

1995 No. 85

FOOD

**The Infant Formula and Follow-on Formula Regulations
(Northern Ireland) 1995**

Made 9th March 1995

Coming into operation 17th April 1995

The Department of Health and Social Services for Northern Ireland in exercise of the powers conferred on it by Articles 15(1) (a), (b), (e) and (f), 16(1), 25(1) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(a), and, in respect of regulation 9, being a designated Department(b) for the purposes of section 2(2) of the European Communities Act 1972(c) in relation to informational and educational materials dealing with the feeding of infants and young children, donations of informational or educational equipment or materials, and donations and low price sales of supplies of infant formulae, in exercise of the powers conferred on it by the said section 2(2), and of all other powers enabling it in that behalf and after consultation in accordance with Article 47(3) of the said Order with such organisations as appear to it to be representative of interests likely to be substantially affected by these Regulations (in so far as the Regulations are made in exercise of the powers conferred by the said Order), hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995 and shall come into operation on 17th April 1995.

(2) In these Regulations—

“advertisement” has the same meaning as in the Order, except that it does not include any label or wrapper;

“follow-on formula” means a food intended for particular nutritional use by infants in good health who are aged over four months, and constituting the principal liquid element in a progressively diversified diet;

“health care system” means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women,

(a) S.I. 1991/762 (N.I. 7). See Article 2(2) for the definitions of “regulations” and “the Department concerned”

(b) S.I. 1994/1887

(c) 1972 c. 68; the definition of the Treaties referred to in section 2(2) was extended by section 1 of the European Economic Area Act 1993 (c. 51)

including nurseries or child-care institutions and health workers in private practice;

“infant” means a child under the age of twelve months;

“infant formula” means a food intended for particular nutritional use by infants in good health during the first four to six months of life, and satisfying by itself the nutritional requirements of such infants;

“member State” means a member State of the European Community other than the United Kingdom;

“the Order” means the Food Safety (Northern Ireland) Order 1991;

“sell” includes possess for sale and offer, expose or advertise for sale, but does not include—

(a) an advertisement of the type described in Article 21 of the Order (publication in the course of business), or

(b) anything not qualifying as a placing on the market for the purposes of Council Directive 89/398/EEC(a) on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses;

“third country” means a country or territory other than a member State, the United Kingdom, the Isle of Man or any of the Channel Islands;

“young children” means children aged between one and three years.

(3) The Interpretation Act (Northern Ireland) 1954(b) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

Conditions for the sale of infant formulae and follow-on formulae

2.—(1) No person shall sell any food which is labelled or otherwise represented as—

(a) being an infant formula; or

(b) satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life,

unless that food—

(i) has been manufactured in accordance with the requirements set out in regulation 4(1), (2), (9), (10) and (11);

(ii) complies with the compositional criteria referred to in regulation 4(3), and the compositional requirements of regulation 4(12);

(iii) is labelled in accordance with the requirements for an infant formula of regulation 5(1)-(3) and (5); and

(iv) complies with the requirements as to presentation referred to in regulation 5(6).

(2) No person shall sell any food which is labelled or otherwise represented as being a follow-on formula unless that food—

(a) O.J. No. L186, 30.6.89, p. 27

(b) 1954 c. 33 (N.I.)

- (a) has been manufactured in accordance with the requirements set out in regulation 4(5), (6), (9) (10) and (11);
- (b) complies with the compositional criteria referred to in regulation 4(7), and the compositional requirements of regulation 4(12);
- (c) is labelled in accordance with the requirements for a follow-on formula of regulation 5(4) and (5); and
- (d) complies with the requirements as to presentation referred to in regulation 5(7).

(3) Nothing in regulation 2(1) or (2) shall apply to a sale of any food solely intended for export to a third country.

