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,

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(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—