STATUTORY RULES OF NORTHERN IRELAND

2007 No. 506

FOOD

The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007

Made - - - - 19th December 2007

Coming into operation in accordance with regulation 1

The Department of Health, Social Services and Public Safety(**1**) makes the following Regulations apart from regulations 2(5) and 24 in exercise of the powers conferred by Articles 15(1)(e), 16(1), 25(1)(a) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**2**).

The Department of Health, Social Services and Public Safety makes regulations 2(5) and 24 in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(**3**).

The Department of Health, Social Services and Public Safety has been designated for the purposes of section 2(2) of that Act in relation to measures relating to food (including drink) including the primary production of food (**4**)

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Department of Health, Social Services and Public Safety that it is expedient for any reference to an Annex to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(**5**) to be construed as a reference to that Annex as amended from time to time.

In accordance with Article 47(3A) of the Food Safety (Northern Ireland) Order 1991, the Department of Health, Social Services and Public Safety has had regard to relevant advice given by the Food Standards Agency.

There has been open and transparent public consultation during the preparation of the Regulations as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**6**).

(**1**) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.1) Article 3(6)
(**2**) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R.2004 Nos. 482 and 505
(**3**) 1972 c.68, paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51)
(**4**) S.I. 2003/2901
(**5**) OJ No. L401, 30.12.2006, p.1
(**6**) OJ No. L31, 1.2.2002, p. 1 as last amended by Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the Permanent Scientific Panels of the European Food Safety Authority (OJ No. L100, 8.4.2006, p.3), by virtue of Regulation 5 of the Food Safety (Northern Ireland) Order 1991 (Amendment) Regulations (Northern Ireland) 2004 (S.R. 2004 No.482), with effect from 7th

Citation and commencement

1.—(1) These Regulations may be cited as the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007.

(2) Subject to paragraph (3) these Regulations shall come into operation on 11th January 2008.

(3) Regulation 31(2) shall come into operation on 1st January 2010.

Interpretation

2.—(1) In these Regulations—

"the Agency" means the Food Standards Agency;

"the Directive" means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC;

"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.

"the Order" means the Food Safety (Northern Ireland) Order 1991;

(2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Order has the meaning it bears in the Order.

(3) Any expression used both in these Regulations and in the Directive has the meaning that it bears in the Directive.

(4) In these Regulations any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

(5) In these Regulations any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

(6) The Interpretation Act (Northern Ireland) 1954(**7**) shall apply to these Regulations as it applies to an Act of the Assembly.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met

3.—(1) A person shall not market infant formula which contravenes regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17 or 19.

(2) A person shall not market follow-on formula which contravenes regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 16, 18 or 19.

Prohibition on the marketing of products other than infant formula for normal healthy infants

4. A person shall not market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.

December 2004 the consultation requirement contained in Article 47(3) of the 1991 Order is disapplied in any case in which consultation is required by Article 9 of Regulation (EC) No. 178/2002

(**7**) 1954 c.33 (N.I.)

Substances in such quantity as to endanger the health of infants and young children

5. Infant formula and follow-on formula shall not contain any substance in such quantity as to endanger the health of infants and young children.

Protein sources and other food ingredients suitable for infants from birth (infant formula)

6.—(1) Infant formula shall be manufactured from—

(a) the protein sources specified in point 2 of Annex I; 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 and demonstrated in accordance with paragraph (2).

(2) Suitability shall be demonstrated through a systematic review of the available data relating to the expected benefits and safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Protein sources and other food ingredients suitable for infants aged over six months (follow-on formula)

7. Follow-on formula shall be manufactured from—

(a) the protein sources specified in point 2 of Annex II; and

(b) other food ingredients the suitability of which for particular nutritional use by infants aged over six months has been established by generally accepted scientific data and demonstrated in accordance with regulation 6(2).

Compositional criteria for infant formula

8.—(1) Subject to paragraphs (2) and (3), infant formula shall comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

(2) In the case of infant formula manufactured from those cows' milk proteins specified in point 2.1 of Annex I with a protein content between the minimum and 0.5g/100kJ (2g/100 kcal) the suitability of the infant formula for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

(3) In the case of infant formula manufactured from those protein hydrolysates specified in point 2.2 of Annex I with a protein content between the minimum and 0.56g/100kJ (2.25g/100 kcal)—

(a) the suitability of the infant formula for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and

(b) the infant formula shall be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

9. Follow-on formula shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.

Addition of water (infant formula and follow-on formula)

10. In order to make infant formula or follow-on formula ready for use nothing more shall be required than the addition of water.

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula)

11. The prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula set out respectively in Annexes I and II shall be observed.

Listed substances and their purity criteria (infant formula and follow-on formula)

12.—(1) Only the substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula in order to satisfy the requirements of Annexes I and II respectively on—

(a) mineral substances;

(b) vitamins;

(c) amino acids and other nitrogen compounds; and

(d) other substances having a particular nutritional purpose.

(2) Substances used in the manufacture of infant formula and follow-on formula pursuant to paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of paragraph (2) are—

(a) the purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive; and

(b) in the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Notification of infant formula

13. A food business operator shall not place an infant formula on the market that has not yet been placed on the market in the United Kingdom unless he has given prior notice to the Agency by forwarding to it a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

14.—(1) Subject to paragraphs (2) and (3), infant formula and follow-on formula shall not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula shall not contain any residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

(3) Infant formula and follow-on formula shall not contain any residue of a pesticide listed in Annex IX at a level exceeding the maximum residue level specified in that Annex.

(4) The levels referred to in paragraphs (1) to (3) apply in relation to infant formula or follow-on formula—

(a) manufactured as ready for consumption; or

(b) if it is not so manufactured, as reconstituted according to the manufacturers' instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this regulation shall be generally acceptable standardised methods.

Naming of infant formula

15. Infant formula may not be sold unless it is sold under the name—

(a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "infant formula"; or

(b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "infant milk".

Naming of follow-on formula

16. Follow-on formula may not be sold unless it is sold under the name—

(a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "follow-on formula"; or

(b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "follow-on milk".

Labelling of infant formula

17.—(1) Infant formula may not be sold unless the labelling bears the following particulars—

(a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;

(b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use;

(c) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use;

(d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage; and

(e) the words "Important Notice" or their equivalent 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 independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(2) The labelling of infant formula shall—

(a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding; and

(b) not contain the terms "humanised", "maternalised", "adapted" or any similar term.

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

(a) any picture of an infant; or

(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.

(4) The labelling of an infant formula may bear nutrition and health claims only when—

(a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there; and