Export of infant formulae and follow-on formulae to third countries

3.—(1) No person shall export from Northern Ireland to a third country any infant formula which does not comply with—

- (a) the requirements referred to in regulation 4(1)-(4), (9), (10), (11) and (12) or the Codex Standard for Infant Formula(a) established by the Codex Alimentarius;
- (b) the requirements referred to in regulation 5(1)(c)-(h), (2), (3), (5) and (6); and
- (c) the provisions of the Food (Lot Marking) Regulations (Northern Ireland) 1992(b).

(2) The provisions referred to in paragraph (1) shall not apply to the extent that any of them are dispensed with or varied by provisions laid down by the importing country.

(3) No person shall export from Northern Ireland to a third country any food, other than an infant formula, which is labelled or otherwise represented as capable of satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.

(4) No person shall export from Northern Ireland to a third country any follow-on formula which does not comply with—

- (a) the requirements referred to in regulation 4(5)-(12) or the Codex Standard for Follow-up Formula(c) established by the Codex Alimentarius;
- (b) the requirements referred to in regulation 5(4) (c)-(f), (5) and (7); and
- (c) the provisions of the Food (Lot Marking) Regulations (Northern Ireland) 1992.

(5) The provisions referred to in paragraph (4) shall not apply to the extent that any of them are dispensed with or varied by provisions laid down by the importing country.

(6) No person shall export from Northern Ireland to a third country any infant formula or follow-on formula which is not—

(a) Codex Stan 72-1981 (amended 1983, 1985, 1987), Codex Alimentarius, 1994, Vol. 4, p. 17

(b) S.R. 1992 No. 281

(c) Codex Stan 156-1987 (amended 1989), Codex Alimentarius, 1994, Vol 4, p. 43

- (a) labelled in an appropriate language; and
- (b) labelled in such a way as to avoid any risk of confusion between an infant formula and a follow-on formula.

Composition of infant formulae and follow-on formulae

4.—(1) An infant formula shall be manufactured only from—

- (a) the protein sources and food ingredients specified in Schedule 1; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants from birth has been established by generally accepted scientific data.

(2) In the manufacture of any infant formula the prohibitions and limitations on the use of food ingredients set out in Schedule 1 shall be observed.

(3) The composition of an infant formula shall conform to the criteria specified in Schedule 1.

(4) In this regulation a reference to Schedule 1 shall be read as a reference to that Schedule as read with Schedules 5 and 6.

(5) A follow-on formula shall be manufactured only from—

- (a) the protein sources and food ingredients specified in Schedule 2; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants aged over four months has been established by generally accepted scientific data.

(6) In the manufacture of any follow-on formula the prohibitions and limitations on the use of food ingredients set out in Schedule 2 shall be observed.

(7) The composition of a follow-on formula shall conform to the criteria specified in Schedule 2.

(8) In this regulation a reference to Schedule 2 shall be read as a reference to that Schedule as read with Schedules 6 and 7.

(9) If an infant formula or a follow-on formula is not at the time it is sold ready for use, nothing more than the addition of water shall be required to make it ready for such use.

(10) Subject to paragraph (11), in relation to the manufacture of any infant formula or any follow-on formula, the requirements specified in Schedule 1 or Schedule 2, as appropriate in respect of vitamins, mineral substances, amino acids and other nitrogen compounds, and other substances having a particular nutritional purpose shall only be satisfied by the use in the process of manufacture of the vitamin formulations, permitted salts, amino acids and other nitrogen compounds and other substances listed in Schedule 3.

(11) In the case of a vitamin or mineral substance listed in column 1 of Schedule 3 the vitamin formulation or permitted salt to be used shall be one of those listed in column 2 of that Schedule in relation to the vitamin or mineral substance in question.

(12) No infant formula or follow-on formula shall contain any substance in such quantity as to endanger the health of infants.

