

**2007 No. 3521**

**FOOD, ENGLAND**

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

*Made* - - - - *13th December 2007*

*Laid before Parliament* *20th December 2007*

*Coming into force in accordance with regulation 1*

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The Secretary of State makes the following Regulations apart from regulations 2(6) and 24 in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b).

The Secretary of State makes regulations 2(6) and 24 in exercise of the powers conferred on him by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(c).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 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 Secretary of State 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 a reference to that Annex as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has had regard to relevant advice given by the Food Standards Agency.

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(f) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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- (a) 1990 c.16 section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.
  - (b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.
  - (c) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).
  - (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 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).

## **Title, commencement and application**

### **1. These Regulations—**

- (a) may be cited as the Infant Formula and Follow-on Formula (England) Regulations 2007;
- (b) come into force—
  - (i) in the case of regulation 31(2), on 1st January 2010; and
  - (ii) otherwise, on 11th January 2008; and
- (c) apply in relation to England only.

## **Interpretation**

### **2.—(1) In these Regulations—**

“the Act” means the Food Safety Act 1990;

“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;

“food authority” has the meaning that it bears by virtue of section 5(1) of the Act, except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple); and

“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.

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

(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) Where any functions under the Act are assigned—**

- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(a), to a port health authority;
- (b) by an order under section 6 of the Public Health Act 1936(b), to a joint board for a united district; or
- (c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985(c), to a single authority for a metropolitan county,

any reference in these Regulations to a food authority shall be construed, so far as relating to those functions, as a reference to the authority 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 regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17 or 19.

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

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(a) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c.16).

(b) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(c) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

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

4. No person shall 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.

#### **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. 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 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 manufacturer's 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

- (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 the following particulars—

- (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; and
- (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 particulars of—

- (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) unless the advertisement complies with the provisions of regulation 17(1)(e), (2), (3) and (4), regulation 19 and paragraph (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 regulation 18(2) or 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 informational and educational material dealing with the feeding of infants**

**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 Secretary of State or in accordance with guidelines drawn up by the Secretary of State;
- (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 —

- (a) regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 17 or 19;
- (b) the Codex Standard for Infant Formula established by the Codex Alimentarius<sup>(a)</sup>; or
- (c) the Food (Lot Marking) Regulations 1996<sup>(b)</sup>.

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

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(a) Codex Stan 72-1981, volume 4, Codex Alimentarius, 1981.

(b) S.I. 1996/1502.

### **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 —

- (a) regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 18 or 19;
- (b) the Codex Standard for Follow-up Formula established by the Codex Alimentarius<sup>(a)</sup>; or
- (c) the Food (Lot Marking) Regulations 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 not exceeding level 5 on the standard scale.

(2) Each food authority shall enforce and execute these Regulations within its area.

### **Application of various sections of the Food Safety Act 1990**

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

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence)<sup>(b)</sup>, with the modifications that subsections (2) to (4) shall apply in relation to an offence under regulation 28 consisting of a contravention of or a failure to comply with regulation 3, 4 or 13 as they apply in relation to an offence under section 14 or 15 and that in subsection (4)(b) the references to “sale or intended sale” shall be deemed to be references to “marketing or as the case may be placing on the market”;
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 33(1) (obstruction etc. of officers);
- (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences)<sup>(c)</sup>, in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)<sup>(d)</sup>, in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships)<sup>(e)</sup>; and
- (k) section 44 (protection of officers acting in good faith).

### **Amendment of the Medical Food (England) Regulations 2000**

30.—(1) The Medical Food (England) Regulations 2000<sup>(f)</sup> are amended in accordance with paragraph (2).

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(a) Codex Stan 156-1987, volume 4, Codex Alimentarius, 1987.

(b) Section 21 was amended by S.I. 2004/3279.

(c) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.

(d) Section 35(3) was amended by S.I. 2004/3279.

(e) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.

(f) S.I. 2000/845, amended by S.I. 2004/2145 and S.I. 2007/2591; there are other amending instruments but none is relevant.

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

““the Directive” means Commission Directive 1999/21/EC on dietary foods for special medical purposes<sup>(a)</sup> 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 the Slovak Republic and the adjustments to the Treaties on which the European Union is founded<sup>(b)</sup>;

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<sup>(c)</sup>; and

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

### **Revocation and transitional arrangements**

**31.**—(1) Regulations 4, 5, 6, 7, 13, 14, 14A, 15, 16, 17, 18, 19, 20 and 21 of the 1995 Regulations are revoked in so far as they apply in relation to England.

(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—

(i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes or fails to comply with regulation 5, 6, 8, 10, 11, 12 or 14 (1), (2) or (3), and

(ii) there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 2(a)(i) or (ii) of those Regulations;

(b) regulation 3(2), where—

(i) the action that would otherwise constitute the offence consists of marketing follow-on formula which contravenes or fails to comply with regulation 5, 7, 9, 10, 11, 12 or 14 (1), (2) or (3), and

(ii) there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 3 (a) or (b) of those Regulations; or

(c) regulation 4, where there is no offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 2(b)(i) or (ii) of those Regulations.

