EXPLANATORY MEMORANDUM TO

THE INFANT FORMULA AND FOLLOW-ON FORMULA (ENGLAND) REGULATIONS 2007
No. 3521

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This instrument implements, in England, Commission Directive 2006/141/EC on infant formula and follow-on formula and amending Directive 1999/21/EC (OJ No. L401, 30.12.2006, p1) and Council Directive 92/52/EEC (OJ No. L179, 1.7.1992, p129) on infant formula and follow-on formula intended for export to third countries. The main purpose of the instrument is to revoke and remake domestic provisions regarding the composition, labelling and advertising of infant formula and follow-on formula.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Background

4.1 This instrument implements Commission Directive 2006/141/EC on infant formulae and follow-on formulae which consolidates existing Community legislation on the composition, labelling and marketing of these products. These Regulations also implement Council Directive 92/52/EEC.

4.2 This instrument provides for the revocation of the Infant Formulae and Follow-on Formula Regulations 1995 and creates transitional arrangements relating to trade in infant formula and follow-on formula.

5. Extent

5.1 This instrument applies to England. Separate but parallel legislation is being enacted for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The composition, labelling and marketing of infant formula and follow-on formula is controlled by European Community legislation. In summary the legislation seeks to ensure that:

- the essential composition of infant formula and follow-on formula satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data;
- the labelling of infant formula and follow-on formula allows the proper use of such products whilst promoting and protecting 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") and
- information provided to carers about infant feeding does not counter the promotion of breastfeeding.

7.2 In order to fulfil these requirements, a Commission Directive 91/321/EEC (OJ No. L175, 4.7.1991, p35) was agreed in 1991. In 2003, the European Scientific Committee for Food (SCF) updated their recommendations for the composition of infant formula and follow-on formula based on the latest scientific developments. Therefore, Commission Directive 91/321/EEC was revised and replaced by Commission Directive 2006/141/EC which reflects the latest scientific advice on the essential composition of infant formula and follow-on formula and discussions at an international level in the Codex Alimentarius forum and gives effect to the principles and aims of the Code.

7.3 Due to consumer confusion between the infant formula and follow-on formula, provisions were introduced into the labelling and advertising articles of the Directive to ensure any risk of confusion by the consumer between these two categories of products is removed.

7.4 This instrument implements Commission Directive 2006/141/EC, and takes advantage of the flexibility provided in the Directive to further restrict the advertising of infant formula such that infant formula can only be advertised in a scientific journal or for trade purposes prior to the retail stage. These Regulations also implement Council Directive 92/52/EEC which requires that any infant formula exported from the EU must comply with various provisions of the EC regime.

7.5 This instrument will therefore provide for increased consumer protection compared to the previous infant formula legislation because it:

- updates compositional requirements, in line with the most recent advice from pan-European independent scientific experts;

- updates labelling rules clarifying that follow-on formula should only be used by infants from six months of age (the existing Regulations specify that follow-on formula can be used from four months);
- clarifies that only a small number of approved health and nutrition claims can be used on infant formula (i.e. nutrition claims relating to: 'lactose only', 'lactose free', 'added LCPs', the addition of taurine/oligosaccharides/nucleotides and a health claim related to a reduction of risk to allergy to milk proteins).
- lays down a new national notification requirement for infant formulae which will allow the marketing of new infant formula to be monitored 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.

7.6 The instrument also makes provisions for references to the Annexes to Directive 2006/141/EC to be construed as references to that instrument as it may be amended from time to time. The Legislative and Regulatory Reform Act 2006 makes such ambulatory references permissible where it seems necessary or expedient to the Secretary of State. The Annexes to the Directive set out the compositional criteria for infant formula and follow-on formula, specify the permitted nutrition and health claims for infant formula and technical specifications and are subject to regular amendment by the European Commission. Use of the ambulatory references will obviate the need to introduce a new SI each time these Annexes are updated.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

Claire Boville at the Food Standards Agency (Tel: 02072768168 or e-mail: claire.boville@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

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

This transposition note outlines how Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21 (OJ No. L401, 30.12.2006, p.1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (OJ No. L179, 1.7.1992, p.129) will be transposed into legislation in England.

Commission Directive 2006/141/EC lays down rules regarding the composition, labelling, notification and advertising of infant formulae and follow-on formulae.