Labelling, packaging etc of infant formulae and follow-on formulae

5.—(1) No infant formula shall be sold unless it is labelled with the following particulars—

- (a) in the case of a product where the protein source is not entirely cows' milk proteins, the name "infant formula";
- (b) in the case of a product where the protein source is entirely cows' milk proteins, the name "infant milk";
- (c) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;
- (d) in the case of a product which does not contain added iron, a statement to the effect that the product does not contain the total iron requirements recommended for an infant over the age of four months, and that these should be made up from additional sources;
- (e) the available energy value expressed in kJ and kcal, and the content of proteins, lipids and carbohydrates per 100 millilitres of the product ready for use;
- (f) the average quantity of each mineral substance and of each vitamin mentioned in Schedule 1, and where applicable of choline, inositol and carnitine, per 100 millilitres of the product ready for use;
- (g) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation; and
- (h) the words "Important Notice", immediately followed by—
 - (i) a statement concerning the superiority of breast-feeding; and
 - (ii) a statement recommending that the product be used only on the advice of an independent person qualified in medicine, nutrition or pharmacy or having a professional qualification in maternal or child care.

(2) The labelling of an infant formula shall not include—

- (a) any picture of an infant;
- (b) any other picture or text which may idealise the use of the product, but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

(3) The labelling of an infant formula shall include a claim concerning the composition of the product only when—

- (a) the claim is listed in column 1 of Schedule 4, and is expressed in the terms there set out; and
- (b) the condition specified in column 2 of that Schedule in relation to the relevant claim made in column 1 is satisfied.

(4) No follow-on formula shall be sold unless it is labelled with the following particulars—

- (a) in the case of a product where the protein source is not entirely cows' milk proteins, the name "follow-on formula";
 - (b) in the case of a product where the protein source is entirely cows' milk proteins, the name "follow-on milk";
 - (c) a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of four months, that it should form only part of a diversified diet and 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, and the content of proteins, lipids and carbohydrates per 100 millilitres of the product ready for use;
 - (e) the average quantity of each mineral substance and of each vitamin mentioned in Schedule 2, and where applicable of choline, inositol and carnitine per 100 millilitres of the product ready for use; and
 - (f) instructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.
- (5) The labelling of any infant formula and any follow-on formula shall—
- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast-feeding;
 - (b) not contain the terms "humanized", "maternalized" or any similar term suggesting that the product is equivalent or superior to breast milk; and
 - (c) only use the term "adapted" in relation to adapted protein and then only in conformity with the provisions of paragraph (3).
- (6) The provisions of regulation 5(1)(h), (2), (3), and (5) shall also apply so far as they are relevant to the presentation of an infant formula.
- (7) The provisions of regulation 5(5) shall also apply so far as they are relevant to the presentation of a follow-on formula.

Restrictions on advertising of infant formulae

6.—(1) No person shall publish or display any advertisement for an infant formula—

- (a) except —
 - (i) in a publication specialising in baby care and distributed only through the health care system;
 - (ii) in a scientific publication; or
 - (iii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public; and
- (b) which does not comply with the requirements, prohibitions and restrictions relating to labelling contained in regulation 5(1)(h), (2), (3) and (5).

(2) An advertisement for an infant formula shall contain only information of a scientific and factual nature. Such information shall not imply or seek to create a belief that bottle-feeding is equivalent or superior to breast-feeding.

Restrictions on advertising of follow-on formulae

7. No person shall publish or display any advertisement for a follow-on formula which does not comply with the requirements, prohibitions and restrictions relating to labelling contained in regulation 5(5).

Restrictions on promotion of infant formulae

8.—(1) No person shall at any place where any infant formula is sold by retail—

- (a) advertise any infant formula;
- (b) make any special display of an infant formula designed to promote sales;
- (c) give away
 - (i) any infant formula as a free sample; or
 - (ii) any coupon which may be used to purchase an infant formula at a discount;
- (d) promote the sale of an infant formula by means of premiums, special sales, loss leaders or tie-in sales; or
- (e) undertake any other promotional activity to induce the sale of an infant formula.

(2) No manufacturer or distributor of any infant formula shall provide for promotional purposes any infant formula free or at a reduced or discounted price, or any gift designed to promote the sale of an infant formula to—

- (a) the general public;
- (b) pregnant women;
- (c) mothers; or
- (d) members of the families of persons mentioned in sub-paragraphs (b) and (c),

either directly or indirectly through the health care system or health workers.

