

2007 No.

FOOD

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

Made - - - - - *2007*

Coming into operation- - *1st January 2008*

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The Department of Health, Social Services and Public Safety(a) makes the following Regulations apart from regulations 2(6) 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(b).

The Department of Health, Social Services and Public Safety makes regulations 2(6) 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(c).

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

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(e) to be construed as references to those Annexes as amended from time to time.

In accordance with section 47(3) of the Food Safety (Northern Ireland) Order 1991, the Department of Health, Social Services and Public Safety has 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(f) 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.

Citation and commencement

1. These Regulations—

- (a) may be cited as the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007;
- (b) come into operation on
 - (i) in the case of regulation 31(2), on 1st January 2010; and
 - (ii) otherwise on 1st January 2008.

(a) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.1) Article 3(6)

(b) 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

(c) 1972 c.68

(d) S.I. 2003/2901

(e) OJ No. L401, 30.12.2006, p.1

(f) OJ No. L31, 1.2.2002, p. 1 as last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3) 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 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

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(a);

“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) Notwithstanding paragraph (2) any expression used both in these Regulations and in the Directive has the meaning that it bears in the Directive.

(4) any reference in these Regulations to a district council shall be construed, so far as relating to those functions, as a reference to the district council to whom they are so assigned.

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

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

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

3.—(1) No person shall market infant formula which contravenes or fails to comply with regulations 5, 6, 8, 10, 11, 12, 14(1) to (3), 15, 17 or 19.

(2) No person shall market follow-on formula which contravenes or fails to comply with regulations 5, 7, 9, 10, 11, 12, 14(1) to (3), 16 18 or 19.

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

4. No person shall market a product or otherwise represent it 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.

Substances in such quality 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 to safety considerations as well as, where necessary, appropriate studies,

(a) OJ No. L401, 30.12.2006, p.1

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 I; 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 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 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 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. No food business operator may place an infant formula on the market that has not yet been placed on the market in the United Kingdom unless he has notified 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 pesticide 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 to the 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—

- (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 designated 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
 - (b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.
- (5) The labelling of an infant formula may bear particulars of the average quantity of nutrients mentioned in Annex III when such information is not required by paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula

- 18.**—(1) Follow-on formula may not be sold unless the labelling bears—
- (a) a statement to the effect that—
 - (i) the product is suitable only for particular nutritional use by infants over the age of six months,
 - (ii) it should form only part of a diversified diet,
 - (iii) it is not to be used as a substitute for breast milk during the first six months of life, and
 - (iv) the decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant’s specific growth and development needs;
 - (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 II 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.
- (2) The labelling of 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; and
 - (b) not contain the terms “humanised”, “maternalised”, “adapted” or any similar term.
- (3) The labelling of a follow-on formula may bear—
- (a) the average quantity of nutrients mentioned in Annex III when such information is not required by paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use; and
 - (b) in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given in that Annex, per 100 ml of the product ready for use.

Avoidance of the risk of confusion between infant formula and follow-on formula

19. Infant formula and follow-on formula shall be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow on formula.

Presentation (infant formula and follow-on formula)

20.—(1) The provisions of regulations 17(1)(e), (2), (3) and (4) and 19 shall also apply in relation to the presentation of an infant formula.

(2) The provisions of regulations 18(2) and 19 shall also apply in relation to the presentation of a follow-on formula.

(3) For the purposes of this regulation “presentation” includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Restrictions on advertising infant formula

21.—(1) No person shall advertise infant formula—

- (a) except—
 - (i) in a scientific publication, or
 - (ii) 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) where the advertisement contravenes or fails to comply with the requirements, prohibitions and restrictions set out in regulations 17(1)(e), (2), (3) and (4) and 19, in so far as they are relevant to infant formula, and paragraphs (2) and (3).

(2) Advertisements for infant formula shall only contain information of a scientific and factual nature.

(3) Information in advertisements for infant formula shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

22. No person shall advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions of regulations 18(2) and 19.

Restrictions on promotion of infant formula

23.—(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

24.—(1) No person shall produce or publish any informational or educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless that material includes clear information on all the following points—

- (a) the benefits and superiority of breast-feeding;
- (b) maternal nutrition;
- (c) the preparation for and the maintenance of breast-feeding;
- (d) the possible negative effect on breast-feeding of introducing partial bottle-feeding;
- (e) the difficulty of reversing the decision not to breast-feed; and
- (f) where needed, the proper use of an infant formula.

(2) When the material referred to in paragraph (1) contains information about the use of an infant formula it shall include information about—

- (a) the social and financial implications of its use;
- (b) the health hazards of inappropriate foods or feeding methods; and
- (c) the health hazards of improper use of infant formula.

(3) When the material referred to in paragraph (1) contains information about the use of an infant formula it shall not use any pictures which may idealise the use of infant formula.

(4) 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 of Health, Social Services and Public Safety or in accordance with guidelines drawn up by the Department of Health, Social Services and Public Safety;
- (c) the equipment and materials shall not be marked or labelled with the name of a proprietary brand of infant formula; and

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

Free or reduced rate infant formula

25. An institution or organisation which receives any infant formula free or at a reduced rate shall —

- (a) if that infant formula is for use in the institution or organisation only use it for infants who have to be fed on infant formula and only for as long as required by those infants; or
- (b) if that infant formula is for distribution outside the institution or organisation only distribute it for infants who have to be fed on infant formula and only for as long as required by those infants.

