STATUTORY RULES OF NORTHERN IRELAND

1997 No. 213

FOOD

Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 1997

Made - - - -	*14th April 1997*
Coming into operation	*26th May 1997*

The Department of Health and Social Services in exercise of the powers conferred on it by Articles 15(1)(*a*), (*b*), (*e*) and (*f*), 16(1), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**1**), 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 the Regulations, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 1997 and shall come into operation on 26th May 1997.

(2) In these Regulations "the principal Regulations" means the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995(**2**).

Amendment of the principal Regulations

2. The principal Regulations shall be amended as follows—

(a) in paragraph (*c*) of regulation 2(2) after "5(4)" there shall be inserted ", 5(4A)";

(b) in sub paragraph (*c*) of paragraphs (1) and (4) of regulation 3 for "the Food (Lot Marking) Regulations (Northern Ireland) 1992(**3**)" there shall be substituted "the Food (Lot Marking) Regulations (Northern Ireland) 1996(**4**)";

(c) in regulation 4(12) after "infants" there shall be inserted "and young children";

(d) in sub-paragraph (*e*) of paragraph (1) and in sub-paragraph (*d*) of paragraph 4 of regulation 5 (which deal with the labelling of infant formulae and of follow-on formulae), after "carbohydrates" there shall be inserted ", expressed in numerical form,";

(**1**) S.I. 1991/762 (N.I. 7), as amended by S.I. 1996/1633 (N.I. 12). *See* Article 2(2) for the definitions of "the Department concerned" and "regulations"
(**2**) S.R. 1995 No. 85 to which there is an amendment not relevant to these Regulations
(**3**) S.R. 1992 No. 281
(**4**) S.R. 1996 No. 384

(e) in sub-paragraph (*f*) of paragraph (1) and in sub-paragraph (*e*) of paragraph (4) of regulation 5 for "and carnitine" there shall be substituted ", carnitine and taurine, expressed in numerical form,";

(f) after paragraph (3) of regulation 5 there shall be inserted the following paragraph—

"(3A) The labelling of an infant formula may include the average quantity of nutrients mentioned in Schedule 3 when such is not covered by the provisions of paragraph (1)(*f*), expressed in numerical form, per 100 millilitres of the product ready for use.";

(g) after paragraph (4) of regulation 5 there shall be inserted the following paragraph—

"(4A) The labelling of a follow-on formula may include the average quantity of nutrients mentioned in Schedule 3 when such is not covered by the provisions of regulation 5(4)(*e*), expressed in numerical form, per 100 millilitres of the product ready for use, and, in addition, information on vitamins and minerals included in Schedule 8, expressed as a percentage of the reference values given in that Schedule, per 100 millilitres of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference value.";

(h) in Schedule 1 (essential composition of infant formulae when reconstituted as instructed by the manufacturer)—

(i) for the first sub-paragraph of paragraph 2 and sub-paragraphs 2.1 and 2.2 there shall be substituted—

"**2.** *Prote in*

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

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

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

(2.1) Formulae manufactured from cows' milk proteins

Minimum	Maximum
0.45 g/100 kJ	0.7 g/100 kJ
(1.8 g/100 kcal)	(3 g/100 kcal)

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

(2.2) Formulae manufactured from protein partial hydrolysates

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

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained

in the reference protein (breast milk, as defined in Schedule 5); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilisation (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).";

(ii) in paragraph 3 for "0.8 g/100 kJ" and "(3.3 g/100 kcal)" there shall be substituted—

"Minimum	
1.05 g/100 kJ	(4.4 g/100 kcal)";

(iii) in paragraph 3.1 "— fats containing more than 8% trans isomers of fatty acids" shall be deleted;

(iv) after paragraph 3.4 there shall be inserted—

"(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.";

(v) in paragraph 5.1, after the entry relating to Iodine, there shall be inserted

	"(Per 100 kJ) (minimum)	(maximum)	(Per 100 kcal) (minimum)	(maximum)
Selenium[(1a)](µg)	—	0.7	—	3,"

and after the first footnote to that paragraph there shall be inserted—

"(1A) Limit applicable to formulae with added selenium";

(vi) in paragraph 6, for the entry relating to Nicotinamide there shall be substituted—

	"(Per 100 kJ) (minimum)	(maximum)	(Per 100 kcal) (minimum)	(maximum)
Niacin (mg-NE)	0.2	—	0.8	—";

