Executive Note

The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments) Regulations 2007 SSI 2007/ 424

The Scottish Ministers make the following regulations in exercise of the powers conferred by sections 17(1) and (2), 26(1)(a) and 48(1) of the Food Safety Act 1990 and all other powers enabling them to do so.

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

Consultation has taken place as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

This above instrument is made by Scottish Ministers and implements:

- Commission Regulation 1609/2006 authorising the placing on the market of infant formula based on hydrolysates of whey protein derived from cows' milk protein for a two year period,

- Commission Directive 2007/29/EC amending Directive 96/8/EC as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction,

- Commission Directive 2006/82/EC adapting Directive 91/321/EEC on infant formula and follow-on formula and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania,

- Commission Directive 2007/26/EC amending Directive 2004/26/EC to extend its period of application and

- Commission Directive 2006/125/EC on processed cereal based foods and baby foods for infants and young children.

Policy Objectives

1. A food for a particular nutritional use (a 'parnuts' food) is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional purpose.

2. Foods intended for particular nutritional uses are regulated by framework Directive 89/398/EEC and by specific Directives adopted under that framework. Commission Directive 89/398/EEC lays down rules regarding the definition, labelling and advertising of parnuts foods marketed within the EU. The Directive requires that foods for particular nutritional uses meet the nutritional requirements of the persons for whom they are intended and that they are marketed as suitable for consumers with disturbed digestive processes or metabolism or who are in a special physiological condition.

3. Parnuts foods include infant formulas and follow-on formulas, processed cereal-based foods and baby foods for infants and young children, certain weight reduction products, ‘sports foods’ and foods for special medical purposes. Specific Directives lay down more specific provisions for infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children, slimming foods and medical foods.

This SSI will ensure that:

4. Manufacturers can place on the market partially hydrolysed infant formula based on hydrolysates of whey protein from cows’ milk, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex to Commission Regulation 1609/2006, thereby potentially increasing consumer choice.

5. Manufacturers can make use of hunger and satiety claims in relation to slimming foods bringing the prohibitions on claims on these foods into line with the provisions on the use of such claims in relation to foods for general consumption.

6. Certain parnuts products containing nutritional substances not currently included in the Annex to 2001/15/EC do not have to come off the market immediately. The new legislation will permit the continued marketing of certain products, thereby enabling continued consumer choice and reducing the impact of Directive 2001/15/EC on industry as provided for by Commission Directive 2007/26/EC.

7. The definition of the ‘Directive’ referred to in the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Scotland) 2004 Regulations is updated to reflect the consolidated Commission Directive.

8. This instrument will also ensure continued compliance with the European legislation.

Consultation

9. Over 400 interested parties throughout the UK (138 in Scotland), including consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments, have been consulted on these draft Regulations.

10. The Agency received six responses in total to the formal consultation, including one from a Scottish stakeholder. The responses from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, the UK Very Low Calorie Diet Foods Industry group and Lacors offered no specific comments or outlined support for the implementation of the proposed Regulations.

11. None of the respondents, including the one from Scotland, offered any comments on the drafting of the Regulations.

Regulatory Impact

12. The primary business sector that will be affected by the regulatory proposals will be manufacturers of foods for particular nutritional uses. However, consultation has confirmed that the measures proposed impose no significant new financial burdens.

13. The Regulations would not impose any significant new burden on Government or enforcement officers. Rural areas and members of the ethnic communities of any particular racial group are unaffected by these proposals. Charities and voluntary organisations are unaffected by these proposals.

14. The three Regulatory Impact Assessments carried out are attached to this note.

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Final Regulatory Impact Assessment

1. Title of Proposal

The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments) Regulations 2007.

This Regulatory Impact Assessment is for regulation 2 only – derogation from specific compositional requirements of the infant formula and follow-on formula Regulations.

2. Purpose and intended effect of the measure

Objective

The proposed Regulations will, in Scotland:

- Provide for the execution and enforcement of Commission Regulation 1609/2006, which allows partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the UK market, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex of Commission Regulation 1609/2006. These Regulations will amend the Infant Formula and Follow-on Formula Regulations 1995 (as amended) (regulation 2);

- Implement Commission Directive 2007/29/EC to bring the use of hunger and satiety claims prohibited by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 in relation to slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption (regulation 3);

- Implement Commission Directive 2006/82/EC, by updating the definition of "the Directive" referred to in the Foods for Special Medical Purposes (Scotland) Regulations 2000 to reflect the accession of Bulgaria and Romania to the European Union (regulation 4);

- Implement Commission Directive 2007/26/EC to extend the period of derogation provided for in The Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 until 1st January 2010 (regulation 5);

- Implement Commission Directive 2006/125/EC, by updating the definition of "the Directive" in the Processed Cereal-based foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6)

Devolution

The proposed Regulations will apply in Scotland only. Separate parallel implementing legislation will be made in England, Wales, and Northern Ireland.