Export of infant formula to third countries

26.—(1) No person shall export to a third country any infant formula which contravenes or fails to comply with the requirements, prohibitions and restrictions set out in—

- (a) regulations 5, 6, 8, 10, 11 12, 14(1) to (3), 17 or 19;
- (b) the Codex Standard for Infant Formula established by the Codex Alimentarius^(a);
- (c) The Food (Lot Marking) Regulations (Northern Ireland) 1996^(b).

(2) No person shall export to a third country a product represented as suitable for satisfying by itself the nutritional requirements of normal health infants during the first four to six months of life unless that product is infant formula.

Export of follow-on formula to third countries

27. No person shall export to a third country any follow-on formula which contravenes or fails to comply with the requirements, prohibitions and restrictions set out in—

- (a) regulations 5, 7, 9, 10, 12, 14(1) to (3), 18 or 19;
- (b) the Codex Standard for Follow-up Formula established by the Codex Alimentarius^(c);
- (c) The Food Lot Marking Regulations (Northern Ireland) 1996.

Offences and enforcement

28.—(1) If any person contravenes or fails to comply with regulation 3, 4, 13, 21(1), 22, 23, 24, 25, 26 or 27 he shall be guilty of an offence and shall be liable on summary conviction to a fine at not exceeding level 5 on the standard scale.

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

Application of various sections of the Food Safety (Northern Ireland) Order 1991

29.The following provisions of the Order shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Order or Part thereof shall be construed as a reference to these Regulations—

- (a) Article 4 (presumption that food intended for human consumption);
- (b) Article 19 (offences due to fault of another person);
- (c) Article 20 (defence of due diligence), with the modifications that paragraphs (2) to (4) shall apply in relation to an offence under regulation 28 consisting of a contravention of or failure to comply with regulation 3, 4 or 13 as they apply in relation to an offence under Article 13 or 14 and that in paragraph (4)(b) the references to “sale or intended

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

(b) S.R. 1996 No. 384

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

sale” shall be deemed to be references to “marketing or as the case may be placing on the market”;

- (d) Article 30(8) (which relates to documentary evidence);
- (e) Article 34(1) (obstruction etc. of officers);
- (f) Article 34(2), with the modification that the reference to “any such requirement as is mentioned in paragraph (1)(b)” shall be deemed to be a reference to any such requirement as is mentioned in Article 34(1)(b) as applied by sub-paragraph (e);
- (g) Article 36(1) (punishment of offences), in so far as it relates to offences under Article 34(1) as applied by sub-paragraph (e);
- (h) Article 36(2) and (3), in so far as it relates to offences under Article 34(2) as applied by sub-paragraph (f);
- (i) Article 43 (protection of public analyst acting in good faith).

Amendment of the Medical Food Regulations (Northern Ireland) 2000

30.—(1) The Medical Food Regulations (Northern Ireland) 2000(a) are amended in accordance with paragraph (2).

(2) In regulation 2 (interpretation), for the definition “the Directive” there is substituted the following—

“the Directive” means Commission Directive 1999/21/EC on dietary foods for special medical purposes(b) as amended by—

the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and Slovak Republic and the adjustments to the Treaties on which the European Union is founded(c);

Commission Directive 2006/82/EC adapting Directive 91/321 on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania(d); and

Commission Directive 2006/141 on infant formulae and follow-on formulae and amending Directive 1991/21/EC(e).

Revocation

31.—(1) Regulations 5, 6, 7, 17, 18, 19, 20 and 21 of the 1995 Regulations are revoked.

(2) The 1995 Regulations are revoked in so far as they apply in relation to England.

(3) No person commits an offence under regulation 28(1) consisting of a contravention of or a failure to comply with—

- (a) regulation 3(1), where there is no contravention of or failure to comply with regulation 2(a) of the 1995 Regulations;
- (b) regulation 3(2), where there is no contravention of or failure to comply with regulation 3 of the 1995 Regulations; and
- (c) regulation 4, where there is no contravention of or failure to comply with regulation 2(b) of the 1995 Regulations.

(4) The 1995 Regulations are amended in so far as they apply in relation to England in accordance with paragraph (5).

(a) S.R. 2000 No.187; relevant amendment regulation is S.R. 2007 No. [the miscellaneous amendments regulation)

(b) OJ No. L91, 7.4.99, p.29

(c) OJ No. L236, 23.9.2003, p.33

(d) OJ No. L362, 20.12.2006, p.94

(e) OJ No. L401, 30.12.2006, p.1

(5) The following paragraph is added at the end of regulation 22 (offences and enforcement) of the 1995 Regulations—

“(4) No person commits an offence under paragraph (1) consisting of a contravention of or a failure to comply with—

- (a) regulation 2(a), where there is no contravention of or failure to comply with regulation 3(1) of the 2007 Regulations;
- (b) regulation 2(b), where there is no contravention of or failure to comply with regulation 4 of the 2007 Regulations; and
- (c) regulation 3, where there is no contravention of or failure to comply with regulation 3(2) of the 2007 Regulations.

(5) In this regulation “the 2007 Regulations” means the Infant Formula and Follow-on Formula (England) Regulations 2007.”.

(6) In this regulation “the 1995 Regulations” means the Infant Formula and Follow-on Formula Regulations 1995(a).

32. [DN saving until 2009 – Article 18]

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 0th Month 2007.



A Name

A senior officer of the Department of Health, Social Services and Public Safety

(a) S.R. 1995 No. 85, amended by S.R. 1997 No.213, S.R. 2000 No.235, S.R. 2003 No.529, S.R. 2006 No.2 and S.R. 2007/[miscellaneous amendments S.I.].