
 STATUTORY INSTRUMENTS

2007 No.

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

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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⁽¹⁾ and now vested in him⁽²⁾.

The Secretary of State makes regulations 2(6) and 24 in exercise of the powers conferred on her by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972⁽³⁾.

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⁽⁴⁾.

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⁽⁵⁾ 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⁽⁶⁾ there has

⁽¹⁾ 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.

⁽²⁾ 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.

⁽³⁾ 1972 c.68.

⁽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

been open and transparent public consultation during the preparation and evaluation of these Regulations.

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 1st January 2008;
- (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⁽⁷⁾, to a port health authority;
- (b) by an order under section 6 of the Public Health Act 1936⁽⁸⁾, 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⁽⁹⁾, 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.

number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L100, 8.4.2006, p.3).

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

⁽⁸⁾ 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

⁽⁹⁾ 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 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) to (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) 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 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;
 - (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; or

(b) where the advertisement contravenes or fails to comply with the provisions of regulation 17(1)(e), (2), (3) or (4), regulation 19 or paragraph (2) or (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 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 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) to (3), 17 or 19;
- (b) the Codex Standard for Infant Formula established by the Codex Alimentarius⁽¹⁰⁾;
- (c) The Food (Lot Marking) Regulations 1996⁽¹¹⁾.

⁽¹⁰⁾ Codex Stan 72-1981, volume 4, Codex Alimentarius, 1981.

⁽¹¹⁾ S.I. 1996/1502.

(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 —

- (a) regulation 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⁽¹²⁾;
- (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)⁽¹³⁾, with the modifications that subsections (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 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)⁽¹⁴⁾, in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)⁽¹⁵⁾, 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)⁽¹⁶⁾; and
- (k) section 44 (protection of officers acting in good faith).

⁽¹²⁾ Codex Stan 156-1987, volume 4, Codex Alimentarius, 1987.

⁽¹³⁾ Section 21 was amended by S.I. 2004/3279.

⁽¹⁴⁾ Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.

⁽¹⁵⁾ Section 35(3) was amended by S.I. 2004/3279.

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

Amendment of the Medical Food (England) Regulations 2000

30.—(1) The Medical Food (England) Regulations 2000⁽¹⁷⁾ are amended in accordance with paragraph (2).

(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⁽¹⁸⁾ 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⁽¹⁹⁾;

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⁽²⁰⁾; 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 5, 6, 7, 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 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).

(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.

⁽¹⁷⁾ S.I. 2000/845, amended by S.I. 2007/[miscellaneous amendments SI]; there are other amending instruments but none is relevant. relevant amendment instrument is S.I. 2007/[miscellaneous amendments SI].

⁽¹⁸⁾ OJ No. L91, 7.4.99, p.29.

⁽¹⁹⁾ OJ No. L236, 23.9.2003, p.33.

⁽²⁰⁾ OJ No. L362, 20.12.2006, p.94.

(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⁽²¹⁾.

⁽²¹⁾ 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/[miscellaneous amendments S.I.].

PARTIAL REGULATORY IMPACT ASSESSMENT

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

Implementing

COMMISSION DIRECTIVE 2006/141/EC ON INFANT FORMULAE AND FOLLOW-ON FORMULAE AND AMENDING DIRECTIVE 1999/21/EC AND COUNCIL DIRECTIVE 92/52/EEC ON INFANT FORMULA AND FOLLOW-ON FORMULA INTENDED FOR EXPORT TO THIRD COUNTRIES

[Please note that in this partial Regulatory Impact Assessment (RIA) we ask stakeholders questions and request information to help the Agency estimate the impact of implementing the Regulations.

The finalised RIA will estimate the cost and impact of implementing the proposed Regulations as compared to the cost of maintaining the previous UK Regulations]

2. Purpose and intended effect of the Regulations

Objective

2.1 These regulations, referred to as 'the Regulations' for the purposes of this RIA, will implement a European Commission Directive on infant formulae and follow-on formulae which consolidates existing Community legislation on the composition, labelling and marketing of infant formulae and follow-on formulae. The Directive reflects the latest scientific advice on the essential composition of infant formulae and follow-on formulae and discussions at an international level in the Codex Alimentarius forum and gives effect to the WHO Code on the Marketing of Breastmilk Substitutes. These Regulations also implement Council Directive 92/52/EEC.

- **Background**

2.2 European Community controls on the composition and labelling of infant formulae and follow-on formulae were introduced in 1991 through Commission Directive 91/321/EEC which also introduced restrictions on the marketing of infant formulae. Directive 91/321/EEC was amended by Directives 96/4/EC, 1999/50/EC, Directive 2003/14/EC and two recent Acts concerning the accession of new Member States. Council Directive 92/52/EEC also laid down rules regarding the export of infant formula and follow-on formula to third countries.

2.3 In Great Britain these Directives were implemented by the Infant Formula and Follow-on Formula Regulations 1995 (SI 1995/77), the 1997 Great Britain wide amendment and separate but parallel amending Regulations for England, Scotland and Wales made in 2000 and 2003.

Northern Ireland has similar legislation. This legislation is referred to as the 'previous Regulations' for the purposes of this RIA.

2.4 Directive 91/321/EC (referred to as the 'previous Directive') has been recently repealed (with its amending Directives) and replaced by Directive 2006/141/EC (referred to as 'the Directive'). In summary, the Directive seeks to ensure that:

- the essential composition of infant formulae and follow-on formulae satisfy the nutritional requirements of infants in good health as established by generally-accepted scientific data;
- the labelling of infant formulae and follow-on formulae allows the proper use of such products and promotes and protects breastfeeding;
- the rules on composition, labelling and advertising are in line with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ("the Code");
- Information provided to carers about infant feeding does not counter the promotion of breastfeeding.

2.5 These aims are given effect by the main provisions of the Directive which provide for:

- a general requirement that no product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal, healthy infants during the first months of life until the introduction of complementary feeding;
- a general requirement that infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children;
- detailed requirements for the essential composition of infant formulae and follow-on formulae;
- a general limit on the level of any individual pesticide residue that may be present in infant formulae and follow-on formulae and specific lower limits for a few very toxic pesticides;
- mandatory and non-mandatory particulars for the labelling of infant formulae and follow-on formulae;
- the requirements for the labelling of infant formula and follow-on formula to also apply to presentation and advertising;
- restrictions on the nutrition and health claims that can be made in relation to infant formulae;
- the labelling, presentation and advertising of infant formula and follow-on formula to avoid any risk of confusion by the consumer between these two categories of products;
- restrictions on the advertising of infant formulae;
- the provision of information on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition.

3. Provisions of the Regulations

3.1 This section:

- sets out the detailed provisions of the Regulations;

- highlights the significant changes between the Regulations and the previous Regulations;
- notes the Articles of the Directive which each Regulation implements;
- requests information from stakeholders to help finalise the RIA, or guide the drafting of the Agency Guidance Notes which will complement these Regulations. The Agency will publish a draft of the Guidance Notes for consultation before 1 January 2008; and
- where appropriate, sets out the Agency view on the scope for action within the domestic Regulations in the light of the European legislative framework which applies to foods for particular nutritional uses (defined as ‘parnuts’ foods for the purposes of this RIA).

Title, commencement and application (regulation 1)

3.2 This regulation notes:

- that the Regulations may be cited as the “Infant Formula and Follow-on Formula (England) Regulations 2007”
- the coming into force dates of the various provisions
- that the Regulations apply in England only.

Parallel Regulations will apply in Scotland, Wales and Northern Ireland.

Interpretation (regulation 2; implements Article 2 of the Directive)

3.3 Regulation 2(1) provides certain definitions.

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

3.5 Regulation 2(3) provides that any expression used in the Regulations and in the Directive has the meaning that it bears in the Directive.

- The definitions of the following terms included in the Directive will apply for the purposes of the Regulations: ‘Infants’, ‘Young children’, ‘Infant formulae’, ‘Follow-on formulae’, ‘Formulae’, ‘Pesticide residue’.
- The definitions of the following terms included in Regulation (EC) No. 1924/2006 (the European Nutrition and Health Claims Regulation) will apply for the purposes of the Regulations: ‘Claim’, ‘Nutrition claim’, ‘Health claim’, ‘Reduction of disease risk claim’.
- The terms ‘Member State’ and ‘third country’ have the meaning they have in the Directive. Thus, a Member State is country which is part of the European Union. A Third Country is any country which is not part of the European Union.
- The term “advertisement” has not been defined in the Regulations (a definition was given in the previous Regulations). The term “advertising” is used in the Directive but is not defined. The term, when used in the Regulations, will have the same meaning as in the Directive. It is considered that any attempt to define the term runs the risk of limiting its scope bearing in mind the wide range of forms that advertising has taken in recent years. The Agency will provide further guidance about what may constitute ‘advertising’ in its Guidance Notes.