Scope of this RIA

The purpose of a Regulatory Impact Assessment (RIA) is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, consumers and enforcement bodies. Given that the proposed changes in regulations 4 and 6 do not change any of the requirements of national legislation we do not anticipate that implementation of these Regulations will impose any costs or savings on businesses. Therefore, an RIA has not been prepared to accompany Regulations 4 and 6. However, stakeholders were consulted on the changes and asked to provide any information relating to costs or savings if any were identified. This RIA estimates the cost and impact of implementing regulation 2 to provide for the execution and enforcement of Commission Regulation 1609/2006, which allows partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the UK market, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex of Commission Regulation 1609/2006. Separate RIAs accompany this one to cover each of regulations 3 and 5 respectively.

Background (regulation 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/EC as amended by 96/4/EC, 1999/50/EC and 2003/14/EC.

The main aims of these Directives were to ensure that:

- The essential composition of infant formulae and follow-on formulae satisfy the specific nutritional requirements of infants in good health as established by generally-accepted scientific data;

- The labelling of infant formulae and follow-on formulae allows the proper use of such products and is such that it promotes and protects breastfeeding;

- The rules on composition, labelling and advertising are in conformity with the principles and aims of the International Code of Marketing of Breast-Milk Substitutes ("the Code");

- Member States (MS) may take appropriate measures in order that information about infant feeding given to pregnant women and mothers of infants ensures appropriate use of infant formulae and follow-on formulae and is not counter to the promotion of breastfeeding

Directive 91/321/EEC (as amended) sets out the compositional requirements for infant formula and follow-on formula. The annexes of the Directive give criteria for protein, carbohydrate, fat, minerals, vitamins and other nutrients as components of infant formula and follow-on formula based on advice from the EU independent Scientific Committee on Food[1] (SCF). These criteria include, where necessary, the maximum and minimum levels and source of each nutrient.

The following are the criteria for protein source and the associated maximum and minimum levels as currently applicable to infant formula:

- Cows' milk protein (1.8g/100 kcal – 3g/100 kcal);

- Soya protein isolates (2.56g/100 kcal – 3g/100 kcal);

[1] First Report of the Scientific Committee for Food on the essential requirements of infant formula and follow-up milks based on cows' milk proteins, 1983; updated in 1989, and 1991)

- Protein partial hydrolysates from cows' milk (2.25g/100 kcal – 3g/100 kcal)

Following advice issued by the European Food Safety Authority[2] (EFSA; the role of EFSA was carried out previously by the SCF), Commission Regulation 1609/2006 provides a derogation from certain provisions of 91/321/EEC to allow an infant formula with a protein content of 1.86g per 100kcal energy, based on hydrolysates of whey protein derived from cows' milk protein, to be placed on the market in the EU, provided that it also meets the other criteria for protein source and processing listed in the Annex of the Commission Regulation 1609/2006. Infant formula which meets the requirements of Commission Regulation 1609/2006 must also meet the other essential compositional criteria and other Regulations relevant to infant formula.

Provisions in the proposed regulation 2

The key proposal of regulation 2 is to provide, in Scotland, for the execution and enforcement of Commission Regulation 1609/2006 which authorises placing on the market infant formula based on hydrolysates of whey protein from cows' milk, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex of Commission Regulation 1609/2006.

This will be achieved by amending the Infant Formula and Follow-on Formula Regulations 1995.

Rational for Government intervention

Regulation 2 is required to implement a European Commission Regulation which is directly applicable in all Member States. This Regulation will allow companies who have manufactured products which comply with Commission Regulation 1609/2006 to market them in the UK and thereby facilitate increased choice for consumers.

3. Consultation

Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments were consulted formally on these draft Regulations.

The Agency received six responses in total to the formal consultation, including one from a Scottish stakeholder. The responses from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, The UK Very Low Calorie Diet Foods Industry group and Lacors offered no specific comments or outlined support for the implementation of the proposed Regulations. The Scottish respondent was supportive of the proposals.