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

(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—

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

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

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

- (a) regulation 2(a)(i) or (ii), where there is no offence under regulation 3(1) of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 6, 8, 10, 11, 12 or 14 (1), (2) or (3) of those Regulations;
- (b) regulation 2(b)(i) or (ii), where there is no offence under regulation 4 of the 2007 Regulations; or
- (c) regulation 3(a) or (b), where there is no offence under regulation 3(2) of the 2007 Regulations consisting of a contravention of or a failure to comply with regulation 5, 7, 9, 10, 11, 12 or 14 (1), (2) or (3) of those 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<sup>(a)</sup>.

Signed by authority of the Secretary of State for Health

*Dawn Primarolo*  
Minister of State,  
Department of Health

13th December 2007

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(a) S.I. 1995/77, amended by S.I. 1997/451, S.I. 2000/1509, S.I. 2003/3208, S.I. 2005/2626 and S.I. 2007/2591.

## EXPLANATORY NOTE

*(This note is not part of the Order)*

1. These Regulations, which apply in relation to England only, give effect there to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ No. L401, 30.12.2006, p.1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (OJ No. L179, 1.7.1992, p.129).

2. These Regulations made provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (1972 c.68)) and references to an Annex to Directive 2006/141/EC are to be construed as references to that Annex as amended from time to time (*regulation 2(6)*).

3. These Regulations—

- (a) prohibit marketing of infant formula and follow-on formula which contravenes or fails to comply with specified regulations (*regulation 3*);
- (b) prohibit marketing or otherwise representing 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 (*regulation 4*);
- (c) provide that infant formula and follow-on formula may not contain any substance in such quantity as to endanger the health of infants and young children (*regulation 5*);
- (d) provide that infant formula must be manufactured from specified protein sources and other suitable food ingredients (*regulation 6*);
- (e) provide that follow-on formula must be manufactured from specified protein sources and other suitable food ingredients (*regulation 7*);
- (f) provide that infant formula must comply with specified compositional criteria (*regulation 8*);
- (g) provide that follow-on formula must comply with specified compositional criteria (*regulation 9*);
- (h) provide that in order to make infant formula or follow-on formula ready for use nothing more shall be required than the addition of water (*regulation 10*);
- (i) provide that the use of food ingredients in infant formula and follow-on formula must observe specified prohibitions and limitations (*regulation 11*);
- (j) provide that only specified substances may be used in the manufacture of infant formula and follow-on formula in order to satisfy specified requirements of Directive 2006/141/EC and that those substances must meet specified purity criteria (*regulation 12*);
- (k) prohibit a food business operator placing an infant formula on the market that has not yet been placed on the market in the United Kingdom unless that food business operator has given prior notice to the Food Standards Agency (*regulation 13*);
- (l) provide that infant formula and follow-on formula may not contain pesticide residues above specified levels (*regulation 14*);
- (m) provide that infant formula may only be sold under certain names (*regulation 15*);
- (n) provide that follow-on formula may only be sold under certain names (*regulation 16*);
- (o) provide for the labelling of infant formula (*regulation 17*);
- (p) provide for the labelling of follow-on formula (*regulation 18*);
- (q) provide that infant formula and follow-on formula must be labelled to make a clear distinction between such products so as to avoid any risk of confusion between them (*regulation 19*);
- (r) apply the provisions of specified regulations to the presentation of infant formula and follow-on formula (*regulation 20*);

- (s) prohibit advertising of infant formula except in specified publications and unless the advertisement complies with the provisions of specified regulations (*regulation 21(1)*);
- (t) impose restrictions on the content of advertisements for infant formula (*regulation 21(2) and (3)*);
- (u) prohibit advertising of follow-on formula where the advertisement contravenes or fails to comply with the provisions of specified regulations (*regulation 22*);
- (v) impose restrictions on the promotion of infant formula (*regulation 23*);
- (w) impose restrictions on the production or publication of informational or educational material dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children (*regulation 24(1), (2) and (3)*);
- (x) prohibit donation of informational or educational equipment or materials by manufacturers or distributors of infant formula unless certain conditions are met (*regulation 24(4)*);
- (y) impose restrictions on what an institution or organisation may do with infant formula that it has received free or at a reduced rate (*regulation 25*);
- (z) prohibit export to a third country of infant formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marking) Regulations 1996 (S.I. 1996/1502) (*regulation 26(1)*);
- (aa) prohibit export to a third country of a product represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life unless that product is infant formula (*regulation 26(2)*);
- (bb) prohibit export to a third country of follow-on formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marking) Regulations 1996 (*regulation 27*);
- (cc) provide that a person who contravenes or fails to comply with specified regulations is guilty of an offence and provide a penalty for contravening or failing to comply with those regulations (*regulation 28(1)*);
- (dd) provide that each food authority must enforce and execute these Regulations within its area (*regulation 28(2)*);
- (ee) apply specified provisions of the Food Safety Act 1990 (1990 c.16) with modifications (*regulation 29*);
- (ff) amend the Medical Food (England) Regulations 2000 (S.I. 2000/845) (*regulation 30*); and
- (gg) revoke the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77) in so far as they apply in relation to England (S.I. 1995/77 extends to the whole of Great Britain) and provide transitional arrangements with regard to S.I. 1995/77 (*regulation 31*).

4. A full regulatory impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Nutrition Division of the Food Standards Agency, Aviation House, 125 Kingsway, London, WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

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STATUTORY INSTRUMENTS

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**2007 No. 3521**

**FOOD, ENGLAND**

The Infant Formula and Follow-on Formula (England)  
Regulations 2007

**£3.00**

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