STATUTORY INSTRUMENTS

1995 No. 77

FOOD

The Infant Formula and Follow–on Formula Regulations 1995

Made - - - -	*15th January 1995*
Laid before Parliament	*16th January 1995*
Coming into force - -	*1st March 1995*

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 6(4), 16(1)(a), (b), (e) and (f), 17(1), 26(1) and (3) and 48(1) of the Food Safety Act 1990(**1**), and of all other powers enabling them in that behalf, and, in respect of regulation 21 of the following Regulations, the Secretary of State (being the Minister designated(**2**) for the purposes of section 2(2) of the European Communities Act 1972(**3**) 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 him by the said section 2(2), and of all other powers enabling him in that behalf, after consultation in accordance with section 48 of the said Act of 1990 with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations (in so far as the Regulations are made in exercise of the powers conferred by the said sections of the said Act of 1990), hereby make the following Regulations:—

Title, commencement and interpretation

1.—(1) These Regulations may be cited as the Infant Formula and Follow–on Formula Regulations 1995 and shall come into force on 1st March 1995.

(2) In these Regulations, unless the context otherwise requires—

"the Act" means the Food Safety Act 1990;

"advertisement" has the same meaning as in the Act, except that it does not include any label or wrapper, and "advertise" and "advertising" shall be construed accordingly;

"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;

(**1**) 1990 c. 16; "the Ministers" is defined in section 4(1) of the Act.
(**2**) S.I.1994/1887.
(**3**) 1972 c. 68.

"food authority" has the same meaning as in the Act, except that it does not include either the council of any district in a non–metropolitan county in England and Wales or the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple);

"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" 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;

"presentation", in relation to an infant formula or a follow-on formula, includes the shape, appearance or packaging of the product concerned, the way in which the product is arranged when it is exposed for sale and the setting in which the product is displayed with a view to sale, but does not include any form of labelling or advertising;

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

(a) an advertisement of the type described in section 22 of the Act (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(**4**) 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) Any reference in these Regulations to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

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

2. 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 regulations 8(1) and (2), 10 and 11;

(ii) complies with the compositional criteria referred to in regulation 8(3), and the compositional requirements of regulation 12;

(iii) is labelled in accordance with the requirements for an infant formula of regulations 13 and 15; and

(iv) complies with the requirements as to presentation referred to in regulation 16(1).

(**4**) OJ No. L186, 30.6.89, p.27.

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

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

(b) complies with the compositional criteria referred to in regulation 9(3), and the compositional requirements of regulation 12;

(c) is labelled in accordance with the requirements for a follow-on formula of regulations 14 and 15; and

(d) complies with the requirements as to presentation referred to in regulation 16(2).

4. Nothing in regulation 2 or regulation 3 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

5.—(1) No person shall export from Great Britain to a third country any infant formula which does not comply with—

(a) the requirements referred to in regulations 8, 10, 11 and 12 or the Codex Standard for Infant Formula(**5**) established by the Codex Alimentarius;

(b) the requirements referred to in regulations 13(1)(c)–(h), (2) and (3), 15 and 16(1); and

(c) the provisions of the Food (Lot Marking) Regulations 1992(**6**).

(2) The provisions referred to in paragraph (1) above 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 Great Britain 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.

6.—(1) No person shall export from Great Britain to a third country any follow-on formula which does not comply with—

(a) the requirements referred to in regulations 9, 10, 11 and 12 or the Codex Standard for Follow–up Formula(**7**) established by the Codex Alimentarius;

(b) the requirements referred to in regulations 14(c)–(f), 15 and 16(2); and

(c) the provisions of the Food (Lot Marking) Regulations 1992.

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

7. No person shall export from Great Britain to a third country any infant formula or follow-on formula which is not—

(a) labelled in an appropriate language (or appropriate languages); 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

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

(**5**) Codex Stan 72–1981 (amended 1983, 1985, 1987), Codex Alimentarius, 1994, vol. 4, p. 17.
(**6**) S.I. 1992/1357.
(**7**) Codex Stan 156–1987 (amended 1989), Codex Alimentarius, 1994, vol. 4, p. 43.

(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.

9.—(1) 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.

(2) 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.

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

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

10. 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.

11.—(1) Subject to paragraph (2) below, 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.