None of the respondents offered any specific comments on the drafting of the Regulations.

4. Options

Options for transposing the provisions of the new regulation are as follows::

Option 1: do nothing i.e. fail to implement the Commission Regulation,

[2] Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the safely and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1.86g protein/100kcal (adopted October 2005, EFSA)

Option 2: implement the provisions of the Commission Regulation as required by European law.

5. Costs and Benefits

Sectors and Groups affected

Businesses

The new provisions affecting the composition of infant formula would benefit those businesses involved in the manufacture and sale of these products as well as those involved in the production of ingredients.

According to the Mintel[3] 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 formula and follow-on formula. The supply structure for infant formula and follow-on formula is characterised by three major manufacturers accounting for 97% of sales. Infant formula and follow-on formula are distributed via a wide range of retail outlets, with around 15% sales by volume being through NHS baby clinics.

Consumers

The legislation will facilitate increased consumer choice. We do not envisage any differential effect of the legislation on consumers because of gender, age, health or income. We do not envisage that the legislation would have differential effects on disabled people or those living in different regions or in rural communities. We consider that the proposal will have no impact on racial equality issues.

Voluntary Organisations and Charities

We are not aware of any charities or voluntary organisations that would be affected by the legislation.

Public Sector

Government and Enforcement authorities would not be affected by the legislation.

Benefits

Option 1 – Failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government. Failure to implement would also be a risk to Government as it would result in a breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty. Other Member States could also initiate action under Article 227. Ultimately the UK would be forced to implement..

Option 2 – Implementation would benefit consumers by increasing consumer choice, benefit industry by allowing new products to be placed on the market, and benefit Government by removing the risk of infraction procedures.

[3] Baby Food, Drinks and Milk, UK, November 2005, Mintel

Costs

Option1 – Failure to implement would prevent consumers having access to a product which has been approved for use in the EU and would disadvantage UK companies which would be unable to market a product suitable for infants. Lack of implementation could bring to the Government the cost of potential infraction proceedings and inadequate regulation of the market, which will impact on businesses and consumer choice.

Option 2 – there are no costs to consumers, businesses, enforcement authorities or Government associated with the implementation of these new Regulations apart from costs to Government to administer this legislation.

The environmental impact of either option is likely to be negligible.

Administrative Burden

The administrative burden is the cost of complying with a regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). There are currently less than 10 manufacturers of infant formula and follow-on formula in the UK. We believe that the only additional administrative burden to these companies would be the one-off costs to read and understand these Regulations. There would be no other additional administrative costs.

Flexibility

The Commission Regulation does not offer any flexibility on the implementation of its provisions.

6. Small Firms Impact Test

As the supply of infant formula and follow-on formula is characterised by a small number of large firms accounting for 97% of sales in this area the impact of these Regulations on small firms will be minimal. The Forum of Private Business (Scotland) Ltd and the Federation of Small Businesses were both included as part of the consultation process in Scotland, however, neither organisation provided any comment.

7. Test run of Business Forms

There are no new forms associated with this piece of legislation.

8. Competition Assessment

As stated above, the supply structure for infant formula and follow-on formula is characterised by three major manufacturers accounting for 97% of the sales. It is possible that implementation of this amendment may act to encourage or facilitate new entry or growth within this market. As such we consider this amendment to have the potential of being pro-competitive.

9. Enforcement, Sanctions and Monitoring

Local food authorities are responsible for enforcing the Regulations. The amending Regulations bring no new enforcement responsibilities i.e. they remain as per outlined in the Infant Formula and Follow-on Formula Regulations 1995. Persons convicted of an offence under these Regulations would be liable to a fine not exceeding level 5 of the standard scale

10. Implementation and Delivery Plan

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 will provide for the execution and enforcement of Commission Regulation 1609/2006.

The Commission Regulation does not provide for any specific review date and there is no provision in the main Infant Formula and Follow-on Formula Directive for a review. The UK would, however, participate in any future revision of the requirements of the EU legislation that may be taken forward at an EU level.

11. Post-implementation review

In line with Scottish Executive 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.

12. Summary and Recommendation

In summary, making these Regulations will enable us to fulfil our community obligations and will benefit consumers and industry. Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

For these reasons the Agency recommends that the UK should implement the provisions of Commission Regulation 1609/2006, Commission Directives 2006/82/EC and 2006/125/EC via the Food for Particular Nutritional Uses (Scotland) Miscellaneous Amendments Regulations 2007.