Provision of information and education regarding infant and child feeding

9.—(1) No person shall produce or publish any informational and educational (or informational or educational) materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless (subject to paragraph (2)) such materials include clear information on all the following points:

- (a) the benefits and superiority of breast-feeding;
- (b) maternal nutrition and the preparation for, and the 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; and

(e) where needed, the proper use of an infant formula or of infant formulae, whether manufactured industrially or home-prepared.

(2) When the materials referred to in paragraph (1) contain information about the use of an infant formula, they—

(a) shall include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of an infant formula; and

(b) shall not use any pictures which may idealise the use of infant formulae.

(3) No manufacturer or distributor of an infant formula shall make a donation of any informational or educational equipment or materials except in accordance with the following conditions—

(a) the donation shall be made following a request by the intended recipient;

(b) the donation shall be made with the written authority of the Department or in accordance with guidelines drawn up by the Department;

(c) the equipment and materials may bear the name or logo of the donor but shall not be marked or labelled with the name of a proprietary infant formula; and

(d) the equipment or materials shall be distributed only through the health care system.

(4) Any institution or organisation which receives any infant formula free or at a reduced price shall ensure that such infant formula is only used by or distributed for infants who have to be fed on infant formula, and that such use or distribution continues only so long as is required by such infants.

Offences and Enforcement

10.—(1) If any person contravenes any of the provisions contained in regulations 2, 3, 6, 7, 8 and 9 he shall be guilty of an offence and shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(2) Each district council shall enforce and execute these Regulations in its own district.

Application of provisions of the Food Safety (Northern Ireland) Order 1991

11. The following provisions of the Order shall apply for the purposes of these Regulations (except regulation 9) as they apply for the purposes of Articles 7, 13 or 14 of the Order, and any reference in them to the Order shall be construed for the purposes of these Regulations as a reference to these Regulations (except regulation 9)—

(a) Articles 2(4) and 3 (extended meaning of “sale” etc.);

(b) Article 4 (presumptions that food intended for human consumption);

- (c) Article 19 (offences due to fault of another person);
- (d) Article 20 (defence of due diligence);
- (e) Article 30(8) (which relates to documentary evidence);
- (f) Article 34 (obstruction etc of officers).

Amendments to existing Regulations

12.—(1) The Skimmed Milk with Non-Milk Fat Regulations (Northern Ireland) 1961(a) shall be amended as follows—

- (a) at the end of regulation 9(3) there shall be added, “or any infant formula which complies with the requirements as to its manufacture and composition specified in regulation 4(5), (6), (7), (9), (10), (11) and (12) of the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995.”;
- (b) in regulation 3(1)(a) there shall be deleted, “(as modified by the Second Schedule in respect of the specified foods referred to therein)”;
- (c) in Part I of the First Schedule, sub-paragraph (i) of the Proviso in paragraph 1 shall be deleted;
- (d) the Second Schedule shall be deleted.

(2) The Food Labelling Regulations (Northern Ireland) 1984(b) shall be amended by the deletion of paragraph 2 in Part I of Schedule 6.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 9th March 1995

(L.S.)

D. A. Baker

Assistant Secretary

(a) S.R. & O. (N.I.) 1961 No. 190; the relevant amending Regulations are S.R. 1976 No. 70, S.R. 1982 No. 43 and S.R. 1992 No. 463

(b) S.R. 1984 No. 407; to which there are amendments not relevant to these Regulations

**Essential Composition of Infant Formulae when reconstituted as instructed
by the Manufacturer***(All values refer to the product ready for use)*1. *Energy*

<i>Minimum</i>	<i>Maximum</i>
250 kJ (60 kcal/100 ml)	315 kJ (75 kcal/100ml)

2. *Proteins*(Protein content = nitrogen content \times 6.38) for cows' milk proteins.(Protein content = nitrogen content \times 6.25) for soya protein isolates.

