

Draft Guidance Notes on The Infant Formula and Follow-on Formula Regulations 2007

Introduction

1. These Guidance Notes aim to help industry, enforcement officers and other interested parties interpret the provisions of the Infant Formula and Follow-on Formula (England) Regulations 2007 and equivalent Scotland, Wales and Northern Ireland Regulations¹ (referred to in the rest of this document as 'the Regulations').

2. The Guidance Notes:

- focus mainly on the provisions of the Regulations which relate to labelling, notification, avoidance of risk of confusion between infant formula and follow-on formula, advertising, promotion, and the provision of information and education relating to infant and child feeding.
- replace any LACORS Guidance Notes² on infant formula and follow-on formula and supersede any previous views expressed by the Agency on the interpretation of the regulations which relate to the issues mentioned above.
- reflect the Agency view on how the Regulations should be interpreted and thereby help to promote consistent enforcement.
- apply to parallel Infant Formula and Follow-on Formula Regulations in England, Scotland, Wales and Northern Ireland.

Background

3. The Regulations implement European Commission Directive 2006/141/EC on infant formulae and follow-on formulae (referred to in the rest of this document as 'the Directive') 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 principles and aims of the WHO Code on the Marketing of Breastmilk Substitutes dealing with marketing, information and responsibilities of health authorities. The Regulations also implement Council Directive 92/52/EEC.

¹ The Infant Formula and follow on Formula (Scotland) Regulations 2007
The Infant Formula and follow on Formula (Wales) Regulations 2007
The Infant Formula and follow on Formula (Northern Ireland) Regulations 2007

² www.lacors.gov.uk

4. The Regulations:

- apply with effect from 1 January 2008 the provisions of the Regulations which do not relate to trade in infant formula and follow-on formula (e.g. the provisions which apply to the advertising of infant formula and follow-on formula).
- permit trade in products which comply with the Infant Formula and Follow-on Formula Regulations 1995 (SI 1995/77)³, as amended (referred to as 'the previous Regulations' in the rest of this document) no later than 31 December 2009.
- permit with effect from 1 January 2008 trade in products that comply with the Regulations
- wholly replace the previous Regulations from 1st January 2010.

5. Paragraphs 78 and 79 provide further guidance about revocations and transitional arrangements. In these Guidance Notes, references to Annexes refer to the Annexes of Directive 2006/141/EC.

Interpretation (regulation 2)

6. Regulation 2(1) provides certain definitions.

7. Regulation 2(2) provides that, subject to regulation 2(3), any expression other than one defined in regulation 2(1) that is used both in the Regulations and in the Food Safety Act 1990⁴ (referred to for the purposes of these Guidance Notes as 'the Act') has the meaning it bears in the Act.

8. 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 set out in the Directive apply for the purposes of the Regulations: 'infants', 'young children', 'infant formulae', 'follow-on formulae', 'pesticide residue'.
- The definitions of the following terms set out in Regulation (EC) No. 1924/2006 (the European Nutrition and Health Claims Regulation) apply for the purposes of the Regulations: 'claim', 'nutrition claim', 'health claim', 'reduction of disease risk claim' (refer to paragraph B, p7 for further details)

³ In Northern Ireland, the Infant Formula and Follow on Formula Regulations (NI) 1995 SR No. 77

⁴ http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900016_en_1.htm. In Northern Ireland, the corresponding legislation is the Food Safety (NI) Order 1991.

- The term 'third country' has the meaning that it has in EC legislation. Thus, 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, has 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. Guidance relating to the characteristics of 'advertising' in the context of the Regulations is provided in Appendices I and II.
- The terms 'sell', 'market' and 'placing on the market' have not been defined in the Regulations (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(8) of the Directive is included in the Regulations at regulation 20(3).

9. 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 regulations each time the Annexes to the Directive are updated. The Regulations will be amended by further regulations if the main Articles of the Directive are updated. The information in the Annexes to the Directive is summarised below:

- Annex I – The essential composition of infant formula when reconstituted as instructed by the manufacturer.
- Annex II - The essential composition of follow-on formula when reconstituted as instructed by the manufacturer.
- Annex III – The list of nutritional substances that can be added to infant formula and follow-on formula for particular nutritional uses.
- Annex IV – The lists of nutrition and health claims that are permitted for use in relation to infant formula, with details of the conditions warranting the claims.
- Annex V – The list of indispensable and conditionally indispensable amino acids in breast milk.
- Annex VI – Specification for the protein content and source and the processing of protein used in the manufacture of infant formula with a protein content less than 0.56 g/100 kJ (2.25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein.
- Annex VII – Reference vales for nutrition labelling for foods intended for infants and young children.
- Annex VIII – List of pesticides which shall not be used in agricultural production intended for the production of infant formulae and follow-on formulae
- Annex IX – List of the specific maximum residue levels of pesticides or metabolites of pesticides in infant formula and follow-on formula

- Annex X – Repealed Directive with a list of subsequent amendments, and the list of time limits for transposition into national law
- Annex XI – Correlation table between Directive 91/321/EEC and Directive 2006/141/EC.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met (regulation 3)

10. 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 regulations 17 and 18 to presentation) 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 regulations 18 and 19 to presentation) and risk of confusion with infant formula (regulation 19).

Regulations 4 to 11

11. These regulations relate mainly to compositional aspects of infant formula and follow-on formula. Guidance is not provided on these provisions.