Summary costs and benefits table

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1 Non Implementation	There are no benefits associated with Option 1	Option 1 would prevent consumers accessing a product approved for use in the EU, and UK companies would be unable to market it. The Government could face the cost of potential infraction proceedings and inadequate regulation of the market.
2	Option 2 would increase consumer	There would be costs to Government to

Implementation	choice, allow new products on to the market, and remove the risk of infraction	administer this legislation, and there would be one-off costs to manufacturers to read and understand the Regulations.

13. Declaration

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

Signed by the responsible Minister:.....

Date:.....……

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Final Regulatory Impact Assessment

1. Title of proposal

The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments) Regulations 2007

This Regulatory Impact Assessment is for regulation 3 only - to allow the use of 'reduced hunger' and 'increased satiety' claims on foods intended for use in energy restricted diets for weight reduction)

2. Purpose and intended effect of the measure

Objective

The proposed Regulations will, in Scotland:

- Provide for the execution and enforcement of Commission Regulation 1609/2006, which allows partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the UK market, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex of Commission Regulation 1609/2006. These Regulations will amend the Infant Formula and Follow-on Formula Regulations 1995 (as amended) (regulation 2);

- Implement Commission Directive 2007/29/EC to bring the use of hunger and satiety claims prohibited by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 in relation to slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption (regulation 3);

- Implement Commission Directive 2006/82/EC, by updating the definition of "the Directive" referred to in the Foods for Special Medical Purposes (Scotland) Regulations 2000 to reflect the accession of Bulgaria and Romania to the European Union (regulation 4);

- Implement Commission Directive 2007/26/EC to extend the period of derogation provided for in The Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 until 1st January 2010 (regulation 5);

- Implement Commission Directive 2006/125/EC, by updating the definition of "the Directive" in the Processed Cereal-based foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6)

Devolution

The proposed Regulations will apply in Scotland only. Separate parallel implementing legislation will be made in England, Wales and Northern Ireland.

Scope of this RIA

The purpose of a Regulatory Impact Assessment (RIA) is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, consumers and enforcement bodies. Given that the proposed changes in regulations 4 and 6 do not change any of the requirements of national legislation we do not anticipate that implementation of these Regulations will impose any costs or savings on businesses. Therefore, an RIA has not been prepared to accompany Regulations 4 and 6. However, stakeholders were consulted on the changes and asked to provide any information relating to costs or savings if any were identified. This RIA estimates the cost and impact of implementing regulation 3 to bring the use of hunger and satiety claims prohibited by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 in relation to slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption. Two separate RIAs accompany this one to cover each of regulations 2 and 5.

Background (regulation 3)

European community controls on the composition, labelling and advertising of foods intended for use in energy restricted diets for weight reduction were introduced in 1996 through Commission Directive 96/8/EC. This Directive is implemented in UK legislation by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997. These rules are based on advice from the European Scientific Committee for Food (SCF) and cover both products that are presented as replacements for the whole of the daily diet (total diet replacements for weight loss) and those products that are presented as replacements for one or more meals of the daily diet (meal replacements for weight loss). These foods are more commonly described as slimming foods.

The compositional controls in the legislation govern the amounts of energy, protein, fat, vitamins and minerals in these foods. The labelling provisions include nutrition information, instructions for preparation, warning about possible laxative effects and specific statements intended to ensure the nutritional, medical and health safety of individuals are safeguarded.

However, since the recently adopted European Regulation 1924/2006 on nutrition and health claims made on foods allows claims describing or referring to ‘a reduction in the sense of hunger’ or ‘an increase in the sense of satiety’ to be made on foods for general consumption under certain conditions, these claims should also be allowed for slimming foods. Directive 2007/29/EC therefore brings these provisions in line with the provisions on the use of such claims in relation to foods for general consumption.

Provisions in the proposed regulation 3

Regulation 3 implements, in Scotland, Commission Directive 2007/29/EC which restricts claims relating to the rate or amount of weight loss which may result from their use, but allows claims describing or referring to ‘a reduction in the sense of hunger’ or ‘an increase in the sense of satiety’ to be made on slimming foods.

Rationale for Government intervention

The Directive and the implementing legislation address the risk that slimming foods would be subject to stricter controls on the use of these claims than foods for general consumption and other parnuts foods. Therefore, new legislation will ensure that such manufacturers of such products are not disadvantaged and will enable continued consumer choice.