The Agency would welcome stakeholders views and supporting evidence on what should be considered as ‘advertising’ for the purposes of these Regulations.

- The term ‘sell’ has not been defined (the previous Regulations provided a definition of the term ‘sell’). The term, when used in the Regulations, will have the same meaning as in the Directive.
- Wording to reflect the meaning given to the term ‘presentation’ in Article 13(1) of the Directive is included in the Regulations at regulation 20(3).

3.6 The Regulations do not include Schedules, as in the previous Regulations, which repeat the Annexes to the Directive. Instead, the Regulations cross refer to the Annexes of the Directive (see regulation 2(5)).

3.7 Regulation 2(6) provides that the Regulations will refer ‘automatically’ to the amended Annexes to the Directive without the need to introduce a new amending S.I. each time the Annexes to the Directive are updated. However, the Regulations will have to be amended using a new S.I. if the main Articles of the Directive are updated.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met (regulation 3; implements Article 3, paragraph 1 of the Directive)

- 3.8 This regulation provides that no person shall:
- market infant formula which contravenes or fails to comply with the relevant provisions in the Regulations relating to its composition (regulations 6, 8, 11, 12), naming and labelling (regulations 15 and 17), preparation instructions (regulation 10), safety (regulation 5), pesticide residue levels (14), presentation (regulation 20, applying regulation 17) and risk of confusion with follow-on formula (regulation 19).
 - market follow-on formula which contravenes or fails to comply with the relevant provisions in the Regulations relating to its composition (regulations 7, 9, 11, 12), naming and labelling (16 and 18), preparation instructions (regulation 10) safety (regulation 5), pesticide residue levels (14), presentation (regulation 20, applying regulation 18) and risk of confusion with infant formula (regulation 19).

Prohibition on the marketing of products other than infant formula for normal healthy infants (regulation 4; implements Article 3, paragraph 2 of the Directive)

3.9 Regulation 4 provides that 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 quantity as to endanger the health of infants and young children (regulation 5; implements Article 4 of the Directive)

3.10 Regulation 5 provides that infant formula and follow-on formula shall not contain any substance in such quantity as to endanger the health of infants and young children. This obligation applies even if the substances are not regulated by other legislation. More general food law (such as the Food Hygiene (England) Regulations 2006 (S.I. 2006/14)) also applies to infant formula.

Protein sources and other food ingredients suitable for infants from birth (infant formula) (regulation 6; implements Article 5 of the Directive)

3.11 Regulation 6(1) provides that infant formula shall be manufactured from:

- the protein sources specified in point 2 of Annex I to the Directive, namely cow's milk protein, protein hydrolysates (either fully or partially hydrolysed) and soya²² protein isolates, either alone or in a mixture with cow's milk proteins; and
- other 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 regulation 6(2).

3.12 Regulation 6(2) provides that suitability of ingredients used in infant formula 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) (regulation 7; implements Article 6 of the Directive)

3.13 Regulation 7 provides that follow-on formula shall be manufactured from:

- the protein sources specified in point 2 of Annex II to the Directive, namely cow's milk protein, protein hydrolysates (either fully or partially hydrolysed) and soya¹ protein isolates, either alone or in a mixture with cow's milk proteins; and
- Other 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 regulation 6(2).

²² Advice has been issued by the Chief Medical Officer of the Department of Health on the use of soya-based formulas (CMO Update 37, page 2, Feb 2004):
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/CMOupdate/DH_4070172

Compositional criteria for infant formula (regulation 8; implements Article 7(1) of the Directive)

3.14 Regulation 8(1) provides that, subject to paragraphs (2) and (3), infant formula shall comply with the compositional criteria set out in Annex I (i.e. essential composition relating to energy, proteins, taurine, choline, lipids, phospholipids, inositol, carbohydrates, fructo-oligosaccharides and galacto-oligosaccharides, mineral substances, vitamins and nucleotides), taking into account the specifications in Annex V (relating to the indispensable and conditionally indispensable amino acids in breast milk).

3.15 Regulation 8(2) provides that for infant formula manufactured from cows' milk proteins (i.e. those formulae 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 particular nutritional use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants 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.

3.16 Regulation 8(3) provides that 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 particular nutritional use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants 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.

3.17 The addition of any substance to infant formula can be made mandatory only if the substance is added to the relevant section of Annex I of the Directive. This would require the assent of the Standing Committee on the Foodchain and Animal Health (SCoFAH)²³ after the European Food Safety Authority (EFSA)²⁴ had been consulted appropriately.

3.18 A summary of the differences between Annex I to the Directive and Annex I to the previous Directive is included at Appendix I.

Compositional criteria for follow-on formula (regulation 9; implements Article 7(2) of the Directive)

3.19 Regulation 9 provides that follow-on formula shall comply with the compositional criteria set out in Annex II (i.e. essential composition relating to energy, proteins, taurine, lipids, phospholipids, carbohydrates, fructo-

²³ http://ec.europa.eu/food/committees/regulatory/index_en.htm

²⁴ <http://www.efsa.europa.eu/en.html>

oligosaccharides and galacto-oligosaccharides, mineral substances, vitamins and nucleotides), taking into account the specifications in Annex V (relating to the indispensable and conditionally indispensable amino acids in breast milk).

3.20 The addition of any substance to follow-on formula can be made mandatory only if the substance is added to the relevant section of Annex II of the Directive. This would require the assent of the SCoFCAH after the EFSA had been consulted appropriately.

3.21 A summary of the differences between Annex II to the Directive and Annex II to the previous Directive is included at Appendix II.

Addition of water (infant formula and follow-on formula) (regulation 10; implements Article 7(3) of the Directive)

3.22 Regulation 10 provides that 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) (regulation 10; implements Article 7(4) of the Directive)

3.23 The regulation provides that the prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula set out in Annexes I and II, as the case may be, shall be observed.

Listed substances and their purity criteria (infant formula and follow-on formula) (regulation 12; implements Article 8 of the Directive)

3.24 Regulation 12(1) provides that 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 Annex I on mineral substances, vitamins, amino acids and other nitrogen compounds; and other substances having a particular nutritional purpose.

3.25 Regulation 12(2) provides that substances used in the manufacture of infant formula and follow-on formula pursuant to regulation 12(1) must meet the relevant purity criteria.

3.26 Regulation 12(3) provides that for the purposes of regulation 12(2), the relevant purity criteria 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. (The EU Directives that lay down specific purity criteria for substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive, are Commission Directive 95/45/EC (purity criteria concerning colours for use in foodstuffs) and Commission Directive 96/77/EC (specific purity criteria on food additives other than colours and

sweeteners). These Directives are implemented into domestic legislation by the Colours in Food Regulations 1995 (S.I. 1995 No. 3124) and the Miscellaneous Food Additives Regulations 1995 (S.I. 1995 No. 3187) respectively.)

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

Notification of infant formula (regulation 13; implements Article 9 of the Directive)

3.27 The regulation provides that 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.

3.28 The Agency will publish draft guidance about the specific conditions under which notification is required before 1 January 2008. The guidance will state that:

- From 1 January 2008 onwards, notification will be required in the following cases:
 - On marketing of a new brand of infant formula with a new composition.
 - On marketing of a re-formulated brand of infant formula where the original formulation of the brand was marketed before 1 January 2008.
 - On marketing of a re-formulated brand of infant formula where the original formulation of the brand was placed on the market and notified to the Agency on or after 1 January 2008.
- Notification will not be required for:
 - Brands placed on the market before 1 January 2008.
 - follow-on formula.
- The manufacturer or importer of the infant formula will be responsible for notifying the Agency. Wholesalers, intermediary companies involved in the distribution of infant formula or retailers do not have to notify the Agency when placing an infant formula on the market.
- Notifying businesses will be required to submit their notification to the relevant FSA office within their Region (FSA, FSA Scotland, FSA Wales or FSA Northern Ireland).

3.29 The Agency will provide a form that stakeholders may wish to use when notifying the Agency of the marketing of an infant formula. A draft of the form is included in Appendix III (the form will be finalised and published by the Agency before 1st January 2008). This notification procedure will be analogous to the notification procedure required on marketing of 'Article 9' parnuts foods and foods for special medical purposes (FSMPs).

Stakeholders are invited to comment on the proposed notification procedure and on the format of the proposed notification form in Appendix III. Stakeholders may wish to propose alternative notification methods which still fulfil the requirements of the Directive.

