EXECUTIVE NOTE TO

THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) REGULATIONS 2007 S.S.I. 2007/549

The above instrument is made (except regulations 2(5) and 24) in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990, and (with regard to regulation 2(5)) paragraph 1A of Schedule 2 to, and (with regard to regulation 24) section 2(2) of the European Communities Act 1972 and all other powers enabling them to do so.

Regulations 2(5) and 24 of the instrument are made in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972.

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

Policy Objectives

The purpose of this instrument is to implement, in Scotland, 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 Formulae and Follow-on Formulae intended for export to third countries.

Directive 2006/141/EC consolidates existing Community legislation on the composition, labelling and marketing of infant formulae and follow-on formulae. 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.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for certain references to Annexes to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC to be construed as references to those Annexes as amended from time to time.

The Food Standards Agency proposes to consult by means of a letter to interested parties (IP letter) during any Community negotiations on proposals to amend the instruments referred to in

these Regulations. Where those negotiations result in amendments to an instrument, the Agency would issue a further IP letter to inform parties of the fact in addition to publishing details of the amendments on the Agency's website.

The purpose of paragraph 1A of Schedule 2 to the European Communities Act 1972 is to avoid unnecessary amendment of domestic legislation in circumstances where a Community instrument is amended. Therefore the Agency would not intend to amend these Regulations each time the Annexes to Directive 2006/141/EC are amended. However, the Agency will continue to consider whether it is appropriate to make amendments to these regulations where there is amendment of these provisions of the Community legislation. In the meantime the Agency will ensure transparency through the means described above.

Policy Background

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 and 2003/14/EC, and by two recent Acts concerning the accession of new Member States. Council Directive 92/52/EEC also laid down rules regarding the export of infant formula and follow-on formula to third countries.

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 by separate but parallel amending Regulations for Scotland, England and Wales made in 2000 and 2003. Northern Ireland has similar legislation.

Directive 91/321/EC has been recently repealed (with its amending Directives) and replaced by Directive 2006/141. The aims of the Directive 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 complimentary 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 formulae and follow-on formulae 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 such 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.

Consultation

Article 9 of EC Regulation (EC) No. 178/2002 of the European Parliament and of the Council, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of foods safety, requires open and transparent public consultation on the revision of food law, save in respect of measures made in circumstances of urgency. These Regulations were not made in circumstances of urgency and therefore full public consultation was undertaken as follows:

The Food Standards Agency Scotland consulted publicly with a total of 112 stakeholders (industry, consumer groups, health professionals and enforcement authorities) on the new instrument from 3 July to 29 September 2007. The consultation documents were also made available on the Food Standards Agency website. A total of six responses were received from Scottish stakeholders and this included substantive comments on the draft instrument. Within Government, the Food Standards Agency Scotland consulted with Scottish Government Health Officials.

Guidance Notes to accompany the Regulations, which aim to help industry, enforcement officers and other interested parties interpret the provisions of the domestic legislation, are currently the subject of public consultation.

Financial Implications

The instrument will impact upon consumers, carers, health professionals, manufacturers, enforcement authorities and Government.

Savings to the NHS and wider health benefits are difficult to quantify but are 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.

Costs to industry are expected relating to re -labelling (one off costs of approximately £25,000) and administration of notification procedures (£840 – £1560 per annum). Non-commercial reformulation costs to industry are also possible.

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FINAL REGULATORY IMPACT ASSESSMENT (RIA)

1. TITLE OF PROPOSAL

The Infant Formula and Follow-on Formula (Scotland) 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 EFFECTS OF THE MEASURE

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 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 and 2003/14/EC, and by two recent Acts concerning the accession of new Member States. Council Directive 92/52/EEC also laid down rules regarding the export of infant formula and follow-on formula to third countries.

2.3 In Great Britain, these Directives were implemented by the Infant Formula and Follow-on Formula Regulations 1995 (SI 1995/77), the 1997 Great Britain-wide amendment, and by separate but parallel amending Regulations for Scotland, England 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 (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 complimentary 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 formulae and follow-on formulae 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 such 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 (Scotland) Regulations 2007 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 the Agency's website at: www.food.gov.uk

Rationale for Government intervention

2.7 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 Scotland is in line with the provisions of 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

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

the marketing of new infant formula more effectively (no such provision exists in the current legislation); and

- lays down a new requirement that infant formula and follow-on formula be labelled, presented and advertised in such a way as to avoid confusion between them.