Listed substances and their purity criteria (infant formula and follow-on formula) (regulation 12)

12. Regulation 12(3) provides that for the purposes of regulation 12(2), the relevant purity criteria for substances used in the manufacture of IF and FOF are:

- 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) (as regards Northern Ireland, the Colours in Food Regulations (NI) 1996 SR No.49) and the Miscellaneous Food Additives Regulations 1995 (S.I. 1995 No.

3187) (as regards Northern Ireland, the Miscellaneous Food Additives Regulations (NI) 1996 SR 50) respectively.

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

13. Other substances having a particular nutritional purpose must be listed in Annex III before they can be added to infant formula or follow-on formula products which are placed on the market.

Notification of infant formula (regulation 13)

14. Regulation 13 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.

15. Further guidance on how and when to notify the Agency can be found at: <http://www.food.gov.uk/multimedia/pdfs/parnutsguidancenotes.pdf>

Labelling of infant formula (regulation 17)

16. Manufacturers are encouraged to use the Agency 'Clear Labelling' guidance when developing infant formula labelling. The guidance can be accessed from:

<http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/clearfoodlabelling>

[NB - The Agency has published a consultation on a draft revision of the 'Clear Food Labelling Guidance', which can be accessed from: <http://www.food.gov.uk/multimedia/pdfs/consultation/clearfoodguide07.pdf>]

17. Manufacturers are also encouraged to clearly state the age range that the product is suitable for on the front of the packaging. The font size for the age range declaration should be no smaller than that used for the term 'infant milk' or 'infant formula' on the front of the packaging.

Labelling relating to the preparation, storage and disposal of infant formula and follow-on formula

18. Regulation 17 (1)(d) and 18(1)(d) require that instructions are provided for appropriate preparation, storage and disposal of the product. The Agency recommends that these instructions should include information noting that:

- Powdered infant formulae and follow-on formulae are not sterile, which means they can contain harmful bacteria. It is therefore important to take care when preparing formula to reduce the risks.
- All equipment used for feeding and preparing feed must be thoroughly cleaned and sterilised before use, and bottles should be made up fresh for

each feed, as storing made-up formula milk may increase the chance of a baby becoming ill.

19. Further advice about the preparation and storage of formula can be found at the websites below:

<http://www.food.gov.uk/news/newsarchive/2005/nov/infantformulastatementno v05> (advice to consumers)

<http://www.food.gov.uk/news/newsarchive/2006/dec/infantform> (advice to health professionals)

20. Regulations 17(1)(d) and 18(1)(d) require, in addition to instructions for appropriate preparation, storage and disposal of the product, a 'warning against the health hazards of inappropriate preparation and storage'. This statement should stress the importance for the baby's health of correct preparation of infant formula without which there is an increased risk of the baby suffering from serious stomach upsets, diarrhoea, constipation etc. This statement should appear on the label in a conspicuous place and be clearly visible and easily understandable. The statement should include wording such as 'Failure to follow instructions may make your baby ill'.

Labelling relating to the 'Important Notice' requirement

21. The Important Notice (concerning the superiority of breast feeding and advice on when infant formula should be used) required on infant formula by virtue of regulation 17(1)(e) should be afforded a high degree of prominence on the label. It should be clearly visible and understandable. Please refer to Appendix III for guidance on the presentation of 'Important Notice' information on websites.

Labelling about the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding

22. Regulations 17(2) and 18(2) seek to ensure that the labelling of infant formula and follow-on formula provides the necessary information about the appropriate use of the products so as not to discourage breast feeding and does not contain the terms 'humanised', 'maternalised' and 'adapted' or any similar term.

23. In the light of this provision, non-mandatory text or pictures on infant formula labelling should not make reference to terms such as 'breastmilk', 'breastfeeding' or 'the ideal method' of infant feeding. References to such terms may also not comply with regulation 17(3) in relation to idealisation of infant formula and 17(4) in relation to the use of nutrition and health claims.

Labelling of infant formula to avoid idealising the product

24. Regulation 17(3) provides that the labelling of 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.

25. The following are examples of representations which may be considered to 'idealise' the use of infant formula should they feature on infant formula labelling:

- Pictures of infants, young children or carers (e.g. mothers or fathers).
- Pictures or text which implies that infant health, happiness or well being, or the health, happiness and wellbeing of carers, is associated with infant formula.
- References to infants or carers emotions.
- Baby or child related subjects (e.g. toys, cots or building blocks) and anthropomorphic characters, pictures and logos.
- Non-mandatory pictures or text which refer, directly or indirectly, to breastmilk, breastfeeding, or to terms such as the 'ideal method' of infant feeding.

Use of nutrition and health claims in relation to infant formula

26. 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.

27. The following definitions, which are set out in European Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, apply for the purposes of these Regulations:

- 'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;
- 'nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:
 - (a) the energy (calorific value) it
 - (i) provides
 - (ii) provides at a reduced or increased rate; or

(iii) does not provide; and/or

(b) the nutrients or other substances it

(i) contains

(ii) contains in reduced or increased proportions; or

(iii) does not contain;

- 'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

28. Annex IV provides lists of the nutrition and health claims that can be made in relation to infant formula. All other nutrition and health claims in relation to infant formula or its ingredients are therefore prohibited.