3. Consultation

Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments were consulted informally on the draft European legislation and formally on these draft Regulations.

During the negotiations of the amendment to the Commission Directive 2007/29/EC, the Agency consulted informally with all of the above stakeholders, including SMEs. We received two written responses to our *informal* consultation, from the Infant and Dietetic Foods Association and the European Very Low Calorie Diet Industry Group who supported the proposed amendment to the European Directive.

The Agency received seven responses in total to the *formal* consultation, including two from Scottish stakeholders. The responses from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, The UK Very Low Calorie Diet Foods Industry group and Lacors offered no specific comments or outlined support for the implementation of the proposed Regulations.

None of the respondents, including the two from Scotland, offered any comments on the drafting of the Regulations so no changes were made to the text of the SSI as a result of the consultation.

4. Options

Options for transposing the provisions of the new regulation are as follows:

Option 1: do nothing i.e. fail to implement the Directive

Option 2: implement the provisions of the Directive as soon as possible as required by European law.

5. Costs and Benefits

Sectors and Groups affected

Businesses

The businesses which benefit by the amending Directives, and hence the new Regulations, are food businesses producing/distributing slimming foods. According to Mintel[4], the slimming food sector in the UK is estimated to be worth 32 million pounds, with one company accounting for 60% of the market share.

Consumers

We do not envisage any differential effect of the legislation on consumers because of gender, age, health or income. We do not envisage that the legislation would have differential effects on disabled people or those living in different regions or in rural communities. We consider that the proposal will have no impact on racial equality issues.

Voluntary Organisations and Charities

[4] 2006 Mintel report on slimming foods

We are not aware of any charities or voluntary organisations that would be affected by the legislation.

Public Sector

Government and Enforcement Authorities would not be affected by the legislation.

Benefits

Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.

Option 2: implementation brings the Government benefits by removing the risk of incurring infraction proceedings, and benefits industry by restoring a level playing field with regards to the claims that can be made on slimming products in comparison to claims made on general foods.

Costs

Option 1: Failure to implement would also be a risk to Government in that it would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the possibility of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement. Failure to implement would bring risks and disbenefits to consumers, industry, enforcement authorities and Government. Failure to implement would represent an unjustified restriction on a particular sector of industry and could mislead consumers.

Option 2: The Agency considers that there are no costs to consumers, enforcement authorities or Government associated with implementation of Commission Directive 2007/29/EC apart from costs to Government to administer the legislation. However, failure to implement would result in companies producing slimming foods being significantly disadvantaged. There may be costs to businesses who choose to re-label their products in light of this change in legislation but this would normally be done as part of normal label redesign.

The environmental impact of either option is likely to be negligible.

Administrative Burden

The administrative burden is the cost of complying with a regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). We believe that the only additional administrative burden to these companies would be the one-off costs to read and understand this Regulation. There would be no other additional administrative costs.

Flexibility

The Commission Directive 2007/29/EC does not offer any flexibility on the implementation of its provisions.

6. Small Firms Impact Test

Small businesses have been consulted informally and have not indicated that they will be put at any disadvantage as a result of the Regulation. The Forum of Private Business (Scotland) Ltd and the Federation of Small Businesses were both included as part of the consultation process in Scotland, however, neither organization provided any comment.

7. Test Run of Business Forms

There are no new forms associated with this piece of legislation.

8. Competition assessment

As Option 2 does not have a direct cost impact on industry, neither will it have a significant negative impact on competition in the slimming foods industry. Indeed, the change in the UK situation is likely to allow continued marketing of product and promote innovative product formulation in this industry.

9. Enforcement, Sanctions and Monitoring

Local authorities are responsible for enforcing The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997. The responsibilities for enforcement, sanctions and monitoring would remain unchanged. Persons convicted of an offence under these Regulations would be liable to a fine not exceeding level 5 of the standard scale.

10. Implementation and Delivery Plan

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (Scotland) Regulations 2007 will implement, in Scotland, Commission Directive 2007/29/EC.

The Directive does not provide for any specific review date and there is no provision in the main Directive for a review. The UK would, however, participate in any future review of the Directive that may be taken forward at an EU level.

11. Post-implementation review

In line with Scottish Executive 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.