(vii) after paragraph 6 there shall be inserted—

"**7.** The following nucleotides may be added:

	Maximum (mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0.60	2.50
uridine 5'-monophosphate	0.42	1.75
adenosine 5'-monophosphate	0.36	1.50
guanosine 5'-monophosphate	0.12	0.50
inosine 5'-monophosphate	0.24	1.00”;

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

(i) in Schedule 2 (essential composition of follow-on formulae when reconstituted as instructed by the manufacturer)—

(i) in paragraph 2

(aa) in the first sub-paragraph following the statement of minimum and maximum amounts, after the word “casein” there shall be inserted “or breast milk”;

(bb) after the fourth such sub-paragraph there shall be inserted the following sub-paragraph—

— “For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Schedule 5.”;

(ii) in paragraph 3.1 “—fats containing more than 8% trans isomers of fatty acids” shall be deleted;

(iii) after paragraph 3.4 there shall be inserted—

“(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.”;

(iv) after paragraph 6 there shall be inserted—

“**7.** *The following nucleotides may be added:*

	Maximum (mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0.60	2.50
uridine 5'-monophosphate	0.42	1.75
adenosine 5'-monophosphate	0.36	1.50
guanosine 5'-monophosphate	0.12	0.50
inosine 5'-monophosphate	0.24	1.00”;

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

(j) in Schedule 3 (nutritional substances)—

(i) in section 2 (mineral substances), after the entry relating to Potassium, there shall be inserted—

"(Mineral substances)	(Permitted salts)
Selenium (Se)	Sodium selenate Sodium selenite"

(ii) in section 3 (amino acids and other nitrogen compounds), after the item "taurine", there shall be inserted—

"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";

(k) in Schedule 4 (compositional criteria for infant formulae, warranting a corresponding claim), after entry number 6, there shall be added—

"(Claim related to)	(Conditions warranting the claim)
7. Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen or reduced antigen properties	(a) The formulae shall satisfy the provisions laid down in paragraph 2.2 of Schedule 1 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 sensitisation, 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.";

(l) after Schedule 7 (the mineral elements in cows' milk) there shall be inserted—

"SCHEDULE 8 Regulation 5(4A)

Reference Values for Nutrition Labelling for Foods intended for Infants and Young Children

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

Transitional provision

3. In any proceedings in respect of any sale or export before 31st March 1999 which is alleged to constitute a contravention of regulation 2 or 3 of the principal Regulations the defendant shall not be convicted of an offence under regulation 10 of the principal Regulations if that sale or export would not have been a contravention of regulation 2 or 3, as appropriate, of the principal Regulations before amendment by these Regulations.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

J. R. Kearney
Assistant Secretary

14th April 1997.

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations amend the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995 (S.R. 1995 No. 85) ("the principal Regulations"), which implemented *inter alia* Commission Directive 91/321/EEC (O.J. No. L175, 4.7.91, p. 35) on infant formulae and follow-on formulae, so as to take account of amendments made to that Directive by Commission Directive 96/4/EC (O.J. No. L49, 28/2/96, p. 12).

The amendments now being made relate to the labelling of infant and follow-on formula (regulation 2, (*d*), (*e*), (*f*) and (*g*), and to compositional criteria etc. including those contained in various Schedules (regulation 2(*c*), (*h*), (*i*), (*j*) and (*k*)). A new schedule, Schedule 8 (reference values for nutrition labelling for foods intended for infants and young children), is added (regulation 2(1)).

There is an amendment to regulation 2(2) so that the sale of infant formulae or follow-on formulae which do not comply with the labelling requirements of regulation 5(4A) (inserted in the principal Regulations by these Regulations) is prohibited (regulation 2(*a*)), References to the Food (Lot Marking) Regulations (Northern Ireland) are updated (regulation 2(*b*)).

Regulation 3 contains a transitional provision which provides that it is not an offence, before 31st March 1999, to sell or export infant formulae or follow-on formulae which do not comply with the principal Regulations but which do comply with the provisions of the principal Regulations before amendment by these Regulations.

In Great Britain the corresponding Regulations are the Infant Formula and Follow-on Formula (Amendment) Regulations 1997. The Ministry of Agriculture, Fisheries and Food has prepared a compliance cost assessment in relation to those regulations and a copy of that assessment is held at Health Protection, Department of Health and Social Services, Annexe 4, Castle Buildings, Stormont, Belfast BT4 3RA from where a copy may be obtained on request.