29. The following points should be noted in relation to regulation 17(4):

- Claims are regulated wherever they appear on the labelling. It is not the case that statements constitute claims only when they appear in headings or banners.
- Claims which refer to or describe a physiological function are considered as health claims and as such cannot be used in relation to infant formula unless they are included in Table 2 of Annex IV. For example, claims relating to 'prebiotics', such as 'contains prebiotics', are considered health claims because they describe a physiological function and are not permitted.
- Permitted nutrition claims cannot be used in conjunction with additional statements. For example, 'contains LCPs' is permitted, whereas 'with LCP care' is not. Such additional statements may mean that the claim can no longer be clearly identified as a nutrition claim and is instead a health claim or implied health claim.
- Nutrition or health claims about named, patented, mixtures of ingredients can be used only if the composition of the patented mixture is explained on the labelling. Thus, it would not be permitted to include claims such as 'contains LCPmix' on infant formula packaging if terms such as 'LCPmix' are not further explained on the labelling. Claims such as 'contains LCPmix - a patented mixture of long chain polyunsaturated fatty acids' would be permitted on the labelling (subject to the relevant conditions in table 1 of Annex IV). Nutrition claims can be made only in relation to patented mixtures of the substances included in the left hand column of Table 1 in Annex IV of the Directive. Health claims other than those listed in Table 2 of Annex IV of the Directive, cannot be used. Thus, claims such as 'Contains LCPmix for brain and eye development.' cannot be used.
- If the labelling of 'formula brand x' refers to the health properties of 'substance y' in breastmilk, and the same labelling contains a nutrition claim for substance y in relation to a brand x formula or group of formulae,

then this may constitute an implied health claim for substance y and is considered non-compliant. As a result, the following type of claim would not be permitted: 'Breastmilk contains ingredient y which helps fortify the immune system. Formula brand x contains ingredient y.'

Extending the list of permitted nutrition and health claims in relation to infant formula

30. The European Food Safety Authority (EFSA), is likely to be consulted on any changes to Annex IV'⁵ These Guidance Notes will be updated if the Commission publish guidance on the process whereby new claims may be added to Annex IV.

Labelling of follow-on formula (regulation 18)

31. Manufacturers should use the Agency 'Clear Labelling' guidance when developing follow-on formula labelling.

32. Manufacturers are also encouraged to clearly state the age range that the product is suitable for on the front of the packaging. The font size for the age range declaration should be no smaller than that used for the terms 'follow-on milk' or 'follow-on formula' on packaging.

33. The statement required on follow-on formula labelling by virtue of regulation 18(1)(a) should be afforded a high degree of prominence on the label. It should be clearly visible and understandable.

34. For guidance relating to regulation 18(2), refer to paragraph 22.

The use of claims in relation to follow-on formula

35. European Regulation (EC) No 1924/2006, on nutrition and health claims made on foods lays down provisions regarding the use of claims in relation to follow-on formula.

36. A weblink to the Regulation 1924/2006 and an introduction to the controls it puts in place is given below:

<http://www.food.gov.uk/consultations/consulteng/2007/claims2007eng>

37. The Annex to Regulation 1924/2006 contains the list of permitted nutrition claims of relevance to follow-on formula and the criteria for using them. The list of permitted health claims is being compiled and there are several ways in which claims can be added. Until the list of health claims is adopted (expected in January 2010), existing national legislation will apply.

⁵ http://ec.europa.eu/food/committees/regulatory/scfcah/general_food/summary21_en.pdf

38. The Trade Descriptions Act 1968 and the Food Safety Act 1990, makes it an offence to falsely describe a food or mislead as to its nature, substance or quality.

39. The Food Labelling Regulations also make it an offence to make medicinal claims which state or imply that a product can prevent, treat or cure a human disease. Regulation 1924/2006 allows disease risk reduction claims to be made, but only once they have been authorised.

40. Health claims about follow-on formula are to be authorised in one of the following ways: as part of the national list of claims based on generally accepted scientific evidence; on the basis of a dossier of new scientific evidence, or proprietary data; on a dossier establishing claims for children's health and development; on a dossier establishing a reduction in a disease risk factor. More information about these can be found in the draft Agency guidance to compliance with 1924/2006: www.food.gov.uk/multimedia/pdfs/nhcguideuk07.pdf (the Agency has consulted on this document and, although we are currently revising it as a result of consultation comments received, the draft version gives an indication of our initial interpretation).

41. Claims about follow-on formula which the Advertising Standards Authority (ASA) have found to be unsubstantiated should not be used (e.g. in follow-on formula labelling and advertising).

General guidance with regard to infant formula and follow-on formula advertising

42. When advertising to the public or health care professionals, formula manufacturers should consider the requirements of regulations 18, 19, 21 and 22 together. Read together, the aims of these regulations are to ensure that:

- infant formula is advertised only in scientific publications or for trade purposes (regulation 21).
- consumers recognise other advertisements by formula manufacturers as advertising follow-on formula exclusively. Such advertisements should not promote, either directly or indirectly, infant formula, or formula milks/bottlefeeding in general. (regulations 18, 19 and 22)

43. In order to achieve compliance, companies will therefore need to ensure that formula advertising does not:

- promote a range of formula products by making the brand the focus of the advert, rather than specific products (e.g. where follow-on formula or growing-up milks are mentioned only in a footnote or in a picture of a tin of formula within the advertisement)
- feature text or images which relate to pregnancy (e.g. pregnancy test kits) or the feeding or care of infants under six months
- include pictures or text which directly or indirectly relate or compare products to breastmilk

- focus on carers emotions in relation to the feeding or care of infants under six months
- feature babies which consumers may perceive as being under six months (even if they are over six months)
- focus primarily on the promotion of ingredients, or the effect of ingredients, which are common to both follow-on formula and infant formula

44. Companies will also need to ensure that carelines, websites or mother and baby clubs, and any advertisements for these means of communication, supply only factual information to consumers and health care professionals.