Council Directive 92/52/EEC lays down rules regarding the export of infant formula and follow-on formula to third countries and prior to being implemented by the Infant Formula and Follow-on Formula (England) Regulations 2007 it was implemented by the Infant Formula and Follow-on Formula Regulations 1995 (S.I.1995/77).

Article	Objective	Implementation	Responsibility
Article 1	This Directive is a 'specific' Directive within the meaning of Article 4(1) of Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses. It also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.	Article 1 is a general provision and does not require specific implementation	

Article 2.	Provides for the interpretation of and definitions for terms used in the Directive.	Regulation 2(3) This regulation provides that any expression used in the Regulations has the same meaning that it bears in the Directive.	Secretary of State.
Article 3 (1).	Infant formulae and follow-on formulae may be marketed in the Community only if they comply with the requirements of the Directive.	Regulation 3 This regulation prohibits the marketing of infant formula or follow-on formula which contravenes or fails to comply with specified regulations	Secretary of State.
Article 3 (2).	No product other than infant formula may be marketed as satisfying by itself the nutritional requirements of normal healthy infants in the first months of life, or until the introduction of complementary feeding.	Regulation 4 This regulation prohibits the marketing of products other than infant formula for normal healthy infants	Secretary of State.
Article 4.	Infant formula and follow-on formula shall not contain any substance in such quantity as to endanger the health of infants and young children.	Regulation 5 This regulation provides that infant formula and follow on formula may not contain substances in such quantity as to endanger the health of infants and young children	Secretary of State.
Article 5.	Provides that infant formula shall be manufactured from protein sources given in Annex I and other suitable food ingredients. Such suitability shall be demonstrated through a systematic review of the	Regulation 6 This regulation provides that infant formula must be manufactured from protein sources and other food ingredients suitable for infants from birth	Secretary of State.

	available data relating to the expected benefits and to satisfy considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.		
Article 6.	Provides that follow on formula shall be manufactured from protein sources given in Annex 2 and other suitable food ingredients.	Regulation 7 This regulation provides that follow-on formula must be manufactured from protein sources and other food ingredients suitable for infants aged over six months	Secretary of State.
Article 7 (1)	Infant formulae shall comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V. In the case of infant formulae manufactured from cows' milk proteins defined in point 2.1 of Annex I with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. In the case of infant formulae	Regulation 8 This regulation provides that infant formula must comply with specified compositional criteria	Secretary of State.

	manufactured from protein hydrolysates defined in point 2.2 of Annex I with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in Annex VI.		
Article 7 (2)	Follow-on formulae shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.	Regulation 9 This regulation provides that infant formula must comply with specified compositional criteria .	Secretary of State.
Article 7 (3)	In order to make infant formula and follow-on formula ready for use, nothing more shall be required, as the case may be, than the addition of water	Regulation 10 This regulation 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.	Secretary of State.
Article 7 (4)	Prohibitions and limitations on the use of food ingredients as set out in Annex I and II	Regulation 11 This regulation provides that the use of food ingredients in infant formula and follow on formula must observe specified prohibitions and limitations	Secretary of State.

Article 8.	Only substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula.	Regulation 12 This regulation provides that only specified substances may be used in the manufacture of infant formula and follow-on formula.	Secretary of State.
Article 9.	Notification requirements, when a food business operator places an infant formula on the market he shall notify the competent authority of the Member State where the product is being marketed by forwarding to it a model of the label used for the product	Regulation 13 This regulation prohibits a food business operator placing an infant formula product on the market where that product has not been placed on the market before in the United Kingdom unless he has notified the Food Standards Agency by forwarding to it a model of the label used for the product.	Secretary of State.
Article 10 (1) first paragraph	Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0.01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.	Regulation 14 (1) This regulation provides that infant formula and follow-on formula shall not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.	Secretary of State
Article 10(1) second paragraph	Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.	Regulation 14(5) This regulation provides that analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods	Secretary of State.
Article 10	The pesticides listed in Annex VIII shall	Regulation 14 (2)	Secretary of