Pesticide residues (infant formula and follow-on formula) (regulation 14; implements Article 10 of the Directive)

3.30 Regulation 14(1) provides that, 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.

3.31 Regulation 14(2) provides that infant formula and follow shall not contain any pesticide residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

3.32 Regulation 14(3) provides that 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.

3.33 Regulation 14(4) provides that 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.

3.34 Regulation 14(5) provides that the analytical methods for determining levels of pesticide residues for the purposes of this regulation shall be generally acceptable standardised methods.

Naming of infant formula (regulation 15; implements the provisions of Article 11 which apply to the English names for infant formula and infant milk)

3.35 The regulation provides that infant formula may not be sold unless it is sold under the name of 'infant formula', in the case of a product which is not manufactured entirely from cow's milk proteins, and 'infant milk' in the case of a product which is manufactured entirely from cows' milk proteins.

Naming of follow-on formula (regulation 16; implements the provisions of Article 12 which apply to the English names for follow-on formula and follow-on milk)

3.36 The regulation provides that follow-on formula may not be sold unless it is sold under the name of 'follow-on formula', in the case of a product which is not manufactured entirely from cow's milk proteins, and 'follow-on milk' in the case of a product which is manufactured entirely from cows' milk proteins.

Labelling of infant formula (regulation 17; implements the paragraphs of Article 13 which are relevant to infant formula)

3.37 Regulation 17(1) provides that 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 100 ml of the product ready for use;
- c) the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100 ml 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 storage²⁵.
- 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.

3.38 Regulation 17(2) provides that the labelling of infant formula shall 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.

3.39 Regulation 17(3) provides that 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.

3.40 The Agency will produce Guidance Notes about the interpretation of the term 'idealise' as it applies to these Regulations.

The Agency would welcome stakeholders views and supporting evidence on the interpretation of the term 'idealise' for the purposes of these Regulations.

²⁵ Further information about the labelling of formula as 'non-sterile' is detailed in Appendix IV.

3.41 Regulation 17(4) provides that 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.

3.42 The labelling of infant formulae may bear nutrition and health claims only in the cases listed in Annex IV of the Directive, and in accordance with the conditions set out therein. Annex IV contains 'positive lists' of permitted nutrition and health claims that can be used in relation to infant formula, provided that the formula meets the conditions warranting the use of the claims. New claims could be added to the lists only with the assent of the SCoFCAH. Should the SCoFCAH be requested to consider a new claim, the Commission have stated that "*with respect to modifications of the list of authorised claims for infant formula the EFSA would be consulted on claims that were likely to have an impact on public health.*"²⁶

3.43 Regulation 17(5) provides that 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 17(1)(c) expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula (regulation 18; implements the paragraphs of Article 13 which are relevant to follow-on formula)

3.44 Regulation 18(1) provides that 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;

²⁶ Statement to the minutes of the 19th July 2006 Standing Committee on the Food Chain and Animal Health,
http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/summary21_en.pdf

- (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.

3.45 Regulation 18(2) provides that 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.

3.46 Regulation 18(3) provides that 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.
- (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 (regulation 19; implements Article 13(7) of the Directive)

3.47 This regulation provides that infant formula and follow-on formula shall be labelled in such a way that it enables consumers to make a clear distinction between these types of products so as to avoid any risk of confusion between infant formula and follow on formula.

3.48 Guidance on the interpretation of this regulation will be included in the Agency Guidance Notes.

The Agency would welcome suggestions about how manufacturers can ensure that infant formula and follow on formula are packaged, presented and advertised in a way which avoids any risk of confusion between them. These suggestions will be considered by the Agency when the guidance on this regulation is drafted.

Presentation (infant formula and follow-on formula) (regulation 20; implements Article 13(8) of the Directive)

3.49 Regulation 20(1) provides that the requirements, prohibitions and restrictions listed below will apply in relation to the presentation of infant formula:

- The ‘Important Notice’ requirements (regulation 17(1)(e)).
- The requirements relating to the appropriate use of the product so as not to discourage breastfeeding (regulation 17(2)(a)).

- The prohibitions on the use of the terms ‘humanised’, ‘maternalised’, ‘adapted’ or any similar term (regulation 17(2)(b)).
- The prohibitions on the use of any pictures of infants or any other picture which may idealise the use of the product (regulation 17(3)), but may include graphic representations for easy identification of the product or for illustrating methods of preparation.
- The conditions of use of nutrition and health claims relating to infant formula (regulation 17(4)).
- The requirement to ensure that infant formula shall be presented in such a way that it enables consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion between them (regulation 19).

3.50 Regulation 20(2) provides that the requirements, prohibitions and restrictions listed below shall also apply in so far as they are relevant to the presentation of follow-on formula:

- The requirements relating to the appropriate use of the product so as not to discourage breastfeeding (regulation 18(2)(a)).
- The prohibitions on the use of the terms ‘humanised’, ‘maternalised’, ‘adapted’ or any similar term (regulation 18(2)(b)).
- The requirement to ensure that follow-on formula shall be presented in such a way that it enables consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion between them (regulation 19).

3.51 Regulation 20(3) notes that 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 (regulation 21; implements Article 14(1) of the Directive)

3.52 This regulation is made pursuant to Article 14(1) of the Directive, which contains a flexibility allowing Member States to further restrict or prohibit the advertising of infant formula over and above the requirements of the Directive. The Directive provides that advertising of infant formula “shall be restricted to publications specialising in baby care and scientific publications.” The Agency proposes to further restrict the advertising of infant formula by means of regulation 21(1)(a), which would require that no person shall advertise infant formula except in:

- a scientific publication or
- for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public.

These provisions would thus prohibit the advertising of infant formula in publications specialising in baby care and distributed only through the health care system. The latter permission, which is included in the previous Regulations, may provide a means to advertise infant formula to the general

public. As such, the Agency has proposed the restrictions contained in Article 21(1)(a) which mean that infant formula may not be advertised either within the healthcare system or in publications which are available to the general public outside the health care system.

The Agency would welcome stakeholders views on the proposal to further restrict the advertising of infant formula.

3.53 Regulation 21(1)(b) provides that any advertisement for infant formula must:

- Comply with the 'Important Notice' requirements (regulation 17(e)).
- Provide the necessary information about the appropriate use of the product so as not to discourage breastfeeding (regulation 17(2)(a)).
- Not include the terms 'humanised', 'maternalised', 'adapted' or any similar term (regulation 17(2)(b)).
- Not include any pictures of infants or any other picture which may idealise the use of the product (regulation 17(3)) but may include graphic representations for easy identification of the product or for illustrating methods of preparation.
- Comply with the conditions of use of nutrition and health claims relating to infant formula (regulation 17(4)).
- enables consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion between them (regulation 19).
- Comply with the requirements of regulation 21(1) and 21(2).

3.54 Regulation 21(2) provides that any advertisement for infant formula shall only contain information of a scientific and factual nature.

3.55 Regulation 21(3) provides that information in advertisements for infant formula shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding.

Restrictions on advertising of follow-on formula (regulation 22; implements Article 13(3) and 13(8) of the Directive, in so far as they apply to follow-on formula)

3.56 The regulation provides that no person shall advertise follow-on formula where the advertisement contravenes or fails to comply with the requirements, prohibitions and restrictions set out in regulations 18(2) and 19.

3.57 As a result, the regulation provides that advertisements for follow-on formula shall-

- Provide the necessary information about the appropriate use of the product so as not to encourage breastfeeding;
- Not contain the terms "humanised", "maternalised", "adapted" or any similar term; and

- Enable consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion between them.

3.58 The Agency considers that the Regulations cannot impose further requirements or restrictions on the advertising of follow-on formula than those provided for in the Directive for the reasons set out in the following paragraphs.

3.59 Directive 2006/141 on infant formulae and follow on formulae (and Directive 91/321 which it replaced) was made pursuant to framework Directive 89/398/EEC. These Directives were made under what is now Article 95 of the EC Treaty (internal market). Directives 2006/141 and 89/398 together harmonise the rules on infant formula and follow-on formula. In consequence, it is no longer open to Member States to introduce national rules in this area except in so far as they are specifically authorised by the Directives (eg Article 14(1) of Directive 2006/141).

3.60 Once an area has been fully harmonised, it is no longer open to Member States to rely on the justification in Article 30 of the EC Treaty when adopting national rules which amount to a measure equivalent to a quantitative restriction on trade between Member States under Article 28 or 29 of the Treaty. Further, Article 10(1) of Directive 89/398 expressly prohibits Member States from restricting trade in products which comply with Directives 89/398 and 2006/141, for reasons related to the composition, manufacturing specifications, presentation or labelling. Article 18 of Directive 2006/141 requires Member States to permit trade in products which comply with the Directive.

3.61 Directive 2006/141 clearly regulates the advertising and presentation of infant formula and follow-on formula and so further restrictions in those harmonised areas may not be imposed by Member States.