Avoidance of the risk of confusion between infant formula and follow-on formula (in relation to labelling, presentation and advertising) (regulation 19)

45. 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 such products so as to avoid any risk of confusion between infant formula and follow-on formula.

46. This provision also applies to the presentation and advertising of infant formula and follow-on formula, by virtue of regulations 20(1), 20(2), 21(1)(b) and 22.

47. In the light of this requirement, manufacturers should ensure the following when drafting infant formula and follow-on formula labelling:

- the specific terms ‘infant formula’ and ‘follow-on formula’ should be clearly featured on the packaging, in similar font size to that used for the brand name.
- Infant formula and follow-on formula packaging should feature different labelling elements (such as pictures and blocks of text) in differing spatial arrangements (Appendix IV).
- The colour scheme of infant formula packaging should be clearly different to the colour scheme of follow-on formula packaging.
- References to breastmilk or breastfeeding should not be made on follow-on formula packaging as consumers may associate these terms with feeding infants from birth, whereas follow-on formula should be used only from six months.

Presentation (infant formula and follow-on formula) (regulation 20)

48. Regulation 20(3) notes that for the purposes of this regulation, which specifically applies regulation 19 to presentation, “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.

49. The aspects of presentation which relate to labelling of infant formula and follow-on formula have been discussed previously. In relation to in store presentation, companies should ensure that:

- 'shelf-talkers' (attachments that add a company's logo or sale message to the edge of a shelf) and other in-store promotional devices for follow-on formula are not used in the vicinity of infant formula.
- Follow-on formula is located at a different part of the store to infant formula.

Restrictions on advertising infant formula (regulation 21)

50. Regulation 21 provides that infant formula can be advertised only in:

- scientific publications (where such publications report the results of original scientific research and reviews) or
- trade publications (prior to the retail stage), where the intended readership of the publications is other than the general public,

and only if subject to the conditions outlined in regulation 21(b), which provides that any advertisement for infant formula must not contravene or fail to comply with the provisions of regulations 17(1)(e), (2), (3), (4), regulation 19 or paragraph (2) or (3).

51. Further guidance about infant formula advertising is given in Appendices I and II.

The use of 'Important Notice' information in infant formula advertisements

52. The 'Important Notice' which must appear in any advertisement for infant formula by virtue of regulation 17(1)(e), should be afforded a high degree of prominence in the advertisement. It should be clearly visible and understandable.

Advertising in relation to the appropriate use of infant formula and follow-on formula so as not to discourage breastfeeding

53. Regulations 21(b) and 22 apply regulations 17(2) and 18(2) in relation to infant formula and follow-on formula. As a result, advertisements for these products must provide the necessary information about the appropriate use of the products so as not to discourage breast feeding and must not contain terms such as 'humanised', 'maternalised' or 'adapted'.

54. In the light of these provisions, non-mandatory text or pictures in infant formula and follow-on formula advertisements should not make reference to terms such as 'breastmilk', 'breastfeeding' or 'the ideal method' of infant feeding.

The use of pictures of infants or any other picture or text which may idealise the use of the product

55. Regulation 21(1)(b) applies regulation 17(3) in relation to advertisements for infant formula. As a result, the guidance detailed in paragraphs 24 and 25 should be applied to infant formula advertisements.

The use of nutrition and health claims in infant formula advertisements

56. Regulation 21(1)(b) applies regulation 17(4) in relation to advertisements for infant formula. As a result, the considerations detailed in paragraphs 26 to 29 should be applied to infant formula advertisements.

Ensuring that there is a clear distinction between advertisements for infant formula and follow-on formula

57. Regulation 21(b) applies regulation 19 in relation to advertisements for infant formula and follow-on formula. To comply with this provision, companies should follow the guidance detailed in paragraphs 42 to 47.

Characteristics of 'information of a scientific or factual nature'

58. Regulation 21(2) provides that any advertisement for infant formula shall only contain information of a scientific and factual nature, and therefore, such advertisements should not include subjective or emotive language.

Ensuring that advertisements do not imply or create the belief that bottle-feeding is equivalent or superior to breastfeeding

59. 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. Advertisements should therefore not include pictures or text which relate or compare infant formula to breastmilk.

Promotions of company 'milks' or 'formulae'

60. Consumers may understand that generic references to 'formula milks' or 'formulae' in advertisements refer to a number of formula products including infant formula. In order to achieve compliance, companies will need to ensure that such terms are not used in advertising, subject to the exceptions detailed in regulation 21.

Additional Notes in relation to infant formula advertising

61. Whilst trade to trade advertisements are allowed under Regulation 21, they must comply with the provisions which control advertisements.

62. The regulations do not extend to the advertising of products related to feeding infants and young children other than infant formula and follow-on

formula such as breast pads, sterilising equipment, bottles and teats etc. provided that such advertisements do not contain references to a named infant formula.

63. Any general advertisement placed by a manufacturer must not feature an infant formula brand name and if this advertisement includes a response mechanism this must be of an 'opt-in' type, so that only parents or carers actively requesting information on infant formula milks can be sent this information and nothing else. Attempting to solicit requests for information, providing information on products outside the scope of the initial enquiry or making undue references to proprietary infant formula brand names in a response to a request for product information is considered advertising and is not permitted under regulation 21.