(2).	not be used in agricultural products intended for the production of infant formulae and follow-on formulae. However, for the purpose of controls: (a) pesticides listed in Table 1 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress; (b) pesticides listed in Table 2 of Annex VIII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.	This regulation provides that 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.	State
Article 10 (3)	By way of derogation from paragraph 1, for the pesticides listed in Annex IX, the maximum residue levels specified therein shall apply.	Regulation 14 (3) This regulation provides that infant formula and follow-on formula shall not contain any residue of a pesticide listed in Annex IX of the Directive at a level exceeding the maximum residue level specified in that Annex.	Secretary of State
Article 10 (4)	The levels referred to in paragraphs 2 and 3 shall apply to the products as proposed	Regulation 14 (4) This regulation provides that the levels referred apply in	Secretary of State

	ready for consumption or as reconstituted according to the instructions of the manufacturers.	relation to infant formula or follow-on formula manufactured as ready for consumption; or if it is not so manufactured, as reconstituted according to the manufacturer's instructions.	
Article 11.	Provides for the name under which infant formula and follow-on formula shall be sold in the language of each Member State.	Regulation 15 (a) This regulation provides that infant formula which is not manufactured entirely from cows' milk may only be sold with the name 'infant formula' Regulation 16 (a) This regulation provides that follow-on formula which is not manufactured entirely from cows' milk may only be sold with the name 'follow-on formula'	
Article 12.	Provides for the name under which infant formula and follow-on formula manufactured entirely from cows' milk protein shall be sold in the language of each Member State.	Regulation 15 (b) This regulation provides that infant formula which is manufactured entirely from cows' milk may only be sold with the name 'infant milk' Regulation 16 (b) This regulation provides that follow-on formula which is not manufactured entirely from cows' milk may only be sold with the name 'follow-on milk'	

Article 13 (1)(a)	The labelling of infant formula requires a statement that to the effect that is suitable for particular nutritional use by infants from birth when they are not breast fed.	Regulation 17 (1) (a) This regulation provides that infant formula may not be sold unless the labelling bears a statement that to the effect that is suitable for particular nutritional use by infants from birth when they are not breast fed	Secretary of State
Article 13.1 (b)	The labelling of follow –on formula In the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to 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 and child care, based on the individual infant's specific growth and development needs.	**Regulation 18 (1)(a)** This regulation provides that follow-on formula may not be sold unless the labelling bears the particulars as given in Article 13.1 (b) of the Directive (which are set out in the regulation).	Secretary of State

Article 13 (1)(c)	In the case of infant formulae and follow-on formulae, 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.	Regulation 17.1(b) and 18.1 (b) These regulations provide that 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.	Secretary of State
Article 13 (1)(d)	In the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in Annexes I and II respectively, and where applicable of choline, inositol and carnitine, expressed in numerical form, per 100 ml of the product ready for use.	Regulation 17 (1) (c) & 18 (1) (c) These regulations provide that 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.	Secretary of State
Article 13 (1)(e)	In the case of infant formulae and follow-on formulae, instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.	Regulation 17 (1)(d) & 18 (1) (d) These regulations provide instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.	Secretary of State
Article 13 (2) (a)	For infant formulae and follow-on formulae the average quantity of nutrients mentioned in Annex III when such declaration is not covered by paragraph 1(d) of this Article, expressed in numerical form, per 100 ml of the product ready for use.	**Regulation 17(5) and Regulation 18. (3) (a)** These regulations provide that the labelling of infant formula and follow-on formula may bear particulars of the average quantity of nutrients mentioned in Annex III when such information is not required by paragraph (1) (c) of the relevant regulation, expressed in numerical form, per 100 ml of the product ready for use.	Secretary of State

Article 13 (2)(b)	For follow-on formulae in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use.	**Regulation 18 (3) (b)** This regulation provides that 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.	Secretary of State
Article 13 (3)	The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast feeding. The use of the terms "humanised", "maternalised", "adapted", or similar terms shall be prohibited.	Regulation 17 (2) (a) and (b) and Regulation 18 (2) (a) and (b) These regulations provide that the labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast feeding. The use of the terms "humanised", "maternalised", "adapted", or similar terms shall be prohibited.	Secretary of State
Article 13 (4)	The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words "Important Notice" or their equivalent, a statement concerning the superiority of breast feeding and 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	Regulation 17 (1) (e) This regulation requires the words “important notice” or their equivalent immediately followed by a statement concerning the superiority of breastfeeding and 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.	Secretary of State