(2) In the case of a vitamin or a 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

13.—(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) he 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.

14. 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) nstructions for appropriate preparation of the product and a warning against the health hazards of inappropriate preparation.

15. 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 the term "adapted" may be used only in relation to adapted protein and then only in conformity with the provisions of regulation 13(3).

16.—(1) The provisions of regulations 13(1)(h), (2) and (3) and 15 shall also apply so far as they are relevant to the presentation of an infant formula.

(2) The provisions of regulation 15 shall also apply so far as they are relevant to the presentation of a follow-on formula.

Restrictions on advertising of infant formulae

17.—(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 regulations 13(1)(h), (2) and (3) and 15.

(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

18. 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 15.

Restrictions on promotion of infant formulae

19. 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.

20. 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) above,

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

Provision of information and education regarding infant and child feeding

21.—(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) below) 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) above 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 Secretary of State or in accordance with guidelines drawn up by the Secretary of State;

(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

22.—(1) If any person contravenes or fails to comply with any of the provisions contained in regulations 2, 3, 5, 6, 7, 17, 18, 19, 20 and 21 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 food authority shall enforce and execute these Regulations in its area.

Application of provisions of the Food Safety Act 1990

23. The following provisions of the Act shall apply for the purposes of these Regulations (except regulation 21) as they apply for the purposes of section 8, 14 or 15 of the Act, and, unless the context otherwise requires, any reference in them to the Act shall be construed for the purposes of these Regulations as a reference to these Regulations (except regulation 21)—

(a) section 2 (extended meaning of "sale" etc.);

(b) section 3 (presumption that food is intended for human consumption);

(c) section 20 (offences due to fault of another person);

(d) section 21 (defence of due diligence);

(e) section 30(8) (which relates to documentary evidence);

(f) ection 33 (obstruction etc. of officers);

(g) section 36 (offences by bodies corporate);

(h) section 44 (protection of officers acting in good faith).

Amendments to existing Regulations

24. The Skimmed Milk with Non–Milk Fat Regulations 1960(**8**) and the Skimmed Milk with Non–Milk Fat (Scotland) Regulations 1960(**9**) shall be amended in each case as follows—

(a) at the end of regulation 2(3) there shall be added the following words—

"or any infant formula which complies with the requirements as to its manufacture and composition specified in regulations 9(1), (2) and (3), 10, 11 and 12 of the Infant Formula and Follow–on Formula Regulations 1995."; and

(b) the following deletions shall be made—

(i) in regulation 3(1)(a), the words "(as modified by the Second Schedule to these Regulations in respect of the specified foods referred to therein)";

(ii) in Part I of Schedule 1, sub–paragraph (j) of the Proviso in paragraph 1;

(iii) Schedule 2.

25. The Food Labelling Regulations 1984(**10**) and the Food Labelling (Scotland) Regulations 1984(**11**) shall be amended by the deletion in each case of paragraph 2 in Part I of Schedule 6.

Angela Browning
Parliamentary Secretary, Ministry of Agriculture, Fisheries and Food

3rd January 1995

Signed by authority of the Secretary of State for Health:

Cumberlege
Parliamentary Under Secretary of State, Department of Health

28th December 1994

John Redwood
Secretary of State, Welsh Office

15th January 1995

Fraser of Carmyllie
Minister of State, Scottish Office

30th December 1994

(**8**) S.I. 1960/2331; relevant amending instruments are S.I. 1976/103 and 1981/1174.
(**9**) S.I. 1960/2437, amended by S.I. 1976/294 and 1981/1319.
(**10**) S.I. 1984/1305, to which there are amendments not relevant to these Regulations.
(**11**) S.I. 1984/1319, to which there are amendments not relevant to these Regulations.

SCHEDULE 1 Regulations 8, 11 and 13(1)(f)

ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER
(All values refer to the product ready for use)

Energy

1.

Minimum	*Maximum*
250 kJ	315 kJ
(60 kcal/100 ml)	(75 kcal/100 ml)

Proteins

2. (Protein content=nitrogen content × 6.38) for cows' milk proteins.

(Protein content=nitrogen content × 6.25) for soya protein isolates.

(2.1) Formulae manufactured from unmodified cows' milk proteins

Minimum	*Maximum*
0.56 g/100 kJ	0.7 g/100 kJ
(2.25 g/100 kcal)	(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 the 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)

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 Schedule 5).