2.1 Formulae manufactured from unmodified cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.56 g/100 kJ (2.25 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

— The chemical index of the proteins present shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule 6); nevertheless, for calculation purposes, the concentrations of methionine and cystine may be added together.

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

2.2 Formulae manufactured from modified cows' milk proteins (alteration of the casein/whey protein ratio)

<i>Minimum</i>	<i>Maximum</i>
0.45 g/100 kJ (1.8 g/100 kcal)	0.7 g/100 kJ (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 5).

2.3 Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.56 g/100 kJ (2.25 g/100 kcal)	0.7 g/100 kJ (3 g/100 kcal)

— Only soya protein isolates may 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 6).

— 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 5).

— The L-carnitine content shall be at least equal to 1.8 μ moles/100 kJ (7.5 μ moles/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

<i>Minimum</i>	<i>Maximum</i>
0.8 g/100 kJ (3.3 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

3.1 The use of the following substances is prohibited:

- sesame seed oil;
- cotton seed oil;
- fats containing more than 8% tran isomers of fatty acids.

3.2 Lauric acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

3.3 Myristic acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

3.4 Linoleic acid (in the form of glycerides = linoleates)

<i>Minimum</i>	<i>Maximum</i>
70 mg/100 kJ (300 mg/100 kcal)	285 mg/100kJ (1200 mg/100 kcal)

4. Carbohydrates

<i>Minimum</i>	<i>Maximum</i>
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ (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
 - gelatinised starch
- } naturally free
} of gluten

4.2 Lactose

<i>Minimum</i>	<i>Maximum</i>
0.85 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

<i>Minimum</i>	<i>Maximum</i>
—	20% of the total carbohydrate content

4.4 Pre-cooked starch and/or gelatinised starch

<i>Minimum</i>	<i>Maximum</i>
—	2g/100ml, and 30% of the total carbohydrate content

5. Mineral substances

5.1 Formulae manufactured from cows' milk proteins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	35	60	145
Chloride (mg)	12	29	50	125
Calcium (mg)	12	—	50	—
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg) ¹	0.12	0.36	0.5	1.5
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (µg)	4.8	19	20	80
Iodine (µg)	1.2	—	5	—

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 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.25	0.5	1	2
Zinc (mg)	0.18	0.6	0.75	2.4

6. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE) ²	14	43	60	180
Vitamin D (µg) ³	0.25	0.65	1	2.5
Thiamin (µg)	10	—	60	—
Riboflavin (µg)	14	—	40	—
Nicotinamide(µg-NE) ⁴	60	—	250	—
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 (mg)	1.9	—	8	—
Vitamin K (µg)	1	—	4	—
Vitamin E (mg α-TE) ⁵	0.5/g of	—	0.5/g of	—
	polyunsaturated fatty acids		polyunsaturated fatty acids	
	expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ		expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal	

(1) Limit applicable to formulae with added iron

(2) RE = all trans retinol equivalent

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

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

(5) α-TE = d-α-tocopherol equivalent

**Essential Composition of follow-on formulae when reconstituted as instructed
by the manufacturer***(All values refer to the product ready for use)*1. *Energy*

<i>Minimum</i>	<i>Maximum</i>
250 kJ/100 ml (60 kcal/100 ml)	334 kJ/100 ml (80 kcal/100ml)

2. *Proteins*(Protein content = nitrogen content \times 6.38) for cows' milk proteins.(Protein content = nitrogen content \times 6.25) for soya protein isolates.

<i>Minimum</i>	<i>Maximum</i>
0.5 g/100 kJ (2.25 g/100 kcal)	1 g/100 kJ (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 as defined in Schedule 6).

— 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 protein 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.

3. *Lipids*

<i>Minimum</i>	<i>Maximum</i>
0.8 g/100 kJ (3.3 g/100 kcal)	1.5 g/100 kJ (6.5 g/100 kcal)

3.1 The use of the following substances is prohibited:

— sesame seed oil;

— cotton seed oil;

— facts containing more than 8% trans isomers of fatty acids.