	responsible for maternal and child care.		
Article 13 (5)	The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.	Regulation 17 (3) The text of this regulation reflects Article 13(5)	Secretary of State.
Article 13 (6)	The labelling of infant formulae may bear nutrition and health claims only in the cases listed in Annex IV and in accordance with the conditions set out therein.	Regulation 17(4) The text of this regulation reflects Article 13 (6)	Secretary of State.
Article 13 (7)	Infant formulae and follow-on formulae 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 formulae and follow-on formulae.	Regulation 19 This regulation provides for the avoidance of the risk of confusion between infant formula and follow-on formula and reflects the text of Article 13 (7)	Secretary of State.
Article 13 (8)	The requirements, prohibitions and restrictions referred to in paragraphs 3 to 7 shall also apply to: (a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are	Regulation 20, 21(1)(b) and 22 Regulation 20 applies the provisions of Article 13 (3) to (7) to presentation of infant formula and follow-on formula Regulation 21(1)(b) applies the provisions of Article 13 (3) to (7) to advertising of infant formula Regulation 21(1)(b) applies the provisions of Article 13 (3) to (7) to advertising of follow-on formula	Secretary of State.

	displayed; (b) advertising.		
Article 14 (1)	Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae shall be subject to the conditions laid down in Article 13(3) to (7) and Article 13(8)(b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.	Regulation 21 Regulation 21 (1)(a) implements the first sentence of Article 14 (1) by providing 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. In doing so it goes further than the first sentence of Article 14 (1) but this is permitted by the second sentence of Article 14 (1). Regulation 21 (1) (b) implements the words 'such advertisements for infant formula shall be subject to the conditions laid down in Article 13 (3) to (7) and Article 13(8)(b)' which are arguable otiose in view of the direct application of those provisions to advertising by virtue of Article 13(8)(b) Regulation 21 (2) and (3) implement the last two sentences of Article 14 (1) and provide that advertisements for infant formula shall only contain information of a scientific and factual nature and that information in advertisements for infant formula shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.	Secretary of State.
Article 14 (2)	There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula	Regulation 23 (1) This regulation reflects the text of Article 14 (2)	Secretary of State.

	directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.		
Article 14 (3)	Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.	Regulation 23 (2) This regulation reflects the text of Article 14 (3)	Secretary of State
Article 15 (1)	Member States shall ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.	This Article places obligations on the Member State, not the individual and so does not require to be transposed into domestic law	Secretary of State
Article 15 (2)	Member States shall ensure that informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:	Regulation 24 This regulation reflects the text of Article 15(2).	Secretary of State

	(a) the benefits and superiority of breast feeding; (b) maternal nutrition and the preparation for and maintenance of breast feeding; (c) the possible negative effect on breast feeding of introducing partial bottle feeding; (d) the difficulty of reversing the decision not to breast feed; (e) where needed, the proper use of infant formulae. When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealise the use of infant formulae.		
Article 15 (3)	Member States shall ensure that donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this	Regulation 24 (4) This regulation reflects the text of Article 15 (4)	Secretary of State

	purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.		
Article 15.4	Member States shall ensure that donations or low-price sales of supplies of infant formulae to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.	Regulation 25 This regulation reflects the text of Article 15 (4)	Secretary of State.
Article 16	In the Annex to Directive 1999/21/EC, the row relating to manganese set out in the second part of Table I concerning minerals, is replaced by the following: "Manganese (µg) | 0,25 | 25 | 1 | 100" |	Regulation 30 This regulation amends the Medical Food (England) Regulations 2000 by amending the definition of 'the Directive' to take account of the change made to Directive 1999/21 by Article 16	Secretary of State.
Article 17.	The new requirements set out in Article 7(1) and (2) of this Directive shall not apply mandatorily to dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of the	This Article does not need to be directly transposed in domestic law because of the existing provisions of the Medical Food (England) Regulations 2000.	Secretary of State.

	Annex to Directive 1999/21/EC, until 1 January 2012.		
Article 18 (2)	Member States shall adopt and publish, by 31 December 2007 at the latest, the laws, regulations and administrative provisions necessary to comply with Articles 2, 3 and 5 to 17 and Annexes I to VII. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive. They shall apply those provisions in such a way as to: - permit trade in products complying with this Directive by 1 January 2008 at the latest, - without prejudice to Article 17, prohibit, with effect from 31 December 2009 trade in products which do not comply with this Directive. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directive repealed by this	This Article is implemented by regulation 1(b) (coming into force date) and regulation 31 which provides transitional arrangements as regards trade in products which comply with the existing domestic legislation up to 31 December 2009	

	Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.		
Article 18.2	Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	This Article does not require transposition [DN this text to go in this column for Articles 20 and 21]	
Article 19.	Directive 91/321/EEC, as amended by the Directives listed in Annex X, Part A, is repealed with effect from 1 January 2008, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives listed in Annex X, Part B. References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex XI.	Regulation 31 This regulation revokes the existing domestic law but takes account of the provisions of Article 18 (1)	Secretary of State
Article 20.	This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.	This Article does not require transposition	
Article 21	This Directive is addressed to Member States Done at Brussels, 22 December 2006	This Article does not require transposition	

Annex I-IV		These provisions do not have substantive effect and so do not require implementation. See above for the implementation of the Articles that introduce them	
Directive 92/52 Article 1	Article 1 sets out the scope of the Directive	Article 1 is a general provision and does not require specific implementation	
Article 2 and 3	Member States shall ensure that infant formula and follow on formula may be exported from the Community only if they comply with the Directive (Article 2 and conditions set in Article 3)	Regulation 26 This regulation implements Articles 2 and 3 insofar as they apply to infant formula Regulation 27 This regulation implements Articles 2 and 3 insofar as they apply to follow-on formula and Article 3.	
Articles 4 and 5	Member States to notify Commission of implementation and Directive addressed to Member States	These Articles do not require transposition	

FINAL 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

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. 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 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 whilst promoting and protecting 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;
- requirement that infant formula and follow on formula are packaged, presented and advertised in a way which avoids any risk of confusion between them;
- 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.

2.6 The Infant Formula and Follow-on Formula (England) Regulations would give effect to the provisions of the Directive in domestic legislation. The Regulations would be complimented by Guidance Notes which aim to help industry, enforcement officers and other interested parties interpret the provisions of the domestic legislation. The Agency consultation on a draft of the Guidance Notes on The Infant Formula and Follow-on Formula Regulations 2007 can be accessed from:

http://www.food.gov.uk/consultations/consulteng/2007/infformnewguide07eng

3. Rationale for Government intervention

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

- 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)[1] 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. Implementing the Regulations would ensure that infant formula and follow-on formula placed on the market in England is in line with the provisions the Directive.

- The Directive provides for increased consumer protection compared to the existing infant formula legislation because it:
  - 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

[1] 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

- 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 Government has a target to increase breastfeeding rates[2]. A number of studies have demonstrated a link between infant formula advertising and a negative effect on breastfeeding rates (for example, a study carried out in the US[3] which investigated the effect of antenatal exposure to infant formula advertising on the infant feeding choices of a group of new mothers). In the light of the relationship between infant formula advertising and breastfeeding rates, the 'Choosing Health' White Paper made a commitment to review the domestic legislation with a view to further restrict the advertisement of infant formula[4]. The Regulations deliver on this commitment by including a provision to further restrict the ways in which infant formula can be advertised in England.

- The health benefits of breastfeeding to infants 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 diabetes[5]. 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 babies[6]. 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. Implementing the Directive by means of the Regulations would ensure that the domestic legislation which regulates this significant market is consistent with current EU legislation and relevant Codex Alimentarius standards.

4. Consultation

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

4.2 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

[2] http://www.hm-treasury.gov.uk/media/9/6/pbr_csr07_psa12.pdf and http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_078062.pdf

[3] Howard C. *et al* (2000) "Office Prenatal Formula Advertising and Its Effect on Breast-Feeding Patterns." *Obstetrics & Gynecology*, Vol. 95, No. 2, p296-303

[4] 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

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

[6] 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

(www.food.gov.uk). Member States agreed the Directive at the 19th July 2006 meeting of the SCoFCAH.

4.3 In England, the Agency consulted, from 29th June to 28th September, on draft Regulations to implement the Directive. The Agency consultation invited comments and evidence from stakeholders regarding:

- a number of specific provisions in the draft Regulations (the definitions of the terms 'idealise' and 'advertise' for the purpose of the Regulations; the proposed infant formula notification system; provisions which require infant formula and follow on formula to be packaged, presented and advertised in a way which avoids any risk of confusion between them). In the light of stakeholder responses on these specific issues, changes to the provisions of the Regulations were not required. The stakeholder responses were considered when drafting the Guidance Notes.
- their preferred option in relation to the implementation of the Directive (i.e. to maintain the status quo by retaining the previous Regulations or to implement the Directive by means of the new proposed Regulations).
- the potential costs associated with the options for implementation.
- other impacts such as the impact of the proposed Regulations on the charity and voluntary sector, enforcement authorities and on sustainability issues.
- any other aspects of the proposals.