12. Summary and Recommendations

In summary, making these Regulations will enable us to fulfil our community obligations and will benefit industry. Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

For these reasons, the Agency recommends that the UK should implement the provisions of Commission Directive 2007/29/EC via the Food for Particular Nutritional Uses (Scotland) Miscellaneous Amendments Regulations 2007.

Summary costs and benefits table

Option	**Total benefit per annum:** **- economic, environmental, social**	**Total cost per annum:** **- economic, environmental, social** **- policy and administrative**
1 Non Implementation	There are no benefits associated with Option 1	Failure to implement could bring to the Government the cost of potential infraction proceedings. It would also represent an unjustified restriction on a particular sector of industry and could mislead consumers. Companies producing slimming foods would be significantly disadvantaged.
2 Implementation	Option 2 would benefit Government by removing the risk of infraction, and would benefit industry by restoring a level playing field with regards to claims made on slimming products compared to claims made on general foods.	There would be costs to Government to administer this legislation, and there may be costs to businesses which choose to re-label their products but this would normally be done as part of normal label redesign. There would also be one-off costs to manufacturers to read and understand the Regulations.

13. Declaration

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

Signed by the responsible Minister:.....

Date:.....……

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Final Regulatory Impact Assessment

1. Title of proposal

The Food for Particular Nutritional Uses (Scotland) (Miscellaneous Amendments) Regulations 2007.

This Regulatory Impact Assessment is for regulation 5 only - to implement the extension of the period of derogation for addition of substances that may be added to foods for particular nutritional uses.

2. Purpose and intended effect of the measure

Objective

The proposed Regulations will, in Scotland:

- Provide for the execution and enforcement of Commission Regulation 1609/2006, which allows partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the UK market, provided that the protein content is between 1.86g/100kcal and 3g/100kcal and the protein is sourced and processed as provided in the Annex of Commission Regulation 1609/2006. These Regulations will amend the Infant Formula and Follow-on Formula Regulations 1995 (as amended) (regulation 2);

- Implement Commission Directive 2007/29/EC to bring the use of hunger and satiety claims prohibited by The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 in relation to slimming foods into line with the provisions on the use of such claims in relation to foods for general consumption (regulation 3);

- Implement Commission Directive 2006/82/EC, by updating the definition of "the Directive" referred to in the Foods for Special Medical Purposes (Scotland) Regulations 2000 to reflect the accession of Bulgaria and Romania to the European Union (regulation 4);

- Implement Commission Directive 2007/26/EC to extend the period of derogation provided for in The Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 until 1st January 2010 (regulation 5);

- Implement Commission Directive 2006/125/EC, by updating the definition of "the Directive" in the Processed Cereal-based foods and Baby Foods for Infants and Young Children (Scotland) Regulations 2004 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6)

Devolution

The proposed Regulations will apply in Scotland only. Separate parallel implementing legislation will be made in England, Wales and Northern Ireland.

Scope of this RIA

The purpose of a Regulatory Impact Assessment (RIA) is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, consumers and enforcement bodies. Given that the proposed changes in regulations 4 and 6 do not change any of the requirements of national legislation we do not anticipate that implementation of these Regulations will impose any costs or savings on businesses. Therefore, an RIA has not been prepared to accompany Regulations 4 and 6. However, stakeholders were consulted on the changes and asked to provide any information relating to costs or savings if any were identified. This RIA estimates the cost and impact of implementing regulation 5 to extend the period of derogation provided for in The Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002. Two separate RIAs accompany this one to cover each of regulations 2 and 3.

Background (regulation 5)

Directive 2001/15/EC, which is implemented in Scotland by The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 (SSI 2002/397) (referred to as the '2002 Regulations' for the purposes of this RIA), lays down certain requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses.

A food for a particular nutritional use (a 'parnuts' food) is a food which, owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and is sold in such a way as to indicate its suitability for its claimed nutritional purpose. A particular nutritional use means the fulfilment of the particular nutritional requirements of certain categories of persons a) whose digestive processes or metabolism are disturbed or b) whose physiological condition renders them able to obtain special benefit from controlled consumption of certain substances in foodstuffs or c) of infants or children in good health.

Parnuts foods include infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children, certain weight reduction products, 'sports foods'; and foods for special medical purposes. Provisions regarding the addition of substances to infant formulae, follow-on formulae, processed cereal-based foods and baby foods for infants and young children are laid down in separate Directives which apply to those specific categories of parnuts foods.