Restrictions on the promotion of infant formula (regulation 23; implements Articles 14(2) and 14(3) of the Directive)

3.62 Regulation 23(1) provides that 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.

3.63 Regulation 23(2) provides that 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 (regulation 24; implements Article 15(2) of the Directive)

3.64 Regulation 24(1) provides that 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.

3.65 Regulation 24(2) provides that 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.

3.66 Regulation 24(3) provides that 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.

3.67 Regulation 24(4) provides that 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 (regulation 25; implements Article 15(4) of the Directive)

3.68 The regulation provides that 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 (regulation 26; implements the relevant provisions of Council Directive 92/52/EEC)

3.69 The Regulations also implement Directive 92/52/EEC. Regulation 26(1) provides that no person shall export to a third country any infant formula which contravenes or fails to comply with

- a) regulations 5, 6, 8, 10, 11, 12, 14, 17 or 19;
- b) the Codex Standard for Infant Formula established by the Codex Alimentarius²⁷; and
- c) the Food (Lot Marking) Regulations 1996 (S.I. 1996/1502).

3.70 Regulation 26(2) provides that 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.

Export of follow-on formula to third countries (regulation 27; implements the relevant provisions of Council Directive 92/52/EEC)

3.71 The regulation provides that no person shall export to a third country any follow-on formula which contravenes or fails to comply with

- a) regulations 5, 7, 9, 10, 12, 14, 18 or 19;

²⁷Codex Stan 72-1981 (amended 1983, 1985, 1987), Codex Alimentarius 1994, vol.4, p.17.

- b) the Codex Standard for Follow-up Formula established by the Codex Alimentarius²⁸; and
- c) the Food (Lot Marking) regulations 1996 (S.I. 1996/1502).

Offences and enforcement (Regulation 28)

3.72 Regulation 28(1) provides that if any person contravenes or fails to comply with regulations 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.

3.73 Regulation 28(2) provides that each food authority shall enforce and execute these Regulations within its area.

3.74 For the purposes of these Regulations, the term “the food authority”, is defined to reflect the provisions of section 5 of the Food Safety Act 1990. For the purposes of the Regulations, food authorities are –

- the London Boroughs
- metropolitan districts
- unitary authorities
- where there is two-tier local government, both non-metropolitan districts and non-metropolitan counties.

Where there is two-tier local government, the Food Law Code of Practice (England)²⁹ specifies whether the District Council or the County Council Food Authority is to act in particular cases.

Application of various sections of the Food Safety Act 1990 (regulation 29)

3.75 This Regulation applies certain provisions of the Act for the purposes of the Regulations.

Amendment of the Medical Food (England) Regulations 2000 (regulation 30)

3.76 Regulation 30(1) provides that the Medical Food (England) Regulations 2000 are amended in accordance with regulation 30(2).

3.77 Regulation 30(2) provides that in regulation 2 (interpretation) of the Medical Food (England) Regulations 2000, for the definition “the Directive” there is substituted the following definition—

²⁸ Codex Stan 156-1987 (amended 1989), Codex Alimentarius, 1994, vol.4, p.43.

²⁹ <http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copengland>

3.78 “the Directive” means Commission Directive 1999/21/EC on dietary foods for special medical purposes³⁰ as amended by—

- a) 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 founded³¹;
- b) 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 Romania³²; and
- c) Commission Directive 2006/141 on infant formulae and follow-on formulae and amending Directive 1991/21/EC³³.

3.79 The Regulations do not provide for any further changes to the Medical Food (England) Regulations 2000 as the Directive does not make any further changes to Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Revocation and transitional arrangements (regulation 31; implements Article 18 of the Directive)

3.80 The effect of regulation 31 is to:

- Permit trade in products which comply with the 1995 Regulations (the previous Regulations) no later than 31 December 2009.
- Permit trade in products which comply with the Regulations from 1 January 2008.
- Apply the provisions of the Regulations which do not relate to trade in products with effect from 1 January 2008 (e.g. the provisions which apply to the advertising of infant formula and follow-on formula).

The Agency would welcome stakeholders comments on any other aspect of the proposed provisions in these draft Regulations.

⁽³⁰⁾ OJ No. L91, 7.4.99, p.29.

⁽³¹⁾ OJ No. L236, 23.9.2003, p.33.

⁽³²⁾ OJ No. L362, 20.12.2006, p.94.

⁽³³⁾ OJ No. L401, 30.12.2006, p.1.

4. Rationale for Government intervention

4.1 This section outlines the reasons which have led the Agency to propose the new Regulations.

- Since Directive 91/321/EEC was adopted in 1991, there have been advances in scientific knowledge relating to infant feeding and nutrition. While there is no change in the view that 'breast is best', recent reviews of relevant scientific data by the Scientific Committee on Food (SCF)³⁴ indicate that changes to the essential composition and labelling of infant formulae and follow-on formulae are warranted. The Directive reflects these recommendations and aims to update provisions on the composition and labelling of infant formulae and follow-on formulae so that they are in line with the latest expert advice in relation to the nutrition of infants and young children who are not breastfed.
- The new Directive provides for increased consumer protection compared to the existing infant formula legislation because it:
 - updates compositional requirements, in line with the most recent advice from pan-European independent scientific experts (the main purpose of the revision);
 - updates provisions clarifying that follow-on formula should only be used by infants from six months of age (the current Directive in force today specifies that follow-on formula can be used from four months);
 - clarifies the provisions on health and nutrition claims on infant formula;
 - lays down a new national notification requirement for infant formulae which will allow EC countries to monitor the marketing of new infant formula more effectively (no such provision exists in the current legislation); and
 - lays down a new requirement that infant formula and follow on formula be labelled, presented and advertised in such a way as to avoid confusion between them.
- The 'Choosing Health' White Paper made a commitment to review the Infant Formula and Follow-on Formula Regulations with a view to further restrict the advertisement of follow-on formula³⁵. The Regulations deliver on this commitment by including a proposal to further restrict the ways in which infant formula can be advertised in England.
- The Regulations would have potential benefits regarding breastfeeding rates due to the increased restrictions on the advertising of infant formula.

³⁴ Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae and the Opinion of the Scientific Committee on Food on the revision of reference values for nutrition labelling. The relevant opinions of the Scientific Committee for Food can be accessed from: http://ec.europa.eu/food/food/labellingnutrition/children/formulae_en.htm

³⁵ Commitment No. 39 in the Choosing Health White Paper which can be accessed from http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4094550

The health benefits of breastfeeding are well established, and evidence exists to show that breastfed babies are less likely to develop gastric, respiratory and urinary tract infections, obesity in later life, atopic disease and juvenile-onset insulin-dependent diabetes³⁶. The National Institute of Clinical Excellence (NICE) has attempted to monetise some of the benefits associated with breastfeeding. It estimated that a 1% increase in breastfeeding rates would save the NHS approximately £725k per annum in diagnosis and management costs due to lower incidences of otitis media and gastroenteritis in UK babies³⁷. This estimate does not include any quantification of the pain or suffering costs associated with these conditions, or the costs associated with other medical conditions that are potentially linked to too little breast feeding such as heart disease and breast cancer in the mother. The potential bonding and emotional benefits of breast feeding are also left unquantified. These additional factors are likely to greatly increase the true NHS savings and wider health benefits associated with increased breast feeding.

- According to Mintel, UK retail sales of baby foods and drinks in 2004 totalled £319.5 million with £152.4 million (47.7% of the total) accounted for by sales of infant formulae and follow-on formulae. The Government must ensure that the domestic Regulations which apply to this market are consistent with current EU legislation and relevant Codex Alimentarius standards.

5. Consultation

5.1 The Directive was discussed by EU Member States at meetings of the Infant Formula Working Group (WG) and the Standing Committee on the Food Chain and Animal (SCoFCAH) during the period May 2004 to July 2006.

5.2 The Agency represented the interests of the UK during these discussions and consulted with other Government Departments, enforcement bodies, professional experts, non-Government organisations and industry bodies who had an interest in foods for particular nutritional uses at key stages of the negotiation process on each draft of the Directive. Summaries of consultation comments made by stakeholders are posted on the Agency website (www.food.gov.uk). Member States agreed the Directive at the 19th July 2006 meeting of the SCoFCAH.

³⁶ Department of Health Infant Feeding Recommendations:
http://www.dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Maternalandinfantnutrition/DH_4049203

³⁷ Above figures from Postnatal care: Routine postnatal care of women and their babies, Guidance type: Clinical guideline, Date issued: July 2006
<http://guidance.nice.org.uk/CG37#summary>

6. Options

Option 1: Retain the Status Quo

6.1 This option would result in the continued application of the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77)³⁸.