- The Government has a target to increase breastfeeding rates**2** . In November 1994, the Secretary of State for Scotland announced a national target that at least 50% of Scottish mothers should still be breastfeeding their babies at 6 weeks of life by the year 2005. Scottish health boards were asked to set local breastfeeding targets by January 1995. All NHS boards are working towards achieving this target.

- 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. The Regulations will help to deliver on this target by including a provision to further restrict the ways in which infant formula can be advertised in Scotland.

- The health benefits to infants of breastfeeding are well established, and evidence exists to show that breast-fed babies are less likely to develop gastric, respiratory and urinary tract infections, obesity in later life, atopic disease, and juvenile-onset insulin-dependent diabetes**4**. The National Institute of Clinical Excellence (NICE) has attempted to monetise some of the benefits associated with breastfeeding. It is 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 gastroenteristis in UK babies**5**. 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 breastfeeding such as heart disease and breast cancer in the mother. The potential bonding and

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

5 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

emotional benefits of breastfeeding are also left unquantified. These additional factors are likely to greatly increase the true NHS savings and wider health benefits associated with increased breastfeeding.

- 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 regulated this significant market is consistent with current EU legislation and relevant Codex Alimentarius standards.

3. CONSULTATION

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

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

3.3 Separate consultations were carried out by the relevant offices of the Food Standards Agency in the devolved administrations. In Scotland, the Agency consulted from 3 July to 29 September 2007 on draft Regulations to implement the Directive. The Agency consultation invited comments and evidence 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.

3.4 **Consultation Responses**

- 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 Strategy 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 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.

3.5 The Agency in England also received the following responses to the consultation:

- 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), and 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))

3.6 The responses can be accessed by contacting the Agency Information Centre[6]. A summary of the responses, all of which were considered before the Regulations were finalised, can be accessed from the Agency's website at: www.food.gov.uk

4. OPTIONS

Option 1: Retain the Status Quo

4.1 This option would result in the continued application of the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77)[7].

Option 2: Implement the Directive

4.2 This option would result in the implementation of the Directive by means of the Regulations. The Regulations would apply in Scotland, with parallel Regulations being implemented in England, 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.

4.3 Respondents in Scotland felt that Option 2 did not go far enough and in the main their comments echoed the views of a number of other NGOs, that being that the advertising restrictions proposed for Infant Formula should be extended to Follow-on Formula, and that the WHO Code on the marketing of breast milk substitutes should be implemented in its entirety.

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

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

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

4.5 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.

4.6 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).

4.7 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 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 be 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.

4.8 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.

4.9 The Directive represents the EU view on the extent to which 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.

4.10 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.

5. COSTS AND BENEFITS

5.1 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

5.2 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

5.3 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

Adopting the Regulations would bring benefits to:

5.4 **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.

5.5 **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

5.6 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 effect on breastfeeding rates/duration.

5.7 **Infants/health services** – improved breastfeeding rates/duration would bring health benefits to those infants who would otherwise not have been breastfed. Improved breastfeeding rates/duration would also potentially bring savings to the health services as discussed earlier.

5.8 **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 and none of these are based in Scotland).

5.9 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

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

5.10 **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.

5.11 **Industry** - Failing to implement the Regulations would lead to a lack of harmony between the compositional

criteria of formula marketed in the UK when compared to formula marketed throughout the rest of the EU. This may disadvantage industry which may have to make special formulations of infant and follow-on formula specifically for UK consumers.

5.12 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

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

5.13 **Consumers/carers** - Implementing the Regulations would bring no new direct costs for consumers (infants). However, a proportion of any cost increase which manufacturers may face as a result of the Regulations could be passed on to carers who purchase formula products, in the form of higher prices.

5.14 **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**8** compliance costs associated with the new mandatory reformulation, notification or re-labelling requirements of the Regulations.

5.15 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

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8 '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.
10 http://www.food.gov.uk/foodindustry/regulation/ria/ria2006/signpostingria

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 provided any quantified evidence to support their views on the impact of the proposed options.

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

5.16 **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.

5.17 **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.

5.18 **Costs of re-labelling** – In their submissions to the Agency consultation on Signpost labelling[9], the BRC estimated the cost of re-labelling 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 re-labelled as a result of the new Regulations. Thus, the total cost of this re-labelling is estimated at between £25,000 which the Agency considers the most realistic estimate, and £1,250,000.

Charities and the voluntary sector

5.19 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

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

Government

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

6. SMALL FIRMS IMPACT TEST

6.1 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.

7. TEST RUN OF BUSINESS FORMS

7.1 There are no new forms associated with this piece of legislation, other than a revision of a notification form which is already in place.