4.4 The Agency received a number of responses to the consultation, including:

- 1321 responses from individuals (1301 of these responses were associated with a campaign by an alliance of NGOs)
- 6 responses from nutrition experts and health care professionals (British Dietetic Association, Royal College of Nursing, The Nutrition Society, Royal College of Midwives, The Scientific Advisory Committee on Nutrition Subgroup on Maternal and Child Nutrition (SMCN), two individual health workers).
- 11 responses from NGOs, or NGO alliances (The Baby Feeding Law Group (BFLG), National Childbirth Trust (NCT), Baby Milk Action (BMA), UNICEF, The Breastfeeding Manifesto Coalition, Association of Breastfeeding Mothers, The Breastfeeding Network, Save the Children, La Leche, Unite-CPHVA, IBFAN-GIFA).
- 4 responses from formula manufacturers and other industry bodies (Hipp, the Infant and Dietetic Foods Association (IDFA), the National Pharmacists Association (NPA), FTSE).
- 2 responses from enforcement bodies (the Local Authorities Coordinator of Regulatory Services (LACORS) and Trading Standards South-East (TSSE))

The responses can be accessed by contacting the Agency Information Centre[7]. A summary of the responses, all of which were considered before the Regulations were finalised, can be accessed from:

http://www.food.gov.uk/consultations/consulteng/2007/formulaengland2007

4.5 Separate consultations were also carried out by the relevant offices of the Food Standards Agency in the devolved administrations.

- Responses from the following organisations were made to the Scotland, Wales or Northern Ireland consultations - Ayrshire Maternity Unit, NHS Lothian Breastfeeding Strategy Group, West Lothian Breastfeeding Group, Tayside Infant feeding Group, Scottish Government Health and Wellbeing Directorate, Breastfeeding Network Trust, Welsh Assembly Minister for Health, Northern Ireland Human Milk Bank.
- Responses from the following organisations were made to two or more of the Agency consultations in England, Scotland, Wales and Northern Ireland - The Baby Feeding Law

[7] Information Centre - GND 13, Food Standards Agency, Aviation House, 125, Kingsway, London WC2B 6NH, Tel: 0207-276-8181, InfoCentre@foodstandards.gsi.gov.uk

Group (BFLG), National Childbirth Trust (NCT), UNICEF, The Breastfeeding Manifesto Coalition, Association of Breastfeeding Mothers, The Breastfeeding Network, Save the Children, La Leche, Royal College of Midwives, Royal College of Nursing, National Pharmacists Association, University of Leicester.

Summaries of these comments will be made available by the offices of the FSA in Scotland, Wales and Northern Ireland.

4.6 The Agency considered all the responses received during the consultation before finalising the Regulations.

5. Options

Option 1: Retain the Status Quo

5.1 This option would result in the continued application of the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77)[8].

Option 2: Implement the Regulations

5.2 This option would result in the implementation of the Directive by means of the Regulations. The Regulations would apply in England, with parallel Regulations being implemented in Scotland, Wales and Northern Ireland. The Regulations would be accompanied by Agency Guidance which would help industry, enforcement officers and other interested parties interpret the provisions of the legislation. The Guidance would, in particular, provide a detailed Agency view on the action that should be taken by formula manufacturers to ensure compliance with the labelling and advertising provisions of the Regulations.

5.3 The Nutrition Society supported Option 2, to implement the European Directive by means of the proposed Regulations.

5.4 In principle, IDFA and Hipp support the implementation of the Directive, although they believe that the domestic Regulations should go no further than the provisions of the Directive. IDFA, Hipp and the NPA object to the further tightening of the restrictions on infant formula advertising proposed in the Regulations.

5.5 The previous Regulations permit the advertising of infant formula in baby care publications circulated within the health care system. As a result, mothers and pregnant women could be exposed to infant formula advertising should they have access to baby care publications while under treatment within the health care system. This is not supportive of Government policy on the promotion of breastfeeding as infant formula advertising to the public has the potential to impact negatively on breastfeeding rates[3]. To ensure that mothers and pregnant women cannot be exposed to infant formula advertising by these means, the Regulations propose to remove the existing provision in domestic legislation which permits infant formula advertising in baby care publications circulated within the healthcare system. This brings into line the advertising restrictions which apply to all baby care publications, irrespective of where they are made available (either within, or outside the health care system).