3.2 Lauric acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

3.3 Myristic acid

<i>Minimum</i>	<i>Maximum</i>
—	15% of the total fat content

3.4 Linoleic acid (in the form of glycerides = linoleates)

<i>Minimum</i>	<i>Maximum</i>
70 mg/100 kJ	—

(300 mg/100 kcal):

this limit applies only

to follow-on formulae

containing vegetable oils

4. Carbohydrates

<i>Minimum</i>	<i>Maximum</i>
1.7 g/100 kJ (7 g/100 kcal)	3.4 g/100 kJ (14 g/100 kcal)

4.1 The use of ingredients containing gluten is prohibited.

4.2 Lactose

<i>Minimum</i>	<i>Maximum</i>
0.45 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

<i>Minimum</i>	<i>Maximum</i>
—	separately or as a whole: 20% of the total carbohydrate content.

5. Mineral substances

5.1

		<i>Per 100 kJ</i>		<i>Per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Iron	(mg)	0.25	0.5	1	2
Iodine	(µg)	1.2	—	5	—

5.2 Zinc

5.2.1 Follow-on formulae manufactured entirely from cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.12 mg/100 kJ (0.5 mg/100 kcal)	—

5.2.2 Follow-on formulae containing soya protein isolates, alone or mixed with cows' milk proteins

<i>Minimum</i>	<i>Maximum</i>
0.18 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 7.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

6. *Vitamins*

		<i>Per 100 kJ</i>		<i>Per 100 kcal</i>	
		<i>Minimum</i>	<i>Maximum</i>	<i>Minimum</i>	<i>Maximum</i>
Vitamin A	(μgRE) ¹	14	43	60	180
Vitamin D	(μg) ²	0.25	0.75	1	3
Vitamin C	(mg)	1.9	—	8	—
Vitamin E	(mg α -TE) ³	0.5/g of	—	0.5/g of	—
		polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ		polyunsaturated 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 = 400 i.u. of vitamin D(3) α -Te = d- α -tocopherol equivalent

Nutritional substances1. *Vitamins*

<i>Vitamin</i>	<i>Vitamin formulation</i>
Vitamin A	Retinyl acetate Retinyl palmitate Beta-carotene Retinol
Vitamin D	Vitamin D ₂ (ergocalciferol) Vitamin D ₃ (cholecalciferol)
Vitamin B ₁	Thiamin hydrochloride Thiamin mononitrate
Vitamin B ₂	Riboflavin Riboflavin-5'-phosphate, sodium
Niacin	Nicotinamide Nicotinic acid
Vitamin B ₆	Pyridoxine hydrochloride Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B ₁₂	Cyanocobalamin Hydroxocobalamin
Biotin	D-Biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

2. *Mineral substances*

<i>Mineral substances</i>	<i>Permitted salts</i>
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide
Magnesium (Mg)	Magnesium carbonate Magnesium chloride

	Magnesium oxide
	Magnesium salts of orthophosphoric acid
	Magnesium sulphate
	Magnesium gluconate
	Magnesium hydroxide
	Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate
	Ferrous gluconate
	Ferrous lactate
	Ferrous sulphate
	Ferric ammonium citrate
	Ferrous fumarate
	Ferric diphosphate (Ferric pyrophosphate)
Copper (Cu)	Cupric citrate
	Cupric gluconate
	Cupric sulphate
	Copper-lysine complex
	Cupric carbonate
Iodine (I)	Potassium iodide
	Sodium iodide
	Potassium iodate
Zinc (Zn)	Zinc acetate
	Zinc chloride
	Zinc lactate
	Zinc sulphate
	Zinc citrate
	Zinc gluconate
	Zinc oxide
Manganese (Mn)	Manganese carbonate
	Manganese chloride
	Manganese citrate
	Manganese sulphate
	Manganese gluconate
Sodium (Na)	Sodium bicarbonate
	Sodium chloride
	Sodium citrate
	Sodium gluconate
	Sodium carbonate
	Sodium lactate
	Sodium salts of orthophosphoric acid
	Sodium hydroxide
Potassium(K)	Potassium bicarbonate
	Potassium carbonate
	Potassium chloride
	Potassium salts of citric acid
	Potassium gluconate
	Potassium lactate
	Potassium salts of orthophosphoric acid
	Potassium hydroxide