Foods intended for particular nutritional uses are regulated by framework Directive 89/398/EEC and by specific Directives adopted under that framework. Nutritional substances e.g. vitamins, minerals and amino acids may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom those foods are intended are fulfilled and/or in order to satisfy legal requirements laid down in specific directives adopted pursuant to Article 4 of framework Directive 89/398/EEC.

Directive 2001/15/EC was adopted pursuant to Article 4(2) of Directive 89/398/EEC which provides for the future adoption of a Directive containing a list of substances for specific nutritional purposes intended for addition to parnuts foods together with the purity criteria applicable to those substances. This practice of adopting a so-called "positive list" is characteristic of EU food law.

The 2002 Regulations limit the sources of several categories of substances that may be added to certain parnuts foods to those sources listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, Schedule 1 or 2 to the Regulations. The list of substances in the Annex to Directive 2001/15/EC currently excludes a number of substances that are used in the manufacture of certain parnuts foods currently on the market.

At the time of adoption of 2001/15/EC, a number of substances added to parnuts foods could not be included in the Annex because they had not been assessed by the Scientific Committee on Food (SCF), the forerunner of the European Food Safety Authority (EFSA). Thus, Commission Directive 2004/6/EC created a derogation which permitted the use of these substances in parnuts foods until 31st December 2006. The list of these substances is given in the Annex to Directive 2004/6/EC. Each substance listed in 2004/6/EC must be approved by EFSA and must be included in the Annex to 2001/15/EC before 31st December 2006 in order to permit their continued use in parnuts foods within the EC. This is implemented into domestic law by means of The Food for Particular Nutritional uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) (Amendment) Regulations 2004 (SSI 2004/90).

Directive 2004/5/EC and Directive 2006/34/EC (further amendments which added a number of substances to several categories of Directive 2001/15/EC) were implemented in domestic law by means of the Food for Particular Nutritional uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) (Amendment) Regulations 2004 (SSI 2004/90) and The Food for Particular Nutritional uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) (Amendment) Regulations 2006 (SSI 2006/556) respectively.

Provisions in the proposed regulation 5

The key proposal of regulation 5 is to implement, in Scotland, Commission Directive 2007/26/EC to allow for the continued sale of certain parnuts foods to which there has been added a substance listed in Schedule 3 of the 2002 Regulations (as amended) until 1st January 2010.

Rational for Government intervention

The Directive and the implementing Regulations address the risk that certain parnuts products containing nutritional substances not currently included in the Annex to 2001/15/EC would otherwise have to come off the market immediately. The new legislation will permit the continued marketing of valuable products, thereby enabling continued consumer choice and reducing the impact of Directive 2001/15/EC on industry.

3. Consultation

Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments were consulted formally on these draft Regulations.

During the negotiations of the draft amendment to the Commission Directive 2007/26/EC, the Agency consulted informally with all of the above stakeholders, including SMEs. We received one written response to our *informa*l consultation, from the Infant and Dietetic Foods Association, who supported the proposed amendment to the European Directive.

The Agency received seven responses in total to the *formal* consultation, including two from Scottish stakeholders. The responses from IDFA (Infant and Dietetic Foods Association), VEGA (Vegetarian Economy and Green Agriculture), the Nutrition Foundation, The UK Very Low Calorie Diet Foods Industry group and Lacors offered no specific comments or outlined support for the implementation of the proposed Regulations.

None of the respondents, including the two from Scotland, offered any comments on the drafting of the Regulations so no changes were made to the text of the SSI as a result of the consultation.

4. Options

Options for transposing the provisions of the new regulation are as follows:

Option 1: do nothing i.e. fail to implement the Directive

Option 2: implement the provisions of the Directive as soon as possible as required by European law.

5. Costs and Benefits

Sectors and Groups affected

Businesses

Businesses that benefited by the amending Directives, and hence the new Regulations, are food businesses producing/distributing certain parnuts foods. The parnuts food sector in the UK is characterized by approximately 10 large companies. Approximately 40 small companies are also involved in the production/distribution of parnuts products in the UK.

Consumers

The legislation will benefit consumers of certain parnuts foods. We do not envisage any differential effect of the legislation on consumers because of gender, age, health or income. We do not envisage that the legislation would have differential effects on disabled people or those living in different regions or in rural communities. We consider that the proposal will have no impact on racial equality issues.

Voluntary Organisations and Charities

We are not aware of any charities or voluntary organisations that would be affected by the legislation.