5.6 While the Baby Feeding Law Group are supportive of the proposal to further tighten the restrictions on the advertising of infant formula, they propose a ‘third option’ for the wider implementation of the Regulations. Their proposed option involves the implementation of a number of provisions which, they contend, would implement the WHO Code on the Marketing of Breastmilk Substitutes (referred to in this document as the ‘WHO Code’). As part of this approach, the BFLG propose a ban on the advertising of follow-on formula to remove the role of

[8] http://www.opsi.gov.uk/si/si1995/Uksi_19950077_en_1.htm

such advertising being taken by consumers as advertising infant formula and thereby undermining breastfeeding. In support of their proposal, the BFLG cite a legal opinion which formed part of the UNICEF submission to the Agency consultation on the draft Regulations, and two other opinions from legal academics. The following groups submitted comments to the Agency consultation in support of the 'third option' proposed by the BFLG: Baby Milk Action, Breastfeeding Manifesto Coalition, Association of Breastfeeding Mothers, The Breast Feeding Network, NCT, UNICEF UK, Royal College of Nursing, Save the Children, IBFAN-GIFA, La Leche League Great Britain, Unite-CPHVA, Royal College of Midwives. In addition, over 1300 individuals wrote to the Agency and/or the Department of Health calling for domestic UK formula legislation to based on the WHO Code. The Subgroup on Maternal and Child Nutrition of the Scientific Advisory Committee on Nutrition also support a prohibition on the advertising of follow-on formula.

5.7 From an enforcement perspective, LACORS support a prohibition on the advertising of follow-on formula. 'Trading Standards South-East' (TSSE), a group representing the views of 19 enforcement authorities, recognise that such a prohibition would mean that there would be no opportunity to cause confusion between infant formula and follow-on formula. However, TSSE also state that they support the principle of informed consumer choice, and that any ban on follow-on formula advertising would run counter to this principle.

5.8 The Directive represents the EU view on how the recommendations of the WHO Code should be incorporated into European law with respect to the composition, labelling and advertising of infant formula and follow-on formula. Regulation 19 of the Regulations which itself applies to labelling as applied to presentation by regulation 20(1) and applied to advertising by regulation 21, in combination with Agency Guidance Notes, will address the issue of confusion between infant formula and follow-on formula labelling, presentation and advertising. The Agency will monitor the impact of the new rules and after 12 months of application set up an independently chaired review, with stakeholder participation, to check that they are working effectively.

5.9 With regard to Regulation 19, stakeholders were asked, as part of the Agency consultation, to suggest how manufacturers can ensure that infant formula and follow-on formula are appropriately differentiated. IDFA responded by stating that they are not aware of any reliable evidence of confusion between these products. The National Childbirth Trust and Trading Standards South East made a number of suggestions about the packaging/advertising of these products which have been addressed in the draft Guidance Notes.

6. Costs and benefits

6.1 This section aims to identify the costs and benefits associated with options 1 and 2 noted above. None of the submissions to the Agency consultation contained quantitative evidence of the costs or benefits associated with options 1 or 2.

Sectors and groups affected

6.2 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

Benefits of option 1

6.3 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

6.4 Adopting the Regulations would bring benefits to:

Consumers - 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 and health professionals - for whom the Regulations provide increased protection because they:
- clarify the rules which apply to the use of claims in relation to infant formula.
- ensure that the labelling, presentation and advertising of infant formula and follow-on formula will ensure that carers and healthcare professionals can adequately differentiate between these products.
- reduce potential exposure to direct infant formula advertising as a result of the further restriction proposed in the Regulations.

These measures may potentially help to improve breastfeeding rates/duration. It is difficult to quantify this potentially beneficial effect. However, the Howard study demonstrated that reducing exposure to infant formula advertising can have a significant positive effect on breastfeeding rates/duration[3].

Infants/health services – Improved breastfeeding rates/duration would bring health benefits to those infants who would otherwise not have been breastfed[5]. Improved breastfeeding rates/duration would also potentially bring savings to the health service, as discussed in paragraph 3.1.

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).

In addition, by introducing the new regulations, the UK would avoid the risk of infraction proceedings brought by the European Commission for not implementing the requirements in the Directive.

Costs of option 1

6.5 Maintaining the status quo would bring costs to stakeholders as discussed below:

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 could 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.