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. None of these companies are based in Scotland.

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.

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 5.

9.2 Option 1 does not create any new economic or social benefits. It may, however, incur economic disadvantages to industry, which 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 formula. Option 2 may bring new economic costs to industry due to reformulation and re-labelling. 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 AND SANCTIONS

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

13. IMPLEMENTATION AND DELIVERY PLAN

13.1 The Regulations will implement, in Scotland, Directive 2006/141/EC. Should Option 2 be adopted, the regulations would be implemented by 1 January 2008.

14. MONITORING AND REVIEW

14.1 In line with Scottish Government guidance, we will review the continued effectiveness of this Regulation through the use of a Review Regulatory Impact Assessment that will be completed within 10 years.

15. POST- IMPLEMENTATION REVIEW

15.1 The Agency will also 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.

16. SUMMARY AND RECOMMENDATION

16.1 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.

16.2 For these reasons the Agency recommends that the Agency in Scotland implements the provisions of Commission Directive 2006/141/EC by means of the Infant Formula and Follow-on Formula (Scotland) 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 re-labelling (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.

17. DECLARATION AND PUBLICATION

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

Signed……
……..

Date……
……...

Minister's name, title, department……

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THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) REGULATIONS 2007 ("THE REGULATIONS")

TRANSPOSITION NOTE FOR COMMISSION DIRECTIVE 2006/141/EC ON INFANT FORMULAE AND FOLLOW-ON FORMULAE AND AMENDING DIRECTIVE 1999/21/EC ("THE DIRECTIVE")

The Regulations give effect to the Directive by revoking (in part when the Regulations come into force and in entirety on 1st January 2010) the Infant Formula and Follow-on Formula Regulations 1995 and creating a new regulatory regime for infant formula and follow-on formula.

The following table demonstrates how each relevant provision of the Directive has been given effect in the Regulations:

Article	**Implementation**
Article 2: Article 2 defines various terms used in the Directive.	This Article is implemented by regulation 2(3) which provides that expressions used in the Regulation have the same meaning that they have in the Directive.
Article 3 Paragraph 1 permits marketing of infant formula and follow-on formula only if they comply with the Directive. Paragraph 2 prohibits marketing of products (other than infant formula) as meeting all the nutritional requirements of infants.	Paragraph 1 of this Article is implemented by regulation 3. Regulation 3(1) prohibits marketing of infant formula which contravenes or fails to comply with regulations 5,6,8,10,11,12,14(1) to (3), 15, 17 or 19. Those regulations transpose various specific requirements of the Directive. Regulation 3(2) prohibits marketing of follow-on formula which contravenes or fails to comply with regulations 5,7, 9,10,11,12,14(1) to (3), 16, 18 or 19. Those regulations transpose various specific requirements of the Directive. Paragraph 2 of this Article is transposed by regulation 4.
Article 4: This Article prohibits that inclusion of any substance in such quantity as to	This Article is transposed in regulation 5.

endanger the health of infants and young children.	
Article 5 and Annex I: This Article provides that infant formula must be manufactured from specified protein sources and other suitable food ingredients. Suitability is to be demonstrated through systematic review of available data.	This Article is transposed by regulation 6 which, among other things, cross-refers to point 2 to of Annex I to the Directive.
Article 6 and Annex II: This Article provides that follow-on formula must be manufactured from specified protein sources and other suitable food ingredients. Suitability is to be demonstrated through systematic review of available data.	This Article is transposed by regulation 7 which, among other things, cross-refers to point 2 of Annex II to the Directive.
Article 7 and Annexes I, II, V and VI: Article 7(1) requires that infant formula complies with compositional criteria set out in Annex I and specifications in Annex V. It provides for demonstration of suitability of infant formula manufactured from cows' milk. It also provides for demonstration of suitability of infant formula manufactured from protein hydrolysates. Article 7(2) requires that follow-on formula complies with compositional criteria set out in Annex II and specifications in Annex V. Article 7(3) stipulates that, in order to make infant formula and follow-on formula read for use, only the addition of water should be required. Article 7(4) requires for observation of prohibitions and limitations set out in Annexes I and II.	Article 7(1) is transposed in regulation 8. Paragraph (1) deals with compositional criteria, paragraph (2) provides for infant formula manufactured from cows' milk and cross-refers to point 2.1 of Annex I of the Directive and paragraph (3) makes provision for infant formula manufactured from protein hydrolysates and cross-refers to point 2.2 in Annex I of the Directive. Article 7(2) is transposed in regulation 9. Article 7(3) is transposed in Regulation 10. Article 7(4) is transposed in Regulation 11.
Article 8 and Annex III:	