Option 2: Implement the Regulations

6.2 This option would result in the implementation of the Directive *via* the Regulations, a draft of which accompanies this RIA. The new Regulations would apply in England, with parallel Regulations being implemented in Scotland, Wales and Northern Ireland.

The Agency would welcome views from stakeholders regarding their preferred option.

7. Costs and benefits

7.1 This section aims to identify the costs and benefits associated with options 1 and 2 noted above. Where possible, these costs and benefits have been quantified/monetised.

Sectors and groups affected

7.2 The main sectors and groups of stakeholders that would be affected by the implementation of the Regulations are listed below.

- Consumers (infants in the UK, throughout the EU and in third countries)
- Carers of infants
- Professionals involved in maternal and infant health
- Charities and the voluntary sector involved in maternal and infant health
- Manufacturers of infant formula and follow-on formula
- Manufacturers and suppliers of ingredients used in infant formula and follow-on formula.
- Companies involved in the marketing and distribution of infant formula and follow-on formula (e.g. wholesalers and retailers)
- Companies, organisations and institutions which benefit from the advertising of infant formula and follow-on formula.
- Enforcement authorities
- Government

7.3 The costs and benefits associated with options 1 and 2 will be discussed mainly in relation to the affects on these sectors and groups.

³⁸ http://www.opsi.gov.uk/si/si1995/Uksi_19950077_en_1.htm

Benefits of option 1

7.4 Continuing to apply the current Regulations would not bring any additional benefits to any of the sectors or groups listed above.

Benefits of option 2

7.5 Adopting the Regulations would bring benefits to:

- Consumers (infants) as the Regulations require companies to ensure that infant formulae and follow-on formulae are manufactured in accordance with the most current independent expert scientific recommendations regarding infant nutrition. Thus, option 2 would improve the nutrition of infants who are not breastfed.
- Carers, for whom the Regulations provide increased protection because they clarify the rules which apply to the use of claims in relation to infant formula.
- Manufacturers, who would be able to market the same compositions of their products throughout the EU (the three biggest selling companies in the UK infant formula and follow-on formula sectors are multi-nationals).
- Government, who would avoid any risk of infraction proceedings brought by the Commission for not implementing the Directive *via* domestic legislation.
- Option 2 would potentially help to improve breastfeeding rates when compared to Option 1 due to the increased restrictions regarding the advertising of infant formula. However, it is difficult to quantify the likely increase in breastfeeding rates that would be attributable to the new Regulations.

Costs of option 1

7.6 Maintaining the status quo would bring costs to:

- Consumers – Without changes to the current UK legislation, the nutrition of a particularly vulnerable group of the population, i.e. consumers of infant formulae and follow-on formulae, would not be in line with the latest scientific advice on infant nutrition.
- Industry - Failing to implement the Regulations would lead to a lack of harmony between the compositional criteria of formula marketed in the UK when compared to formula marketed throughout the rest of the EU. This may disadvantage industry which may have to make special formulations of infant and follow-on formula specifically for UK consumers.
- Government/enforcement authorities - The Food Standards Agency would be failing in its duty to implement EU law. Any failure to implement the Directive would result in a serious breach of the UK's obligations under the EC treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the possibility of

heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement.

The Agency would welcome views and evidence from stakeholders to help quantify the costs associated with not implementing the Directive.

Costs of option 2

7.7 Adopting the Regulations would bring costs to:

- Consumers/carers - Implementing the Regulations would bring no new direct costs for consumers (infants). However, a proportion of any cost increase which manufacturers may face as a result of the Regulations could be passed on to carers who purchase formula products, in the form of higher prices.
- Industry - New provisions affecting the composition, labelling and marketing of infant formulae and follow-on formulae would affect manufacturers and other businesses involved in the marketing and distribution of these products as well as those involved in the production of ingredients.

The Agency does not currently hold information which would help to estimate the policy or administrative³⁹ compliance costs associated with the new mandatory reformulation or re-labelling requirements of the Regulations.

The Agency considers that the administrative costs associated with notifying infant formula are similar to those associated with notifying Article 9 parnuts food or foods for special medical purposes (FSMPs). As such, the Agency estimates that the administrative cost to a company, over and above what it would do commercially, of completing and submitting a notification form on marketing of a new infant formula product will be approximately in the region of £70-£130. The Agency estimates that it may receive in the region of 12 notifications per year. The resulting total additional administrative cost to industry of complying with this new requirement is therefore likely to be in the region of £840-£1560 per annum.

The cost of preparing scientific dossiers to submit to EFSA for assessment in order to substantiate claims is difficult to calculate because we do not know the level of information that EFSA will require, or the number of dossiers that are likely to be submitted to EFSA to substantiate claims on infant formula, or over what timescales.

³⁹ 'Administrative costs' are the costs of the administrative activities that a business incurs when it complies with information obligations in legislation (ie procuring or preparing information and making this information available to a public authority or third party) excluding costs that would be incurred during the normal course of business; 'Policy costs' are all the costs of complying with regulation, excluding administrative burdens.

The Agency would welcome comments and evidence from industry about the policy and administrative costs which are over and above what a business would do commercially, with respect to the approval of new claims relating to infant formula.

The Agency would welcome comments and evidence from industry about the policy and administrative costs which are over and above what a business would do commercially, in relation to the provisions of the Regulations regarding:

- **Composition (reformulation to ensure compliance with the updated mandatory compositional requirements)**
- **Labelling (re-labelling associated with the new mandatory labelling provisions)**
- **Notification (costs associated with notifying the Agency on marketing of new infant formula)**
- **Any other aspect of the legislation which would impose new administrative burdens, or have an impact on this sector.**

- Charities and the voluntary sector - We are not aware of any charities or voluntary organisations that would be affected by the implementation of the Regulations.

The Agency would welcome comments from charities and the voluntary sector about the impact that implementing the Regulations may have on their work.

- Enforcement and health professionals - We are seeking information on costs to enforcement authorities that could arise as a result of the implementation of the Regulations.

The Agency would welcome comments from enforcement bodies and health professionals about the impact that implementing the Regulations may have on their work.

- Government – Implementing the Regulations will lead to a small increase in costs mainly due to the administrative burden of the notification requirements regarding infant formula.

8. Small firms impact test

8.1 The supply structure for infant formulae and follow-on formulae in the UK is heavily concentrated, with three multi-national manufacturers accounting for 97% of sales. None of the other suppliers of infant formula in the UK are small businesses. As a result, the Regulations are unlikely to have a significant impact on small firms in the UK.

9. Competition assessment

9.1 As noted above, the infant and follow-on formulae sectors are currently characterised by significant concentration with three firms, Nutricia, H.J. Heinz and SMA Wyeth, accounting for 97% of sales in the UK.

9.2 It is not considered that the Regulations are likely to either directly or indirectly limit the number or range of suppliers to these sectors nor will they reduce the incentives for competitive action. The ability of firms to enter these sectors is already greatly dictated by the complexity of producing infant and follow-on formulae. Whilst these regulations may impact upon product specifications, any such impacts will be marginal compared with the existing commercial complexities involved. This commercial entry barrier also makes issues such as the proposed marginal reduction in promotional scope secondary in importance. As such the Agency does not consider that the Regulations have the scope to significantly effect competition adversely in these sectors.

10. Sustainable development

10.1 A preliminary sustainability assessment has been carried out on options 1 and 2, in the light of the information we have to date concerning the costs and benefits listed in section 7.

10.2 Option 1 does not create any new economic or social benefits. It may, however, incur economic disadvantages to industry, who may have to make specific formulae to market in the UK, and to the Government, which may be subject to infraction proceedings for not implementing the updated European Directive. These economic costs cannot currently be quantified by the Agency. Option 1 may also bring social disbenefits (in terms of infant health) as formulae placed on the market in the UK would not be required to be manufactured in accordance with the latest expert scientific recommendations in relation to infant nutrition.

10.3 Option 2 does bring new economic costs to industry due to reformulation and relabelling. In the light of the evidence currently available to the Agency, the magnitude of these economic costs cannot be quantified. Option 2 also brings social benefits in terms of improving infant health by ensuring that formulae are manufactured in accordance with the latest expert scientific recommendations in relation to infant nutrition.

10.4 On the basis of the information that we have to date, there appears to be no significant differences between the environmental costs of Options 1 and 2.

10.5 The Agency cannot complete a sustainability assessment of the two Options until further quantitative information is made available in relation to the economic, environmental and social costs associated with Options 1 and 2.

The Agency would welcome comments from stakeholders on the social and environmental costs and benefits of options 1 and 2 so that a sustainability assessment can be completed.

11. Racial equality

11.1 The Food Standards Agency does not consider that implementing this Regulation will have any impact on racial equality issues.

