all trans retinol equivalent.
(2)In the form of cholecalciferol, of which 10 µg=100 i.u. of vitamin D.
(3)a-TE = d-a-tocopherol equivalent.
7. THE FOLLOWING NUCLEOTIDES MAY BE ADDED:

Maximum(1)(mg/100 kJ)(mg/100 kcal)cytidine 5'-monophosphate0.602.50uridine 5'-monophosphate0.421.75adenosine 5'-monophosphate0.361.50guanosine 5'-monophosphate0.120.50inosine 5'-monophosphate0.241.00
(1)The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/kcal).

SCHEDULE III

NUTRITIONAL SUBSTANCES
1. VITAMINS

VitaminVitamin FormulationVitamin ARetinyl acetateRetinyl palmitateBeta-caroteneRetinolVitamin DVitamin D2(ergocaliferol)Vitamin D3(cholecalciferol)Vitamin B1Thiamin hydrochlorideThiamin mononitrateVitamin B2RiboflavinRiboflavin-5"-phosphate, sodiumNiacinNicotinamideNicotinic acidVitamin B6Pyridoxine hydrochloridePyridoxine-5"-phosphateFolateFolic acidPantothenic acidD-pantothenate, calciumD-panthothenate, sodiumDexpanthenolVitamin B12CyanocobalaminHydroxocobalaminBiotinD-biotin
VitaminVitamin FormulationVitamin CL-ascorbic acidSodium L-ascorbateCalcium L-ascorbate6-palmityl-L-ascorbic acid (ascorbyl palmitate)Potassium ascorbateVitamin ED-alpha tocopherolDL-alpha tocopherolD-alpha tocopherol acetateDL-alpha tocopherol acetateVitamin

KPhylloquinone (Phytomenadione)
MINERAL SUBSTANCES

Mineral SubstancesPermitted SaltsCalcium (Ca)Calcium carbonateCalcium chlorideCalcium salts of citric acidCalcium gluconateCalcium glycerophosphateCalcium lactateCalcium salts of orthophosphoric acidCalcium hydroxideMagnesium (Mg)Magnesium carbonateMagnesium chlorideMagnesium oxideMagnesium salts of orthophosphoric acidMagnesium sulphateMagnesium gluconateMagnesium hydroxideMagnesium salts of citric acidIron (Fe)Ferrous citrateFerrous gluconateFerrous lactateFerrous sulphateFerric ammonium citrateFerrous fumarateFerric diphosphate (Ferric pyrophosphate)Copper (Cu)Cupric citrateCupric gluconateCupric sulphateCopper-lysine complexCupric carbonateIodine (I)Potassium iodideSodium iodidePotassium iodate
Mineral SubstancesPermitted SaltsZinc (Zn)Zinc acetateZinc chlorideZinc lactateZinc sulphateZinc citrateZinc gluconateZinc oxideManganese (Mn)Manganese carbonateManganese chlorideManganese citrateManganese sulphateManganese gluconateSodium (Na)Sodium bicarbonateSodium chlorideSodium citrateSodium gluconateSodium carbonateSodium lactateSodium salts of orthophosphoric acidSodium hydroxidePotassium (K)Potassium bicarbonatePotassium carbonatePotassium chloridePotassium salts of citric acidPotassium gluconatePotassium lactatePotassium salts of orthophosphoric acidPotassium hydroxideSeleniumSodium selenateSodium selenate
3. AMINO ACIDS AND OTHER NITROGEN COMPOUNDS
L-arginine and its hydrochloride
L-cystine and its hydrochloride
L-histidine and its hydrochloride
L-isoleucine and its hydrochloride
L-leucine and its hydrochloride
L-lysine and its hydrochloride
L-cysteine and its hydrochloride
L-methionine
L-phenylalanine
L-threonine
L-tryptophan
L-tyrosine
L-valine
L-carnitine and its hydrochloride
Taurine
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
4. OTHERS
Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

SCHEDULE IV

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE WARRANTING A CORRESPONDING
CLAIM

Claim Related toConditions Warranting the Claim1. Adapted proteinThe protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is not less than 1.0.2. Low sodiumThe sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).3. Sucrose freeNo sucrose is present.4. Lactose onlyLactose is the only carbohydrate present.5. Lactose free 1No lactose is present. (1)6. Iron enrichedIron is added.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 Section 2.2 of Schedule I and the amount of immunoreactive protein measured with methods generally acceptable as appropriate 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.
(1)when determined by a method the detection limits of which will be established a later stage.

SCHEDULE V

ESSENTIAL AND SEMI-ESSENTIAL AMINO ACIDS IN BREAST MILK
For the purpose of this report, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal are the following:

per 100 kJ(1)per 100 kcalArginine1669Cystine624Histidine1145Isoleucine1772Leucine37156Lysine29122Methionine729Phenylalanine1562Threonine1980Tryptophan730Tyrosine1459Valine1980
(1)1 kJ = 0.239 kcal

SCHEDULE VI

AMINO ACID COMPOSITION OF CASEIN AND BREAST MILK PROTEIN
The amino acid composition of casein and breast milk protein:

CASEIN (1)BREAST MILK (1)g/100 g of proteing/100 g of proteinArginine3.73.8Cystine0.31.3Histidine2.92.5Isoleucine5.44.0Leucine9.58.5Lysine8.16.7Methionine2.81.6Phenylalanine5.23.4Threonine4.74.4Tryptophan1.61.7Tyrosine5.83.2Valine6.74.5
(1)amino acid content of foods and biological data on protein FAO Nutritional Studies, no. 24, Rome 1970, items 375 and 383.

SCHEDULE VII

THE MINERAL ELEMENTS IN COWS' MILK
As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat and per g of proteins are the following:

per 100 g SNF (1)per g of proteinsSodium (mg)55015Potassium (mg)1,68043Chloride (mg)1,05028Calcium (mg)1,35035Phosphorus (mg)1,07028Magnesium (mg)1353.5Copper (µg)2256Iodinens2ns2
(1)SNF: 'solids-no fats'
(2)ns: non-specified, varies widely according to season and stock farming conditions

SCHEDULE VIII

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

NutrientLabelling reference valueVitamin A(µg) 400Vitamin D(µg) 10Vitamin C(mg) 25Thiamin(mg) 0.5Riboflavin(mg) 0.8Niacin equivalents(mg) 9Vitamin B6(mg) 0.7Folate(µg) 100Vitamin B12(µg) 0.7Calcium(mg) 400Iron(mg) 6Zinc(mg) 4Iodine(µg) 70Selenium(µg) 10Copper(mg) 0.4

GIVEN under the Official Seal of the Minister for Health and Children, this 16th day of July, 1998.
BRIAN COWEN, T.D.,
Minister for Health and Children

EXPLANATORY NOTE.

These Regulations give effect to Commission Directive 91/321/EEC of 14 May 1991, Council Directive 92/52/EEC of 18 June 1992 and Commission Directive 96/4/EEC of the 16 February 1996 on compositional, labelling and marketing requirements for infant formulae and follow-on formulae intended for infants in good health.
These Regulations come into effect on the 17th of July, 1998.