Restrictions on advertising follow-on formula (regulation 22)

64. This regulation provides that no person shall advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions of regulation 18(2) or 19.

65. As a result, to comply with these provisions, companies should follow the guidance in paragraphs 22 and 42 to 47 in addition to the guidance detailed below.

- In advertisements for follow-on formula, the term 'follow-on formula' should feature conspicuously, in a font size similar to the main copy of the advertisement. The font size for the term 'follow-on formula' should be no smaller than the brand name. The term 'follow-on formula' should not feature solely in:
 - the text of the 'Important Notice'; or
 - pictures of follow-on formula packaging which are featured in the advertisement.
- The inclusion of the information below in any follow-on formula advertisement may help consumers understand that it relates *exclusively* to follow-on formula, and does not relate to infant formula:
 - Follow-on formula is suitable only for particular nutritional use by infants over the age of six months.
 - A clear indication that any infants featured in follow-on formula advertisements are over six months.
- The colour scheme of follow-on formula advertisements should clearly differ from that used in infant formula advertisements.
- To minimise the risk of consumers making a connection between follow-on formula and the act of feeding infants from birth, information in advertisements for follow-on formula should not include pictures or text which relate or compare follow-on formula to breastmilk.

- Manufacturers should ensure that publishers and producers involved in the advertising of infant formula and follow-on formula are aware of the Regulations with regard to the marketing and presentation of an infant formula. In addition, manufacturers should ensure that publishers and producers are aware that any advertisement for follow-on formula in print should not be placed within or adjacent to any article or photo spread featuring the feeding of babies under six months of age.

Restrictions on promotion of infant formula (regulation 23)

66. Regulation 23(1)(b) prohibits ‘any special display...designed to promote sales’. As a result, companies should not use prominent shop window displays, free standing displays or ‘shelf-talkers’ which relate to infant formula products.

67. Regulations 23(1)(d) and (e) prohibit ‘special sales’ to promote the sale of an infant formula or any other special activity at any place where any infant formula is sold by retail to induce the sale of an infant formula. As a result, multi packs (bulk packs) etc., where they are not the normal form in which the product is offered for sale, should not be promoted.

Provision of information and education regarding infant and child feeding (regulation 24)

68. Regulations 24(1) to 24(3) are self-explanatory and do not require further guidance.

69. Guidance on information which is provided by means of websites is provided in Appendix III.

70. With reference to regulation 24(4), the following are considered as some examples of informational or educational equipment or materials for which approval from the Secretary of State⁶ must be sought before formula manufacturers donate them to third parties:

- CDs and DVDs
- Wallcharts, posters
- Booklets or leaflets which are designed for reference purposes
- Electronic files that can be downloaded directly from a website.

71. Companies who wish to seek approval from the Secretary of State for their donation should write to:

In England

Dr Sheela Reddy
Principal Nutritionist
National Programme Delivery - Obesity & Nutrition
Department of Health

⁶ In Scotland, this would be Scottish Ministers.

133 - 155 Waterloo Road
London SE1 8UG

In Scotland

John Froggatt
Deputy Director Child and Maternal Health
Healthcare Policy and Strategy Directorate
Child and Maternal Health Division
Ground Rear
St.Andrew's House,
Regent Road
Edinburgh
EH13DG

In Wales

Maureen Howell
Head of Food and Physical Activity
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ

In Northern Ireland

Andrew Elliott
Director of Population Health
Room C5
Department of Health, Social Services and Public Safety
Castle Buildings
Stormont Estate
BELFAST
BT4 3SQ

Third country exports (regulations 26 and 27)

72. Regulations 26 and 27 require that exports of infant formula or follow-on formula from the UK to third countries (i.e. non-EU countries) meet the compositional requirement of these Regulations as set out in regulations 5 -12 and 14 as appropriate and the labelling requirements of regulations 17-19 as appropriate. In addition the exported products must meet the requirements of the Food (Lot Marking) Regulations 1996 (S.I. 1996/1502) and the Codex Standard for Infant Formula or the Codex Standard for Follow-up Formula.

Offences and enforcement (regulation 28)

73. 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.

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

75. 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 England and Wales 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)⁷ specifies whether the District Council or the County Council Food Authority is to act in particular cases.

76. For the purposes of the Scotland Regulations, food authorities are –

- the Local Authority or;
- the Port Health Authority, where appropriate⁸

77. In Northern Ireland the regulations made under the Food Safety (NI) Order 1991 are enforced by the “district councils” to the extent specified in Article 26 of the Order.

Revocation and transitional arrangements (regulation 31)

78. Regulation 31 read with regulation 1, provides for the revocation of the existing 1995 Regulations and creates transitional arrangements relating to the marketing of infant formula and follow-on formula.

79. The substantive provisions of the 2007 Regulations (relating to trade and other issues such as advertising and export) come into force with effect from 1 January 2008 as provided for by regulation 1(b)(ii). However, at Article 18, Directive 2006/141 provides that trade in products which comply with the previous Directive may continue until 31 December 2009. These arrangements, as set out in the domestic law, are explained below.

⁷ <http://www.food.gov.uk/enforcement/foodlaw/foodlawcop/copengland>

⁸ This is subject to change. It is intended that when the Public Health (Scotland) Bill becomes law Port Health Authorities will be abolished and their functions will transfer to local authorities.