12. Public services threshold test

12.1 UK public enforcement costs are likely to be largely unaffected by the Regulations. The total additional monetary costs to all UK enforcement authorities will be well below the threshold criteria of £5m.

13. Enforcement, sanctions and monitoring

13.1 Local authorities are responsible for enforcing the Regulations, which would bring no new enforcement responsibilities.

14. Implementation and delivery plan

14.1 Should Option 2 be adopted, the Regulations would be implemented by 1st January 2008.

15. Post-implementation review

15.1 There are no specific plans for undertaking a post-implementation review of the Regulations as there are no provisions requiring Member States to do so in the Directive. The UK would, however, participate in any future review of the Directive that may be taken forward at an EU level.

16. Summary and recommendation

Summary costs and benefits table

Option	Total benefit per annum: economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1		

2		
3		
4		

Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed

Date

Minister's name, title, department

The Agency would welcome comments from stakeholders on any aspect of the draft Regulations, the proposed options or the draft RIA not addressed above.

Appendix I

Essential composition of infant formula: a summary of the differences between Annex I of the Directive and Annex I of Directive 91/321/EC (as amended)

Section in Annex 1 of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
1. Energy	Maximum level 315 kj/100ml (75 kcal/100ml)	Maximum level amended to 295 kj/100ml (70 kcal/100ml)
2. Conversion factors to establish protein content	Two factors stated: 6.38 for cows' milk based proteins and 6.25 for soya protein isolate and protein partial hydrolysates	One conversion factor of 6.25 for all protein types
2. Chemical index of proteins	The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.	Text deleted in general protein requirement and replaced by the following for each of the different protein categories (cows' milk, protein hydrolysates, soya protein isolates): 'For an equal energy value, the formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 providing the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies'
2.2 section title	Formula manufactured from protein partial	Replaced by: infant formula manufactured from protein

Section in Annex 1 of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
	hydrolysates	hydrolysates'
2.2 Minimum level of protein	0.56 g/100kJ (2.25 g/100kcal)	Replaced by 0.45 g/100kJ (1.8 g/100kcal)
2.2 Taurine	The taurine content shall be equal to at least 10umoles/100kJ (42 umoles/100kcal)	Deleted from this paragraph (see paragraph 3)
2.2. and 2.3. L-carnitine provision	The L-carnitine content shall be equal to at least 1.8 umoles/100 kJ (7.5 umoles/100kcal)	Replaced by : The L-carnitine content shall be equal to at least 0.3 umoles/100 kJ (1.2 umoles/100kcal)
3. Taurine	-	New section on Taurine: If added to infant formula, the amount of taurine shall not be greater than 2.9 mg/100kJ (12 mg/100kcal)
4. Choline	-	New section on Choline setting a minimum level 1.7 mg/100kJ (7 mg/100kcal) and a maximum level 12 mg/100kJ (50 mg/100 kcal)
5. Maximum level of Lipids	1.5 g/100kJ (6.5 g/100kcal)	Changed to: 1.4 g/100kJ (6.0 g/100kcal)
5.2. Lauric acid and myristic acid	Separate conditions for each specifying a maximum level of 15% of the total fat content for each fatty acid	Replaced by a revised maximum level specifying a 20% limit for each acid individually or as a whole
5.3 Trans fatty acid content	Maximum level of 4%	Replaced by a maximum level of 3%
5.7. provisions relating to docosahexaenoic acid and n-6 LCP	-	New provision stating that the DHA content shall not exceed that of n-6 LCP
6. Phospholipids	-	New provision setting a maximum limit of phospholipids in infant formula of 2 g/l.
7. Inositol	-	New provision setting minimum level of inositol of 1 mg/100kJ (4 mg/100kcal) and a maximum of 10 mg/100kJ (40 mg/100kcal)
8. minimum level of carbohydrate	1.7 g/100kJ (7 mg/100kcal)	2.2 g/100kJ (9 mg/100kcal)
8.1 permitted carbohydrates	No glucose listed	Glucose permitted as a carbohydrate (see section 8.4)
8.2 minimum level of lactose	0.85 g/100kJ (3.5 mg/100kcal)	Minimum level increased to 1.1 g/100kJ (4.5 mg/100kcal)
8.3. Use of sucrose	-	New provision limiting the addition of sucrose to infant formula manufactured from protein hydrolysates only.
8.4. Glucose	-	New provision limiting the addition of glucose to infant formula manufactured from protein hydrolysates only and setting a maximum limit of 0.5 g/100 kJ (2 g/100kcal)

Section in Annex 1 of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
9. Fructo-oligosaccharides and galacto-oligosaccharides	-	New provision allowing the addition of fructo-oligosaccharides and galacto-oligosaccharides. In that case their content shall not exceed: 0.8 g/100 ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 5.
10. Mineral substances in infant formula manufactured from cows' milk formula or protein hydrolysates		
Potassium	Maximum level: 35mg/100 kJ	Revised maximum level: 38mg/100 kJ
Chloride	Maximum level: 29mg/100 kJ	Revised maximum level: 38mg/100 kJ
Calcium		New maximum level: 33mg/100 kJ
Iron	Minimum 0.12 mg/100kJ and maximum 0.36 mg/100kJ	Revised minimum 0.07 mg/100kJ and maximum 0.3 mg/100kJ
Copper	Minimum 4.8 mg/100kJ and maximum 19 mg/100kJ	Revised minimum 8.4 mg/100kJ and maximum 25 mg/100kJ
Iodine	Minimum 1.2 ug/100kJ	Revised minimum 2.5 ug/100kJ and new maximum 12 ug/100kJ
Selenium	Maximum 0.7 ug/100kJ	Revised minimum 0.25 ug/100kJ and new maximum 2.2 ug/100kJ
Manganese	-	New minimum 0.25 ug/100kJ and maximum 0.25 ug/100kJ
Fluoride	-	New maximum 25 ug/100kJ
Calcium and phosphorous ratio	Shall not be less than 1.2 nor greater than 2.0	Shall not be less than 1 nor greater than 2
10.2. Mineral substances in infant formula manufactured from soya protein isolates	All requirements of paragraph above apply except those concerning iron and zinc.	All requirements of previous paragraph apply except those for iron and phosphorous – minimum limit for iron: 0.12 mg/100kJ and minimum limit of 7.5 mg/100kJ and a maximum of 25 mg/100kJ for

Section in Annex 1 of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
		phosphorous
11 Vitamins		
Thiamin	Minimum 10 ug/100kJ	Revised minimum of 14 ug/100kJ and new maximum of 72 ug/100kJ
Riboflavin	Minimum 14 ug/100kJ	Revised minimum of 19 ug/100kJ and new maximum of 95 ug/100kJ
Niacin	Minimum 0.2 mg/100kJ	Revised minimum of 72 ug/100kJ and new maximum of 375 ug/100kJ (preformed Niacin only)
Pantothenic acid	Minimum 70 ug/100kJ	Revised minimum of 95 ug/100kJ and new maximum of 475 ug/100kJ
Vitamin B6	Minimum 9 ug/100kJ	New maximum of 42 ug/100kJ
Biotin	Minimum 0.4 ug/100kJ	new maximum of 1.8 ug/100kJ
Folic acid	Minimum 1 ug/100kJ	Revised minimum of 2.5 ug/100kJ and new maximum of 12 ug/100kJ
Vitamin B12	Minimum 0.025 ug/100kJ	new maximum of 0.12 ug/100kJ
Vitamin C	Minimum 1.9 ug/100kJ	Revised minimum of 2.5 ug/100kJ and new maximum of 7.5 ug/100kJ
Vitamin K	Minimum 1 ug/100kJ	new maximum of 6 ug/100kJ
Vitamin E	0.5 mg/g of polyunsaturated fatty acids expressed as linoleic acid but in no less than 0.1 mg per 100 available kJ	new maximum of 1.2 ug/100kJ

Appendix II

Essential composition of follow-on formula: a summary of the differences between Annex II of the Directive and Annex II of Directive 91/321/EC (as amended)

Section in Annex II of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
1. Energy	Maximum level 335 kJ/100ml (75 kcal/100ml)	Maximum level amended to 295 kJ/100ml (70 kcal/100ml)
2. Conversion factors to establish protein content	Two factors stated: 6.38 for cows' milk based proteins and 6.25 for soya protein isolate and protein partial hydrolysates	One conversion factor of 6.25 for all protein types
2. Chemical index of proteins	The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.	Text deleted in general protein requirement and replaced by the following for each of the different protein categories (cows' milk, protein hydrolysates, soya protein isolates): 'For an equal energy value, the formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex V). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.
2.1 Follow-on formula manufactured from cows' milk protein	Sets a minimum level of 0.5 g/100kJ and a maximum level of 1 g/100kJ for both follow-on frocows	new minimum limit of 0.45 g/100kJ (1.8 g/100 kcal) and maximum level of 0.8 g/100kJ (3.5 g/100 kcal)
2.2 Follow-on formula manufactured from protein hydrolysates	-	New section for follow on formula manufactured from protein hydrolysates setting minimum limit of 0.56 g/100kJ (2.25 g/100 kcal) and a maximum limit of 0.8 g/100kJ (3.5 g/100 kcal)
2.3 Follow-on formula manufactured from soya	-	New section for follow on formula manufactured from soya protein isolates, alone or in mixture with cows' milk proteins setting