Article 8(1) provides that only substances listed in and Annex III may be used in order to satisfy requirements on mineral substances, vitamins, amino acids and other nitrogen compounds and other substances having a particular nutritional use. Article 8(2) applies the purity criteria listed in Community legislation and Article 8(3) provides for substances for which there are no such purity criteria.	Article 8(1) is implemented by regulation 12 which cross-refers to Annex III, I and II. Article 8(2) is implemented by regulation 12(3)(a) and Article 8(3) is implemented by regulation 12(3)(b) both in conjunction with regulation 12(2) which requires that substances meet the relevant purity criteria.
Article 9: Article 9 requires that food business operators placing infant formula on the market notify the competent authorities by sending a model label used for the product.	Article 9(1) is implemented by regulation 13 which requires that notification be sent to the Agency.
Article 10 and Annexes VIII and IX: Article 10(1) restricts the levels of residual pesticide which infant formula and follow-on formula may contain. Article 10(2), in conjunction with Annex VIII, specifies pesticides which may not be used in agricultural products intended for production of infant formula. Article 10(3), in conjunction with Annex IX, provides a derogation from Article 10(1) for listed pesticides. Article 10(4) provides that the levels specified in paragraphs (2) and (3) above apply to the products when ready for consumption or reconstituted.	Article 10(1) is transposed by regulation 14(1). Article 10(2) is transposed by regulation 14(2), which cross-refers to Annex VIII. Article 10(3) is transposed by regulation 14(3), which cross-refers to Annex IX. Article 10(4) is transposed by regulation 14(4)(a) (formula ready for consumption) and 14(4)(b) (reconstituted formula).
Article 11: Article 11 provides for the name	Article 11 is transposed by regulation

under which infant formula and follow-on formula must be sold (except as provided for in Article 12).	15(a) ("infant formula") and regulation 16(b) ("follow-on formula").
Article 12: Article 12 provides for the name under which infant formula and follow-on formula manufactured entirely from cows' milk must be sold.	 Article 11 is transposed by regulation 15(b) ("infant milk") and regulation 16(b) ("follow-on milk").
Article 13 and Annexes I, II , III, IV and VII: Article 13 sets out labelling requirements for infant formula and follow-on which apply in addition to those contained in Directive 2000/13/EC. Article 13(1)(a),(c),(d),(e), (2)(a), (3), (4), (5) and (6) apply to infant formula. Article 13(1)(b),(c),(d),(e), (2)(a),(b), (3) apply to follow-on formula. Article 13(7) and (8) apply to both infant formula and follow-on formula. Article 13(7) is concerned with avoidance of confusion between such products. Article 13(8)(a) with presentation of such products and 13(8)(b) with advertising of such products.	 Article 13, in so far as it relates to infant formula, is implemented by regulation 17, which cross-refers to Annex IV (17(4)). Article 13, in so far as it relates to follow-on formula, is implemented by regulation 18. Article 13(7) is transposed by regulation 19. Article 13(8)(a) is transposed by regulation 20 and Article 13(8)(b) by regulation 21(1)(b) for infant formula and regulation 22 for follow-on formula.
Article 14: Article 14 (1) restricts advertising of infant formula and prohibits advertisements which imply or create a belief that bottle-feeding is equivalent or superior to breast feeding. Article 14(2) and (3) restrict promotion of infant formula including point-of-sale advertising and giving of free samples and gifts.	 Article 14(1) is transposed in regulation 21(a), (2) and (3) (Restrictions on advertising infant formula). The Scottish Ministers have further restricted publication of advertisements to trade magazines of which the general public is not the intended readership, as permitted by this Article. Article 14(2) and (3) are implemented by regulation 23 (Restrictions on promotion of infant formula).