- The effect of regulation 31(1), as read with regulation 1(b)(ii), is to revoke with effect from 1 January 2008 the provisions of the 1995 Regulations which do not relate to trade.
- Regulation 31(3) continues to permit trade in products which comply with the 1995 Regulations until 31st December 2009 by ensuring that no person who places a product compliant with the 1995 Regulations on the market until that time, is guilty of an offence under the 2007 Regulations.
- Regulation 31(4) amends the 1995 Regulations in the manner set out in Regulation 31(5). This means that regulation 31(5) provides that any person who places a product compliant with the 2007 Regulations on the market from 1st January 2008, is not guilty of an offence under the 1995 Regulations.
- Regulation 31(2) and regulation 1(b)(ii) revoke entirely the 1995 Regulations from 1st January 2010.

General recommendations to formula manufacturers

80. Although they are not requirements of the Regulations, the Agency would encourage formula manufacturers to:

- discuss, with their Home Authority, draft labelling, informational material, advertising, website content, and any other material designed for the public and/or health care professionals before such material is finalised for use.
- Recommend to parents/carers that they discuss any questions about infant feeding issues with their health visitor, a member of the health visiting team or a family nurse. Referral to the family GP should be made if the query is identified as requiring medical intervention.

Monitoring and review.

81. Due to the pace of change in marketing, these Guidance Notes will be reviewed and updated periodically to ensure that they remain applicable.

Appendix I – Interpretation of regulations in relation to ‘advertising’ and ‘the provision of information’ with regard to infant formula

Infant formula advertising can be considered as any practice which is designed to influence people’s transactional decisions in relation to infant formula. Infant formula advertising may influence people’s transactional decisions by raising the profile/familiarity of a particular infant formula, or group of formulae.

Where it is permitted, infant formula advertising shall only contain information of a scientific and factual nature. As a result, such advertising must not use:

- subjective language⁹ or
- pictures which are not of a scientific or factual nature

Some examples of where infant formula advertising is not permitted are listed in Appendix II.

⁹ Examples of subjective language include terms such as: ‘better than’, ‘best’, ‘close to’, ‘closer to’, ‘closest to’, ‘as close as possible to’, ‘similar to’, ‘advanced’, ‘most advanced’, ‘unique’, and terms which relate to emotions, feelings or wellbeing.

Appendix II – Examples of where infant formula advertising is not permitted

The conditions under which infant formula may be advertised are detailed in regulation 21. As a result, infant formula cannot be advertised by means such as those listed below. It should be noted that as the nature of advertising is always changing, a complete list of all forms of unsuitable infant formula advertising cannot be drawn up.

- newspapers, magazines, brochures, leaflets, circulars, mailings, e-mails, text transmissions, fax transmissions, catalogues, follow-up literature and other electronic and printed material (including editorial content and advertorials)
- publications for healthcare professionals which are not scientific publications
- posters and other promotional media in public places, including moving pictures
- cinema and video commercials
- non-broadcast electronic media, (refer to Appendix III for further guidance with regard to the internet)
- television and radio broadcast commercials.
- private correspondence, including correspondence between companies and their customers about existing relationships or past purchases
- oral communications, including telephone calls (company 'carelines' are subject to the requirements of the Regulations).
- press releases and other public relations material and activities
- packages, wrappers, labels, tickets, timetables and price lists
- celebrity endorsements

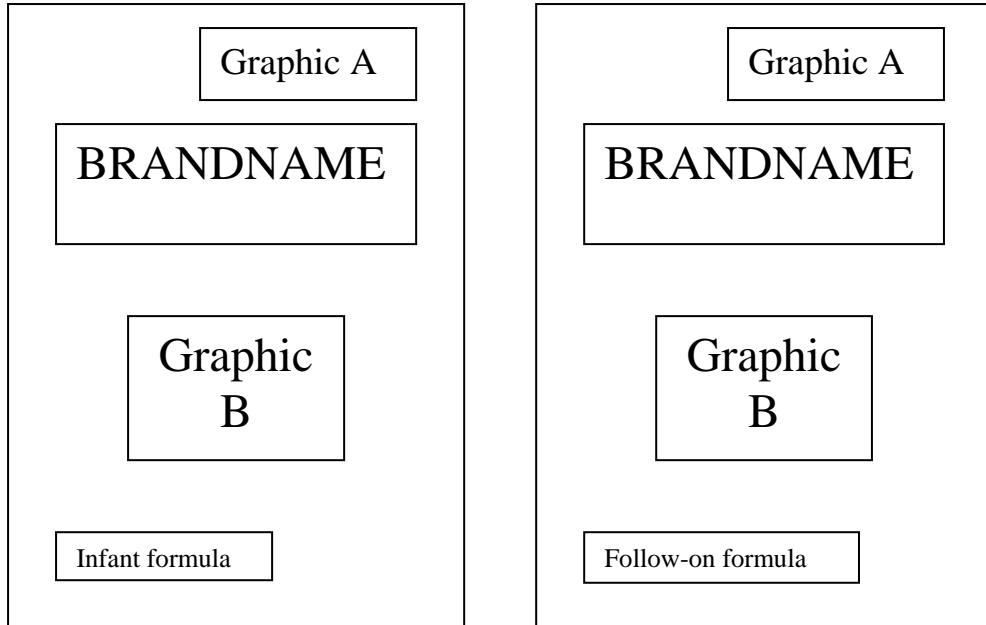
Appendix III – Guidance on website information about infant formula, follow-on formula and infant feeding