Section in Annex II of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
protein isolates, alone or in mixture with cows' milk proteins		minimum limit of 0.56 g/100kJ (2.25 g/100 kcal) and a maximum limit of 0.8 g/100kJ (3.5 g/100 kcal)
3. Taurine	-	New section on Taurine: If added to follow-on formula, the amount of taurine shall not be greater than 2.9 mg/100kJ (12 mg/100kcal)
4. Lipids	Minimum level of 0.8 g/100kJ (3.3 g/100kcal) and a maximum of 1.5 g/100kJ (6.5 g/100kcal)	Revised minimum level of 0.96 g/100kJ (4.0 g/100kcal) and a maximum of 1.4 g/100kJ (6.0 g/100kcal)
4.2. Lauric acid and myristic acid	Separate conditions for each specifying a maximum level of 15% of the total fat content for each fatty acid	Replaced by a revised maximum level specifying a 20% limit for each acid individually or as a whole
4.3 Trans fatty acid content	Maximum level of 4%	Replaced by a maximum level of 3%
4.5 Linoleic acid	Mo maximum level set	New maximum level of 285 mg/100kJ (1200 mg/ 100kcal)
4.6 alpha-linoleic acid	-	New provisions: the alpha-linoleic acid content should not be less than 12 mg/100kJ (50 mg/100kcal) and the linoleic:alpha-linoleic acid ratio should not be less than 5 or greater than 15
4.7 provisions relating to long chain polyunsaturated fatty acids (LCP)	-	New provisions allowing the addition of LCP. If added their content should not exceed: 1% of total fat for n-3 LCP ; 2% of total fat for n-6 LCP (1% of total fat for arachidonic acid (20:4 n-6)); The eicosapentaenoic acid (20:5 n-3) content should not exceed that of docohexaenoic acid (22:6 n-3); The docohexaenoic acid content should not exceed that of n-6 LCP.
5. Phospholipids	-	New provision setting a maximum limit of phospholipids in follow-on formula of 2 g/l.
6. minimum level of carbohydrate	1.7 g/100kJ (7 mg/100kcal)	2.2 g/100kJ (9 mg/100kcal)
6.2 minimum level of lactose	0.45 g/100kJ (1.8 g/100kcal)	Revised minimum level of 1.1 g/100kJ (4.5 g/100kcal)
6.3 use of Honey	-	New provision requiring that honey shall be treated to destroy spores of <i>Clostridium botulinum</i>

Section in Annex II of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
6.4 Glucose	No glucose listed	New provision limiting the addition of glucose to follow-on formula manufactured from protein hydrolysates only and setting a maximum limit of 0.5 g/100 kJ (2 g/100kcal)
7. Fructo-oligosaccharides and galacto-oligosaccharides	-	New provision allowing the addition of fructo-oligosaccharides and galacto-oligosaccharides. In that case their content shall not exceed: 0.8 g/100 ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Article 6.
10. Mineral substances in infant formula manufactured from cows' milk formula or protein hydrolysates		
Sodium	-	New minimum level of 5 mg/100kJ and a new maximum of 14 mg/100kJ
Potassium	-	New minimum level of 15 mg/100kJ and a new maximum of 38 mg/100kJ
Chloride	-	New minimum level of 12 mg/100kJ and a new maximum of 38 mg/100kJ
Calcium	-	New minimum level of 12 mg/100kJ and a new maximum of 33 mg/100kJ
Phosphorous	-	New minimum level of 6 mg/100kJ and a new maximum of 22 mg/100kJ
Magnesium	-	New minimum level of 1.2 mg/100kJ and a new maximum of 3.6 mg/100kJ
Iron	Minimum 0.25 mg/100kJ and maximum 0.5	Revised minimum 0.14 mg/100kJ

Section in Annex II of 2006/141/EC	Provision in 91/321/EC	Revised Provision in 2006/141/EC
	mg/100kJ	
Zinc	-	new maximum of 14 mg/100kJ
Copper	-	New minimum 8.4 mg/100kJ and maximum of 25 mg/100kJ
Iodine	Minimum 1.2 ug/100kJ	Revised minimum 2.5 ug/100kJ and new maximum of 12 ug/100kJ
Selenium	-	New minimum 0.25 ug/100kJ and new maximum of 2.2 ug/100kJ
Manganese	-	New minimum 0.25 ug/100kJ and maximum of 0.25 ug/100kJ
Fluoride	-	new maximum of 25 ug/100kJ
Calcium and phosphorous ratio	Shall not be less than 1.2 nor greater than 2.0	Shall not be less than 1 nor greater than 2
10.2. Mineral substances in infant formula manufactured from soya protein isolates	All requirements of paragraph above apply except those concerning zinc	All requirements of previous paragraph apply except those for iron and phosphorous – minimum limit for iron: 0.22 mg/100kJ and a maximum of 0.65 mg/100kJ and for phosphorous a minimum limit of 7.5 mg/100kJ and a maximum of 25 mg/100kJ will apply.
11 Vitamins		
Thiamin	-	New minimum of 14 ug/100kJ and new maximum of 72 ug/100kJ
Riboflavin	-	New minimum of 19 ug/100kJ and new maximum of 95 ug/100kJ
Niacin	-	New minimum of 72 ug/100kJ and new maximum of 375 ug/100kJ (preformed Niacin only)
Pantothenic acid	-	New minimum of 95 ug/100kJ and new maximum of 475 ug/100kJ
Vitamin B6	-	New minimum of 9 ug/100kJ and a new maximum of 42 ug/100kJ
Biotin	-	New minimum of 0.4 ug/100kJ and a new maximum of 1.8 ug/100kJ
Folic acid	-	New minimum of 2.5 ug/100kJ and new maximum of 12 ug/100kJ
Vitamin B12	-	New minimum of 0.025 ug/100kJ and a new maximum of 0.12 ug/100kJ
Vitamin C	Minimum 1.9 ug/100kJ	Revised minimum of 2.5 ug/100kJ and new maximum of 7.5 ug/100kJ
Vitamin K	-	New minimum of 1 ug/100kJ and a new maximum of 6 ug/100kJ
Vitamin E	0.5 mg/g of polyunsaturated fatty acids expressed as linoleic acid but in no less than 0.1 mg per 100 available kJ	new maximum of 1.2 ug/100kJ

Appendix III – Draft proposed notification form (infant formula)



Notification of Infant Formula

CONTACT DETAILS	For FSA Use Only			
<p>Food Standards Agency Parnut Food Notification Nutrition Division, Nutrition Labelling, Promotions and Dietetic Foods Branch Room 115b, Aviation House, 125 Kingsway, London WC2B 6NH Telephone No. 020 7276 8065 Fax No. 020 7276 8193 E-mail: parnutfoodnotification@foodstandards.gsi.gov.uk</p>	<table border="1"><tbody><tr><td data-bbox="1045 555 1481 645">Date notification received</td></tr><tr><td data-bbox="1045 645 1481 763">Date confirmation sent to manufacturer / importer</td></tr><tr><td data-bbox="1045 763 1481 880">Date letter sent to Local Authority</td></tr></tbody></table>	Date notification received	Date confirmation sent to manufacturer / importer	Date letter sent to Local Authority
Date notification received				
Date confirmation sent to manufacturer / importer				
Date letter sent to Local Authority				

IMPORTANT NOTES

1. Notification of marketing an infant formula when it is first placed on the market in the UK, or when there has been a change of formulation / ingredients to an infant formula already on the UK market, is a statutory requirement under the Infant Formula and Follow-on Formula (England) Regulations 2007 No XX; The Infant Formula and Follow on Formula (Scotland) Regulations 2008 SSI No XX; The Infant Formula and Follow on Formula (Northern Ireland) Regulations 2008 SRNI No XX and The Infant Formula and Follow on Formula (Wales) Regulations 2008 WSI No XX.
2. These Regulations implement Article 9 of Commission Directive 2006/141 EC on Infant Formula and Follow - on Formula.
3. Notification is required when:
 - a new infant formula is placed on the market in the UK
 - a change of formulation is made or new ingredient is added to an infant formula already on the market.
4. The term 'Infant Formula' is defined in the Directive 2006/141/EC referred to above. Copies of this legislation can be obtained from website: <http://ec.europa.eu/food/food/labellingnutrition/>
5. This form may be used as a means of giving the necessary notification to the Food Standards Agency.
The duty to notify falls on:
 - The manufacturer if the product is manufactured in the European Union; OR
 - The importer or UK distributor if the product is manufactured outside the European Union and imported into the UK.Receipt of your form will be acknowledged.
It is an offence without reasonable excuse to sell an infant formula product in the UK if it has not been so notified.
If necessary, the Food Standards Agency may require further information about the product's compliance with the legislation.
6. A **separate** form should be completed for **each** product. Further copies of this form can be obtained from the Food Standards Agency at the address above or from our website: <http://www.food.gov.uk>
7. If you have any queries about the completion of this form, please telephone, fax or e-mail the Food Standards Agency at the address given at the top of this page.