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

Minimum	*Maximum*
0.56 g/100 kJ	0.7 g/100 kJ

— 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 µmoles/100 kJ (7.5 µmoles/100 kcal).

Minimum	*Maximum*
(2.25 g/100 kcal)	(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 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.

Lipids

3.

Minimum	*Maximum*
0.8 g/100 kJ	1.5 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;
— fats containing more than 8% trans isomers of fatty acids.

(3.2) Lauric acid

Minimum	*Maximum*
—	15% of the total fat content

(3.3) Myristic acid

Minimum	*Maximum*
—	15% of the total fat content

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

Minimum	*Maximum*
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	1200 mg/100 kcal)

Carbohydrates

4.

Minimum	*Maximum*
1.7 g/100 kJ	3.4 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

— gelatinised starch) of gluten

(4.2) Lactose

Minimum	*Maximum*
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

Minimum	*Maximum*
—	20% of the total carbohydrate content

(4.4) Pre–cooked starch and/or gelatinised starch

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

Mineral substances

5

(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)(**12**)	0.12	0.36	0.5	1.5
The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.					

(**12**) Limit applicable to formulae with added iron.

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
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

Vitamins

6.

		per 100 kJ		*per 100 kcal*	
		Minimum	*Maximum*	*Minimum*	*Maximum*
Vitamin A	(µg–RE)(**13**)	14	43	60	180
Vitamin D	(µg)(**14**)	0.25	0.65	1	2.5
Thiamin	(µg)	10	—	40	—
Riboflavin	(µg)	14	—	60	—
Nicotinamide	(µg–NE)(**15**)	60	—	250	—
Pantothenic acid	(µg)	70	—	300	—
Vitamin B6	(µg)	9	—	35	—
Biotin	(µg)	0.4	—	1.5	—
Folic acid	(µg)	1	—	4	—
VitaminB12	(µg)	0.025	—	0.1	—
Vitamin C	(mg)	1.9	—	8	—
Vitamin K	(µg)	1	—	4	—
Vitamin E	(mg*–TE)(**16**)	0.5/g of polyunsaturated fatty acids	—	0.5/g of polyunsaturated fatty acids	—

(**13**) RE=all trans retinol equivalent.
(**14**) In the form of cholecalciferol, of which 10 µg=400 i.u. of vitamin D.
(**15**) NE=Niacin equivalent=mg nicotinic acid+mg tryptophan/60.
(**16**) *–TE=d–*–tocopherol equivalent.

	per 100 kJ		*per 100 kcal*	
	Minimum	*Maximum*	*Minimum*	*Maximum*
	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	

SCHEDULE 2 Regulations 9, 11 and 14(e)

ESSENTIAL COMPOSITION OF FOLLOW–ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER
(All values refer to the product ready for use)

Energy

1.

Minimum	*Maximum*
250 kJ/100 ml	335 kJ/100 ml
(60 kcal/100 ml)	(80 kcal/100 ml)

Proteins

2. (Protein content–nitrogen content × 6.38) for cows' milk proteins.

(Protein content–nitrogen content × 6.25) for soya protein isolates.

Minimum	*Maximum*
0.5 g/100 kJ	1 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 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.

Lipids

3.

Minimum	*Maximum*
0.8 g/100 kJ	1.5 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;

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

(3.2) Lauric acid

Minimum	*Maximum*
—	15% of the total fat content

(3.3) Myristic acid

Minimum	*Maximum*
—	15% of the total fat content

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

Minimum	*Maximum*
70 mg/100 kJ (300 mg/100 kcal): this limit applies only to follow-on formulae containing vegetable oils	—

Carbohydrates

4.

Minimum	*Maximum*
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

Minimum	*Maximum*
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

Minimum	*Maximum*
—	separately or as a whole: 20% of the total carbohydrate content

Mineral substances

5

		per 100 kJ		per 100 kcal	
		Minimum	*Maximum*	*Minimum*	*Maximum*
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

Minimum	*Maximum*
0.12 mg/100 kJ	—
(0.5mg/100 kcal)	—

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

Minimum	*Maximum*
0.18 mg/100 kJ	—
(0.75mg/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.