The following points should be noted in relation to websites which feature information about infant feeding, or formula products:

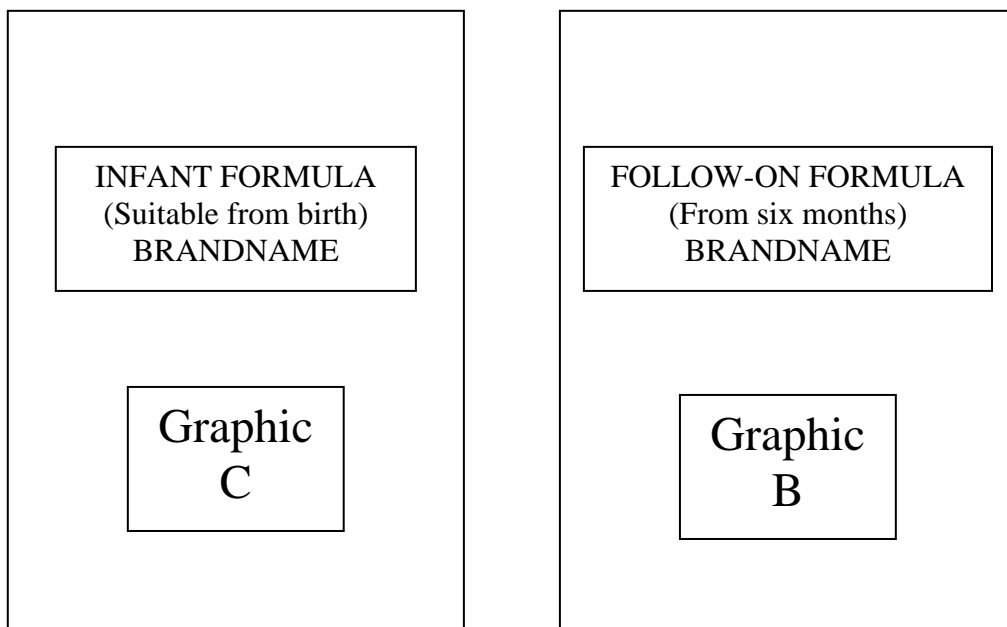
- All website content, including editorial text or pictures, is subject to the Regulations. As a result, editorial website content which advertises infant formula would be in breach of the Regulations.
- Any information about infant formula, or infant feeding, should be accessed only by means of an intermediate page which includes statements highlighting to the viewer that:
 - by proceeding , they will be able to view information about ‘Brand X’ infant milks and other formula products and that if they choose to proceed, they are accepting that ‘Brand X’ is supplying this information at their individual request.
 - those responsible for preparing the website are aware that they are legally obliged to ensure that the content relating to infant formula may not constitute advertising and may only constitute information.
- Where information about infant formula is provided by means of a website, such information should comply with the requirements of Regulation 24(1), 24(2) and 24(3).
- The information described in the above paragraphs should have the same readability as the main text of the website. Any button which must be clicked to progress beyond the information described above should be positioned at the end of the text.

Appendix IV – Differentiating infant formula and follow-on formula

May be more likely to confuse consumers:



May be less likely to confuse consumers:



List of Interested Parties (England)

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 HippOHG
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

List of Interested Parties

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

Interested Parties List (Northern Ireland)

NIFAC

Feed Analyst, AFBI

Beechwood Laboratories

Food Microbiology Branch, AFBI

Food Technology Division

Monitor Laboratories

NI Public Health Laboratory

Eurofins

NI Food and Drink Association

District Council CEHOs

General Consumer Council for NI

Allergy NI

Altnagelvin Area Hospital

Antrim Area Hospital

Belfast City Hospital

Belvoir Park Hospital

British Dietetic Association/Northern Ireland Board

Craigavon Area Hospital

Daisy Hill Hospital

Dalriada Hospital

Dept of Nutrition & Dietetics

Erne Hospital

Omagh Health Centre

Royal Belfast Hospital for Sick Children

Erne Hospital

Tyrone County Hospital

Ulster Community & Hospitals Trust

Cook it! Project Western Health Action Zone

CIEH-NI

Local Authorities Co-ordinators of Regulatory Services (LACORS)

Northern Ireland Food Liaison Group

Eastern Group Environmental Health Committee

Fermanagh District Council

Group Environmental Health Committee

Northern Group Systems

Southern Group Environmental Health Committee

Western Group Environmental Health Committee

Environmental Health Manager (Food Safety & Regulatory Services), Belfast City Council