Article 15: Article 15 requires Member States to ensure the quality of materials dealing with the feeding of infants by ensuring that it contains specific listed information. It also places restrictions on the donation of informational or educational equipment or materials by manufacturers and distributors of infant formula. Article 15(4) restricts the provision of free or low-price infant formula to institutions or organisations.	Article 15 is transposed by regulation 24. Article 15(4) is transposed in regulation 25 (Free or reduced rate infant formula).
Article 16: Article 16 makes a minor amendment to Table I of the Annex to Directive 1999/21/EC.	Article 16 is implemented by regulation 30, which updates the definition of "the Directive" (i.e. Directive 1999/21/EC) in the Foods for Special Medical Purposes (Scotland) Regulations 2000 (S.S.I. 2000/130), so that the provisions of the amended Annex apply.
Article 17: Article 17 provides that the requirements of Article 7(1) and (2) do not apply mandatorily to dietary foods for special medical purposes intended specifically for infants until 1 January 2012.	Article is implemented by regulation 30, which updates the definition of "the Directive" (i.e. Directive 1999/21/EC) in the Foods for Special Medical Purposes (Scotland) Regulations 2000 (S.S.I. 2000/130) to include Directive 2006/141, so that the provisions of the amended Annex apply. Paragraph 4 of that Annex will automatically require that foods for special medical purposes comply with provisions applicable to infant and follow-on formula.
Article 18: Article 18 requires that Member States adopt and publish laws necessary to comply with Articles 2, 3, 5-17 and Annexes I-VII by 31st December 2007, permit trade in compliant products by 1st January 2008 and prohibit non-compliant	Article 18 is implemented as follows: The Regulations will be made on 28th November and laid on 29th November, so meet the 31st December 2007 deadline. Regulation 1(b) specifies that the Regulations, except Regulation 31(2), come into force on

products from 31st December 2009.	1st January 2008 to meet the deadline for permitting compliant products. Regulation 1(a) specifies that Regulation 31(2) (which revokes the 1995 Regulations) comes into force on 1st January 2010 to meet the deadline for prohibition of non-compliant products.

THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) REGULATIONS 2007 ("THE REGULATIONS")

TRANSPOSITION NOTE FOR
COUNCIL DIRECTIVE 92/52 OF 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries ("the Directve")

The Regulations give effect to the Directive by revoking (in part when the Regulations come into force and in entirety on 1st January 2010) the Infant Formula and Follow-on Formula Regulations 1995 (" the 1995 Regulations") and creating a new regulatory regime for infant formula and follow-on formula. The Directive was previously implemented by the 1995 regulations which, extended to Great Britain. The regulations therefore represent the first occasion that there has been an implementation of the Directive in regulations which extend only to Scotland.

The following table demonstrates how each relevant provision of the Directive has been given effect in the Regulations:

Article	**Implementation**
Article 2: Member States are to ensure that infant formulae and and follow-on formulae are to be exported from the Community only if they comply with this Directive. .	Regulation 26 (1) prohibits export to a third country of infant formula which contravenes or fails to comply with certain provisions of the Regulations, the Codex Standard for infant formula established by the Codex Alimentarius and the Food (Lot Marking) regulations 1996. Regulation 27 (1) prohibits export to a third country of follow-on formula which contravenes or fails to comply with certain provisions of the Regulations, the Codex Standard for infant formula established by the Codex Alimentarius and the Food (Lot Marking) regulations 1996. Regulation 28(1) provides that Contravention of Regulation 26(1) or 27 is an offence punishable by a fine not exceeding level 5 on the standard scale.
Article 3	

Paragraph 1 Only Infant Formulae may be represented as suitable for satisfying by itself the nutritional requirements of normal health infants during the first 4-6 months of life. Paragraph 2 Infant Formulae must comply with certain provisions of Directive 91/321/EC *(now replaced by Commission Directive 2006/141/EC on infant formulae and follow-on formulae, article 19(second paragraph) of which provides that references to Directive 91/321/EEC shall be construed as references to Directive 2006/141/EC) .* Paragraph 3 These products must be labelled in a way which avoids confusion between infant formulae and follow-on formulae. Paragraph 4 The provisions of the Directive 91/321/EC (as replaced by 2006/141/EC) must be applied to the presentation of products, in particular their form, aspect or packaging and the packaging materials used.	Regulation 26 (2) prohibits export to a third country a product which is represented as satisfying by itself the nutritional requirements of normal health infants during the first 4-6 months of life unless that product is infant formula. Regulation 26 (1) prohibits export to a third country of infant formula which contravenes or fails to comply with certain provisions of the Regulations, the Codex Standard for infant formula established by the Codex Alimentarius and the Food (Lot Marking) regulations 1996. Regulation 27 (1) prohibits export to a third country of follow-on formula which contravenes or fails to comply with certain provisions of the Regulations, the Codex Standard for infant formula established by the Codex Alimentarius and the Food (Lot Marking) regulations 1996.
Article 4: Paragraph 1 Directive applies from 1 June 1994. Paragraph 2 When Member States adopt these provisions, they shall contain a reference to the directive or shall be accompanied by such a reference at the time of their publication.	The 1995 regulations previously provided for implementation of the Directive. The Explanatory note contains a reference to the Directive.