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

4. *Others*

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

Compositional criteria for infant formulae, warranting a corresponding claim*Claim related to*

1. Adapted protein

2. Low sodium

3. Sucrose free

4. Lactose only

5. Lactose free

6. Iron enriched

Conditions warranting the claim

The 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

The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal)

No sucrose is present

Lactose is the only carbohydrate present

No lactose is present⁽¹⁾

Iron is added

(1) When determined by a method the detection limits of which will be established at a later stage

The essential and semi-essential amino acids in breast milk

For the purpose of these Regulations, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	<i>Per 100 kJ⁽¹⁾</i>	<i>Per 100 kcal</i>
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

(1) 1 kJ = 0.239 kcal

Amino acid composition of casein and breast milk protein

The amino acid composition of casein and breast milk protein (g/100 g of protein):

	<i>Casein¹</i>	<i>Breast milk¹</i>
Arginine	3.7	3.8
Cystine	0.3	1.3
Histidine	2.9	2.5
Isoleucine	5.4	4.0
Leucine	9.5	8.5
Lysine	8.1	6.7
Methionine	2.8	1.6
Phenylalanine	5.2	3.4
Threonine	4.7	4.4
Tryptophan	1.6	1.7
Tyrosine	5.8	3.2
Valine	6.7	4.5

(1) Amino acid content of foods and biological data on protein. FAO Nutritional Studies, No. 24, Rome 1970, items 375 and 383

The mineral elements in cows milk

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-not-fat and per g of proteins are the following:

	<i>Per 100 g SNF¹</i>	<i>Per g of proteins</i>
Sodium (mg)	550	15
Potassium (mg)	1680	43
Chloride (mg)	1050	28
Calcium (mg)	1350	35
Phosphorus (mg)	1070	28
Magnesium (mg)	135	3.5
Copper (μg)	225	6
Iodine	NS ²	NS

(1) SNF: "solids-not-fats"

(2) NS: non specified, varies widely according to season and stock farming conditions

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations implement Commission Directive 91/321/EEC (OJ No. L175, 4.7.91, p.35) on infant formulae (which are foods suitable as the sole source of nutrition for infants during the first four to six months of life and often form an important part of the diet throughout infancy) and follow-on formulae (which are foods given to older infants and young children as an alternative to milk or infant formulae). They also implement Council Directive 92/52/EEC (O.J. No. L179, 1.7.92, p.129) on infant formulae and follow-on formulae intended for export to third countries.

The principal provisions of the Regulations—

- (1) prohibit the sale of food labelled as infant formulae or follow-on formulae unless it complies with the requirements of the Regulations as to composition, labelling, appearance and packaging (regulations 2(1), (2), 4 and 5);
- (2) require infant formulae and follow-on formulae exported to countries not in the European Community to comply with similar compositional standards unless the importing country otherwise permits, and require products to be labelled in an appropriate language and in a way which avoids confusion between infant formulae and follow-on formulae (regulation 3);
- (3) limit the advertising of infant formulae to specified types of publications and restrict the content of advertisements for infant formulae and follow-on formulae (regulations 6 and 7);
- (4) prohibit special displays or promotions of infant formulae at retail outlets (regulation 8(1));
- (5) prohibit the promotion of infant formulae to the general public, expectant mothers, and others by providing such formulae free or at reduced prices (regulation 8(2)),
- (6) lay down requirements as to the information to be contained in informational and educational materials dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, and regulate the cases in which a manufacturer or distributor of infant formulae may make gifts of informational or educational equipment or materials (regulation 9).

The standards for infant formula or follow-on formula established by the Codex Alimentarius can be inspected by arrangement with the library of the Department of Health and Social Services, Dundonald House, Upper Newtownards Road, Belfast BT4 3SF.