Dunnes Stores

Glanbia Foods

J&J Haslett Ltd

James AS. Finlay Ltd

John Henderson Group

Musgrave Supervalu Centra

NI Co-Op

Belfast City Council

Head of Food Policy, DARD

Food Policy, DARD
Trading Standards Service
Chief Nursing Officer, DHSSPS
Nursing Officer - Public Health, DHSSPS
Chief Environmental Health Officer, DHSSPS
Chief Medical Officer, DHSSPS
Health Promotion Branch
Invest Northern Ireland
British Dietician's Association
British Medical Association [NI Branch]
Consultant in Communicable Disease Control , Eastern Health and Social Services Board
Director of Public Health, Eastern Health and Social Services Board
Senior Manager: Public Health, Health Promotion Agency for NI
Consultant in Communicable Disease Control , Northern Health and Social Services Board
Director of Public Health, Northern Health and Social Services Board
Chief Executive Secretary & Registrar, Pharmaceutical Society of Northern Ireland
Director of Public Health, Southern Health and Social Services Board
Consultant in Communicable Disease Control , Southern Health and Social Services Board
Ulster Branch BDA
Ulster Chemists Association
Western Health and Social Services Board
Western Health and Social Services Board
Health Protection Agency
Altnagelvin Hospital HSS Trust
Armagh & Dungannon HSS Trust
Belfast City Hospital HSS Trust
c/o Causeway HSS Trust
Causeway HSS Trust
Craigavon & Banbridge Community HSS Trust
Craigavon Area Hospital Group HSS Trust
Down Lisburn HSS Trust
Down Lisburn HSS Trust
Foyle HSS Trust
Greenpark HSS Trust
Hospital Caterers Association
Hotel Services Department Erne Hospital
Mater Hospital Trust
Newry & Mourne HSS Trust
North and West Belfast HSS Trust
Northern Health and Social Care Trust
Royal Hospitals Trust
South and East Belfast HSS Trust
Ulster Community & Hospitals HSS Trust
United Hospitals HSS Trust
Food Safety Authority of Ireland
Food Safety Promotion Board
CAFRE

Interested Parties List (Scotland)

Organisation
Aberdeen City Council
AG BARR (Finlays NMW)
Angus Council
Argyll & Bute Council
Ayrshire Maternity Unit
Bickiepegs
BMA Scotland
British Hospitality Association
Cairnton House
Care Commission
Charles Tennant & Co Ltd
Chief Medical Officer Directorate
Children In Scotland
City of Edinburgh Council
Clackmannanshire Council
Comhairie Nan Eilean Siar
Co-operative Group (CWS) Ltd
COSLA
Dairy UK - Scotland
Direct & Care Services
Dumfries & Galloway Council
Dundee City Council
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
Edinburgh Community Food Initiative
European Parliament
Falkirk Council
Falkirk Royal Infirmary
Federation of Small Businesses
Fife Council
Food Additives & Ingredients Association
Food Innovation Institute (F2i)
Food Safety Authority of Ireland
Food Training & Consultants Company
Glasgow Caledonian University
Glasgow City Council
Glasgow Metropolitan College
Glasgow Scientific Services
Health & Sport Committee
Health Protection Scotland
Highland Council
Inverclyde Council
JWC Services Ltd.
Lothian NHS
Mackies Of Scotland
Midlothian Council
Mylnefield Reasearch Services Ltd.
National Association of Health Stores
Neogen Europe Ltd.
NHS Ayrshire & Arran

Organisation
NHS Fife
NHS Fife - Nutrition & Dietetic Dept.
NHS Forth Valley
NHS Grampian
NHS Greater Glasgow & Clyde
NHS Health Scotland
NHS Highland
NHS Lanarkshire
NHS Lanarkshire Board
NHS Lothian (West Lothian CHCP)
NHS Tayside
NHS Tayside - Directorate of Public Health
North Ayrshire Council
North Lanarkshire Council
Orkney Islands Council
Perth & Kinross Council
Queen Margeret University College
Regulatory Solutions
Renfrewshire Council
Rowett Research Services
Royal Environmental Health Institute for Scotland
Scottish Borders council
Scottish Borders Council - Trading Services
Scottish Consumer Council
Scottish Executive
Scottish Food Enforcement Liaison Committee
Scottish Government
Scottish Grocers Federation
Scottish Midland Co-op Society
Shetland Islands Council
Soil Association Scotland
South Ayrshire Council
South Lanarkshire Council
Stirling & Clacks TS
Stirling Council
Tayside Contracts
Tayside Scientific Services
The British Dietetic Association
The Halal Food Authority
The Highland Council
The Moray Council
University of Aberdeen
University of Dundee
Vegetarian Economy & Green Agriculture (VEGA)
Walkers Shortbread Ltd
West Dunbartonshire Council
West Lothian Council

List of Interested Parties (Wales)

Aberfan Merthyr Vale Y & C Project
ADAS Wales
All Wales Dietetic Advisory Committee
Blaenau Gwent CBC
BRIDGEND COUNTY BOROUGH COUNCIL
Bridgend LHB
BRITISH HEART FOUNDATION
Caerphilly CBC
Calon Lan Cardiac Rehabilitation
Cardiff & Vale NHS Trust
Cardiff LHB
CARDIFF SCIENTIFIC SERVICES
Cardiff University
Cardiff University
Centre for Research into Environment & Health
Children & Youth Partnership
City & County of Cardiff
Conwy County Borough Council, Education
Department
Good Food Distributors
Gwent Health Care NHS Trust
Gwent Healthcare NHS Trust
HAT Events
Innovis
Monmouthshire and North Gwent LHB
National Federation of Women's Institutes
National Public Health Service
New Sandfields Sustainable Regeneration Ltd
North West Wales NHS Trust
NPHS
Pembrokeshire County Council
Pontypridd & Rhondda NHS Trust
Soroptomists International
South Caernarfon Creameries
Sure Start
Swansea Local Health Board
Swansea NHS Trust
The Bay (Public Affairs Ltd)
The Nutrition Society
TORFAEN COUNTY BOROUGH COUNCIL
Trading Standards Institute (Wales)
UNIVERSITY OF WALES
UWIC
Vale of Glamorgan Local Health Board
Wales Council for Voluntary Action
Welsh Assembly Government
Welsh Consumer Council
Welsh Organic Scheme
Wrexham Local Health Board