Appendix IV

Voluntary microbiological labelling of formula

The World Health Assembly⁴⁰ adopted a resolution in 2005 that Member States should inform healthcare workers, parents and other caregivers about best practices for preparation, use and handling of powdered infant formula, particularly in light of the fact that powdered infant formula is a non-sterile product. The resolution also recommended that caregivers should be informed through an explicit warning on the packaging that powdered infant formula may contain pathogenic micro-organisms.

The European Food Safety Authority (EFSA)⁴¹ further recommended that guidelines for the preparation and storage of powdered infant formula should be prepared for use in the home and healthcare settings. The Department of Health (DH) has revised its bottle feeding advice for parents around preparation and storage of powdered infant formula, and the DH and Food Standards Agency have issued advice jointly to health professionals on the preparation and storage of powdered infant milk⁴².

The Agency undertook research to explore the understanding of the term non-sterile and attitudes towards labelling and advice on powdered infant formula amongst parents and healthcare professionals. The results of the Agency research are available at: <http://www.food.gov.uk/science/surveys/infantformula>. The Agency is working with the infant formula industry to agree a suitable form of words for voluntary labelling which would inform consumers that these products are non-sterile.

⁴⁰ <http://www.who.int/about/governance/en/index.html>

⁴¹ Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the microbiological risks in infant formulae and follow-on formulae. *The EFSA Journal* (2004) 113, 1-35

⁴² <http://www.food.gov.uk/news/newsarchive/2006/dec/infantform>

List of Interested Parties

A G Barr
 Academy of Culinary Arts
 Advertising Association
 Advertising Standards Authority
 Advisory Body for Social Services
 Catering
 Agricultural Industries Confederation
 Agricultural Supply Industry
 Ajinomoto Co Limited
 Alcontrol Laboratories
 Allied Technical Centre
 American Maize-Products Company
 (USA)
 Anglia Bio Science Consultancy
 Apco Europe
 Arkarius Limited
 Asda Stores
 Ashwell Associates
 Assoc of the British Pharmaceutical
 Industry
 Associated British Agriculture
 Association for Breastfeeding Mothers
 Association of Frozen Food Producers &
 Ice Cream Federation
 Association of Port Health Authorities
 Association of Radical Midwives
 Atwood Barry
 Baby Milk Action Group
 Baby Organix
 Babylicious Limited
 Berry Ottaway and Associates Limited
 Bibra Information Services Limited
 Bio Bambini
 Booth Smith & Associates
 Bradford Royal Infirmary
 Breastfeeding Network
 British Bakels Limited
 British Beekeeper's Association
 British Chemical Distributors & Traders
 Association Limited
 British Dental Association
 British Diabetic Society
 British Dietetic Association
 British Egg Industry Council
 British Essence Manufacturers
 Association
 British Independent Grocers Association
 British Medical Association
 British Oat and Barley Millers Association
 British Pasta Product Association
 British Poultry Council
 British Retail Consortium
 Burson Marsteller
 Buckinghamshire NHS Trust
 CASH (Consensus Action on Salt and
 Health)
 Cavaghan & Gray
 Centre for Public Health Excellence,
 National Institute for Health and Clinical
 Excellence
 Chemistry & Industry Magazine
 Christan Hansen UK Limited
 City of York Council
 Civo-institutes TNO
 Coffee Trade Federation Limited
 Community Practitioners and Health
 Visitors Association
 Confederation of Indian Food Trade and
 Industry
 Consumer Education & Research Centre
 Co-operative Group
 Covington & Burling
 Crop Protection Association
 Cumbria County Council
 Dairy Council
 Department of Environment Food and
 Rural Affairs (DEFRA)
 Department for Trade & Industry
 Dept of Molecular & Cellular Pathology
 Derrisford Hospital
 Environment Council
 ENVG
 European Federation of Health
 EHPM
 Product Manufacturers Association
 Faculty of Public Health of the Royal
 College of Physicians of the United
 Kingdom
 Federal Office of Public Health
 Federation of Small Businesses
 Food standards Australia New Zealand
 (FSANZ)
 Food Additives & Ingredients Association
 Food and Drink Federation (FDF)
 Food Commission (UK) Limited
 Food Science Australia library
 Food Standards Australia New Zealand
 Forum Products Limited
 FTSE
 General Dietary Limited

Glisten Confectionery
 Grace GmbH
 HCIMA
 Health Food Manufacturers Association
 Health Promotion Agency
 Hipp Nutrition UK Limited
 Hipp – Werk Georg Hipp OHG
 HJ Heinz Company limited
 Hobbelink
 Holland & Barrett
 Horticulture Research International
 Hotel & Catering International
 Management Association
 Huntingdon Life Sciences
 HUSH (Haemolytic Uraemic Syndrome
 Help)
 ILS Limited
 Imperial College
 Infant and Dietetic Foods Association
 Informa PLC
 Institute of Food Science & Technology
 (IFST)
 IFIS Publishing
 International Food Information Service
 International Laboratory Services Limited
 International Obesity Task Force
 J Ralph Blanchfield Consultancy
 J Sainsbury Plc
 John Russell Associates
 King's College London
 Kreglinger Europe
 L B Croydon Food Team
 L Hepner & Associates Limited
 La Leche League
 Lactation consultants of Great Britain
 (LCGB)
 Lawdata Limited
 Lawson Dr R G
 Leeds Metropolitan University
 LGC Limited
 Lifetreeshop
 Local Authorities Co-ordinators of
 Regulatory Services (LACORS)
 London Chamber of Commerce
 London International Group Plc
 Marks & Spencer Plc
 MCC Public Relations Limited
 Mead Johnson Nutritionals
 Meat & livestock commission (MLC)
 Midwives Information & Resource Service
 Morrisons PLC
 National Association of Local
 Government Officials
 National Association of British & Irish
 millers (NABIM)
 National Association of Health Stores
 National Childbirth Trust
 National Consumer Council
 National Consumer Federation
 National Family & Parenting Institute
 National Institute for Health and Clinical
 Excellence
 National Pharmaceutical Association
 Norton Rose
 Nutricia Limited
 Omya UK Limited
 Organix Brands Plc
 Pioneering Foods
 Pizza hut (UK)
 Proprietary association of Great Britain
 (PAGB)
 Provision Trade Federation
 Reading Scientific Services Limited
 (RSSL)
 RHM technology limited
 Royal College of Midwives (RCM)
 Royal College of Nursing
 Royal College of Paediatrics & Child
 Health (RCPCH)
 Royal Pharmaceutical Society of Great
 Britain (RPSGB)
 Royal Society for the Promotion of Health
 Royal Society of Chemistry
 Royal Society of Health
 Salt Manufacturers Association
 Salford Primary Healthcare Trust
 SCI - where science meets business
 Scottish Breastfeeding Group
 Seale-Hayne College
 Sheffield City Libraries
 Simply Organic - serious food company
 Small Business Service (SBS)
 Society of Chemical Industry
 Solway Foods
 Somerfield Stores Limited
 St Marys Hospital NHS Trust
 Sure Start Breastfeeding Project
 Sure Start Centre
 Sustain
 Syngenta Crop Protection UK limited
 Table jellies association
 Tate & lyle plc
 Tesco stores plc

Trade Association Forum
Truuuly scrumptious baby food Limited
UK Association of Frozen Food
Producers
UNICEF
Unilever UK Limited
University College & Middlesex
University of Dundee
University of Hertfordshire
University of Leeds
University of New South Wales
University of Reading

University of Sussex
Vegetarian Society of the UK Limited
Veterinary Science Library
Vitacare Limited
Waitrose Limited
Ward Prof A G
Webershandwick Public Affairs
Welsh Assembly Government
Which?
Whitehouse Consultancy Limited
Wm Morrison Supermarkets