In addition, the Food Standards Agency would be failing in its duty to implement EU law and could possibly face the cost of infraction procedures.

Costs of option 2

6.6 Adopting the Regulations would bring costs to stakeholders as discussed below:

Consumers and 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 requested comments and evidence from stakeholders about the policy or administrative[9] compliance costs associated with the new mandatory reformulation, notification or re-labelling requirements of the Regulations.

IDFA noted that it is difficult to quantify these policy and administrative costs as formula companies have been working towards compliance with the compositional provisions of the new Directive for a long period of time (since 2003). IDFA also highlighted concerns that the imposition of labelling/packaging restrictions which go beyond what is required in the Directive may make Europe-wide distribution more difficult and will have a negative impact on competition and potentially could result in increased costs to consumers. None of the formula manufacturers, or their representatives provided any monetised estimates of compliance costs, or provide any quantified evidence to support their views on the impact of the proposed options.

In the absence of monestised information from stakeholders, the Agency estimates that Option 2 will incur the following costs on formula manufacturers:

Notification of infant formula - 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.

[9] '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.

Assessment of new claims - 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.

Costs of relabelling – In their submissions to the Agency consultation on Signpost labelling[10], the BRC estimated the cost of relabelling a product line at £1000 per product, whereas the equivalent figure estimated by the FDF was £50,000. The Agency considers that approximately 25 infant formula and follow-on formula product lines marketed by Nutricia, H.J. Heinz and SMA Wyeth (whose products account for 97% of formula sales in the UK, according to the market research company, Mintel) may need to be relabelled as a result of the new Regulations. Thus, the total cost of this relabelling is estimated at between £25,000 which the Agency considers the most realistic estimate, and £1,250,000.

Charities and the voluntary sector

6.7 The Breastfeeding Network noted in their response to the consultation that their workload would be reduced if women were not undermined by the commercialisation of infant feeding. None of the other charities or voluntary organisations who responded to the Agency consultation noted specific impacts of either option on their work.

Enforcement and health professionals

6.8 LACORS is not able to quantify the impact that implementing the proposed Regulations would have in resource terms on enforcement authorities.

Government

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

7. Small firms impact test

7.1 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.

8. Competition assessment

8.1 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.

8.2 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] http://www.food.gov.uk/foodindustry/regulation/ria/ria2006/signpostingria

9. Sustainable development

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

9.2 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. 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. Option 2 may bring new economic costs to industry due to reformulation and relabelling. 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.

9.3 On the basis of the information available, there appears to be no significant differences between the environmental costs of Options 1 and 2.

9.4 None of our stakeholders submitted quantitative estimates of the economic, environmental or social costs and benefits associated with options 1 or 2. As a result, the sustainability assessment with respect to the Regulations cannot be further quantified.

10. Racial equality

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

11. Public services threshold test

11.1 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.

12. Enforcement, sanctions and monitoring

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

13. Implementation and delivery plan

13.1 Should Option 2 be adopted, the Regulations would be implemented by 11th January 2008.

14. Post-implementation review

14.1 The Agency will monitor the impact of the new rules and after 12 months of application set up an independently chaired review, with stakeholder participation, to check that they are working effectively. The UK would also participate in any future review of the Directive that may be taken forward at an EU level.

15. Summary and Recommendations

15.1 In summary, making these Regulations will benefit consumers and enable the UK to fulfil Community obligations. Failure to make these Regulations would result in a serious breach of

the UK's obligations under the EC treaty which would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

15.2 For these reasons the Agency recommends that the UK implements the provisions of Commission Directive 2006/141/EC by means of the Infant Formula and Follow-on Formula (England) Regulations 2007.

Summary of main costs and benefits associated with the options proposed in relation to the implementation of the Regulations.

Option	Costs	Benefits
1	Fines to Government associated with European Commission infraction proceedings against the UK Ongoing costs to industry of developing and marketing UK-specific formula	None
2	Costs to industry relating to relabelling (one-off costs of approximately £25,000 and administration of notification procedures (£840-£1560 per annum) Possible non-commercial reformulation costs to industry	Savings to the NHS and wider health benefits (Difficult to quantify, but likely to be greater than £0, rising by at least £725,000 per annum for each percentage increase in breastfeeding rate attributable to stricter controls on infant formula advertising)

Declaration:

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister*:.....Dawn Primarolo*.....

Date:.....13th December 2007.....……

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