Public Sector

Government and enforcement authorities would not be affected by the legislation.

Benefits

Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.

Option 2: implementation brings benefits to consumers, industry, enforcement authorities and Government. It benefits consumers by maintaining consumer choice; benefits industry by permitting the continued marketing of valuable products; benefits enforcement officers as it does

not introduce new burdens, and benefits Government by removing the risk of incurring infraction proceedings.

Costs

Option 1: Failure to implement would bring risks and disbenefits to consumers, industry and Government. Failure to implement would be a risk to Government in that it would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the possibility of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement. Failure to implement would represent an unjustified restriction on consumer choice and would disadvantage industry by preventing the use of a number of substances that could be used in the manufacture of parnuts foods.

Option 2: The Agency considers that there are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of Commission Directive 2007/26/EC apart from costs to the Government to administer this legislation. However, as stated in the RIA that accompanied the 2002 Regulations (Appendix I), failure to implement would result in companies having to "reformulate certain products or remove them from the market; either of these outcomes would result in considerable costs".

The environmental impact of either option is likely to be negligible.

Administrative Burden

The administrative burden is the cost of complying with a regulation to provide information, less any costs that would be incurred during the normal course of business (i.e. if the legislative information requirement was not in place). We believe that the only additional administrative burden to these companies would be the one-off costs to read and understand this Regulation. There would be no other additional administrative costs.

Flexibility

The Commission Directive 2007/26/EC does not offer any flexibility on the implementation of its provisions.

6. Small Firms Impact Test

The new regulations will allow companies to continue using certain products in these foods. This will allow small businesses, along with larger businesses, to continue to market parnuts foods which contain substances listed in the Annex. Small businesses have been consulted informally and have not indicated that they will be put at any disadvantage as a result of the Regulations. The Forum of Private Businesses (Scotland) Ltd and the Federation of Small Businesses were both included as part of the consultation process in Scotland, however, neither organization provided any comment.

7. Test run of business forms

There are no new forms associated with this piece of legislation.

8. Competition assessment

As Option Two does not have a cost impact on industry, neither will it have a significant negative impact on competition in the parnuts industry. Indeed, the maintenance of the UK situation is likely to allow continued innovative product formulation in this industry. There are no further competition issues to be considered for the amendments proposed over and above those identified in the RIA for the original legislation (Appendix 1).

9. Enforcement, Sanctions and Monitoring

Local food authorities are responsible for enforcing The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002. Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the RIA for the original legislation (Appendix 1). Persons convicted of an offence under these Regulations would be liable to a fine not exceeding level 5 of the standard scale.

10. Implementation and Delivery Plan

The Food for Particular Nutritional Uses (Miscellaneous Amendments)(Scotland) Regulations 2007 will implement in Scotland, Commission Directive 2007/26/EC. The Directive does not provide for any specific review date and there is no provision in the main Directive for a review. However, it is likely that further amendments to the Annex of 2001/15/EC will be made by further amending Directives following future scientific evaluation of more substances by the EFSA. The UK would, however, participate in any future review of the Directive that may be taken forward at an EU level.

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11. Post-implementation review

In line with Scottish Executive 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.

12. Summary and Recommendations

In summary, making these Regulations will enable us to fulfil our community obligations and will benefit consumers and industry. Failure to make these Regulations would result in a serious breach of the UK's obligations under the EC Treaty and would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

For these reasons the Agency recommends that the UK should implement the provisions of Commission Directive 2007/26/EC via the Food for Particular Nutritional Uses (Scotland) Miscellaneous Amendments Regulations 2007.

Summary costs and benefits table

Option	Total benefit per annum: - economic, environmental, social	Total cost per annum: - economic, environmental, social - policy and administrative
1 Non Implementation	Option 1: There are no benefits associated with Option 1	Option 1: Failure to implement would bring to the Government the cost of potential infraction proceedings. It would also represent an unjustified restriction on consumer choice and would disadvantage industry by preventing the use of a number of substances that could be used in the manufacture of parnuts foods.
2 Implementation	Option 2: Implementation would benefit consumers by maintaining consumer choice; industry by permitting the continued marketing of valuable products; enforcement officers by not introducing new burdens, and Government by removing the risk of infraction proceedings.	Option 2: There are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of Commission Directive 2007/26/EC apart from costs to the Government to administer this legislation.

13. Declaration

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

Signed by the responsible Minister:.....

Date:.....……

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