Vitamins

6.

		per 100 kJ		per 100 kcal	
		Minimum	*Maximum*	*Minimum*	*Maximum*
Vitamin A	(µg–RE)(**17**)	14	43	60	180
Vitamin D	(µg)(**18**)	0.25	0.75	1	3
Vitamin C	(mg)	1.9	—	8	—
Vitamin E	(mg*–TE)(**19**)	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case	—	0.5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case	—

(**17**) RE=all trans retinol equivalent.
(**18**) In the form of cholecalciferol, of which 10 µg=400 i.u. of vitamin D.
(**19**) *–TE=d–*–tocopherol equivalent.

	per 100 kJ		per 100 kcal	
	Minimum	*Maximum*	*Minimum*	*Maximum*
	less than 0.1 mg per 100 available kJ		less than 0.5 mg per 100 available kcal	

SCHEDULE 3 Regulation 11

NUTRITIONAL SUBSTANCES

Vitamins

1.

Vitamin	*Vitamin formulation*
Vitamin A	Retinyl acetate
	Retinyl palmitate
	Beta–carotene
	Retinol
Vitamin D	Vitamin D2 (ergocalciferol)
	Vitamin D3 (cholecalciferol)
Vitamin B1	Thiamin hydrochloride
	Thiamin mononitrate
Vitamin B2	Riboflavin
	Riboflavin–5'–phosphate, sodium
Niacin	Nicotinamide
	Nicotinic acid
Vitamin B6	Pyridoxine hydrochloride
	Pyridoxine–5'–phosphate
Folate	Folic acid
Pantothenic acid	D–pantothenate, calcium
	D–pantothenate, sodium
	Dexpanthenol
Vitamin B12	Cyanocobalamin
	Hydroxocobalamin

Vitamin	*Vitamin formulation*
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)

Mineral substances

2.

Mineral substances	*Permitted salts*
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

Mineral substances	*Permitted salts*
	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

Mineral substances	*Permitted salts*
	Manganese citrate
	Manganese sulphate
	Manganese gluconate
Sodium (Na)	Sodium bicarbonate
	Sodium chloride
	Sodium citrate
	Sodiu 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

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

Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

SCHEDULE 4

Regulation 13(3)

COMPOSITIONAL CRITERIA FOR INFANT FORMULAE, WARRANTING A CORRESPONDING CLAIM

Claim related to	*Conditions warranting the claim*
1. Adapted protein	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
2. Low sodium	The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal)
3. Sucrose free	No sucrose is present
4. Lactose only	Lactose is the only carbohydrate present
5. Lactose free	No lactose is present(**20**)
6. Iron enriched	Iron is added

SCHEDULE 5

Regulation 8

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:

	*per 100 kJ(**21**)*	*per 100 kcal*
Arginine	16	69
Cystine	6	24

(**20**) When determined by a method the detection limits of which will be established at a later stage.
(**21**) 1 kJ=0.239 kcal.

	*per 100 kJ(**21**)*	*per 100 kcal*
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

SCHEDULE 6

Regulations 8 and 9

AMINO ACID COMPOSITION OF CASEIN AND BREAST MILK PROTEIN

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

	*Casein(**22**)*	*Breast milk(**22**)*
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

(**21**) 1 kJ=0.239 kcal.

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

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

SCHEDULE 7

Regulation 9

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(**23**)*	*per g of proteins*
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(**24**)	NS

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to Great Britain, come into force on 1st March 1995.

They implement Commission Directive 91/321/EEC (OJNo. 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 (OJ 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, 3 and 8 to 16);

(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 (regulations 5, 6 and 7);

(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 17 and 18);

(4) prohibit special displays or promotions of infant formulae at retail outlets (regulation 19);

(**23**) SNF: “solids–no fats”.
(**24**) NS: non specified, varies widely according to season and stock farming conditions.

(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 20);

(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 21).

The standards for infant formula or follow-on formula established by the Codex Alimentarius are available for inspection at the Library of the Ministry of Agriculture, Fisheries and Food, Whitehall Place, London SW1A 2HH and at the Scottish Office, New St. Andrew’s House, St. James' Square, Edinburgh EH1 3TE.

A Compliance Cost Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies can be obtained from the Consumer Protection Division of the Ministry of Agriculture, Fisheries and Food, Ergon House, 17 Smith Square, London SW1P 3JR.