EXPLANATORY MEMORANDUM TO

THE FOOD FOR PARTICULAR NUTRITIONAL USES (MISCELLANEOUS AMENDMENTS) (ENGLAND) REGULATIONS 2007

2007 No. 2591

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

2. Description

2.1 This instrument applies in relation to England 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.

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

3.1 None

4. Legislative Background

4.1 This instrument implements in relation to England, Commission Regulation 1609/2006 and Commission Directives 2007/29/EC, 2006/82/EC, 2007/26/EC and 2006/125/EC.

4.2 Commission Regulation 1609/2006 derogates from Commission Directive 91/321/EC on infant formula and follow-on formula, which controls the composition, labelling and marketing of infant formula and follow-on

formula. Commission Regulation 1609/2006 introduces a derogation to allow partially hydrolysed infant formula based on hydrolysates of whey protein from cows' milk to be placed on the 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 to Commission Regulation 1609/2006. An amendment to the Infant Formula and Follow-on Formula Regulations 1995 provides for the execution and enforcement of this derogation.

4.3 Commission Directive 2007/29/EC amends Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction (slimming foods) so as to allow the use of hunger and satiety claims in relation to slimming foods bringing the prohibitions on these foods into line with the provisions on the use of such claims in relation to foods for general consumption. Commission Directive 2007/29/EC is implemented by an amendment to the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997.

4.4 Commission Directive 2006/82/EC updates Commission Directive 1999/21/EC on foods for special medical purposes to reflect the accession of Bulgaria and Romania to the European Union. Commission Directive 2006/82/EC is implemented by an amendment to the Medical Food (England) Regulations 2000.

4.5 Commission Directive 2007/26/EC extends the period of derogation provided for in Commission Directive 2004/6/EC which derogates from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products until 1st January 2010. Commission Directive 2007/26/EC is implemented by an amendment to the Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002.

4.6 Commission Directive 2006/125/EC consolidates Commission Directive 96/5/EC and its amendments. Commission Directive 2006/125/EC is implemented by an amendment to the Processed Cereal-based foods and Baby Foods for Infants and Young Children (England) Regulations 2003.

5. Extent

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

6. European Convention on Human Rights

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

7. Policy background

7.1 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.

7.2 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. Parnuts foods marketed in the EU must also be safe for human consumption.

7.3 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.

7.4 This instrument will ensure that:

7.4.1 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.

7.4.2 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.

7.4.3 foods for special medical purposes can be labelled in Bulgarian and Romanian to reflect the accession of Bulgaria and Romania to the European Union.

7.4.4 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.

7.4.5 the definition of the 'Directive' referred to in the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) 2003 Regulations is updated to reflect the consolidated Commission Directive.

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

8. Impact

8.1 The Food Standards Agency consulted with over 400 interested parties on the proposed Regulations. 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.

8.2 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.

8.3 The three Regulatory Impact Assessments carried out are attached to this memorandum.

9. Contact

Bindiya Shah at the Food Standards Agency (Tel: 02072768173 or e-mail: bindiya.shah@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

TRANSPOSITION NOTE: The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007

This transposition note outlines how Commission Regulation 1609/2006 and Commission Directives 2007/29/EC, 2006/82/EC, 2007/26/EC and 2006/125/EC are transposed into legislation in England by the Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007.

Commission legislation and Article	**Objective**	**Implementation**	**Responsibility**
Commission Regulation 1609/2006 Article 1 and Annex	Derogates from Directive 91/321/EC on infant formula and follow-on formula to allow partially hydrolysed formula based on hydrolysates of whey protein from cows' milk to be placed on the market provided that the specific conditions set out in the Annex are met.	Regulation 2 which amends the Infant Formula and Follow-on Formula Regulations 1995 (as amended).	Secretary of State.
Commission Directive 2007/29/EC Article 1	Amends Directive 96/8/EC on the labelling, advertising or presenting of foods intended for use in energy-restricted diets for weight reduction to bring the use of hunger and satiety claims into line with the provisions on the use of such claims in relation to foods for general consumption.	Regulation 3 which amends the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997.	Secretary of State.
Commission Directive 2006/82/EC	Amends Directive 1999/21/EC on foods for special medical purposes to reflect the accession of	Regulation 4 which amends the Medical Food (England) Regulations 2000.	Secretary of State.

Article 1	Bulgaria and Romania to the EU.		
Commission Directive 2007/26/EC Article 1	Amends Directive 2004/6/EC derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade of certain products until 1st January 2010	Regulation 5 which amends the Foods for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002.	Secretary of State.
Commission Directive 2006/15/EC	Consolidates Directive 96/5/EC on processed cereal based foods and baby foods for infants and young children.	Regulation 6 which amends the Processed Cereal-based foods and Baby Foods for Infants and Young Children (England) Regulations 2003.	Secretary of State.

Regulatory Impact Assessment

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007
(Regulatory Impact Assessment for regulation 2 – derogation from specific compositional requirements of the infant formula and follow-on formula Regulations)

Purpose and intended effect of the measure

Objective

1. The proposed Regulations will, in England -

- 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 Medical Food (England) 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) (England) 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 (England) Regulations 2003 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6).

Devolution

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

Scope of this RIA

2. 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, a 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)

3. 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.

4. 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.

5. 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.

6. 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),
    - protein partial hydrolysates from cows' milk (2.25g/100 kcal – 3g/100 kcal).

7. 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 Regulation 2

8. The key proposal of Regulation 2 is to provide, in England, 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.

Rationale for government Intervention

9. 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

[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)

[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)

1609/2006 to market them in the UK and thereby facilitate increased choice for consumers.

CONSULTATION

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

11. The Agency received 5 responses in total to the formal consultation. 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 offered any comments on the drafting of the Regulations.

Options

12. Options for transposing the provisions of the Commission Regulation are as follows:

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

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

Flexibility

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

Costs and benefits

Business sectors affected

14. 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.

15. 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

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

range of retail outlets, with around 15% sales by volume being through NHS baby clinics.

Consumers affected

16. 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

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

Public sector

18. Government and enforcement authorities would be affected by the legislation.

Benefits

19. 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.

20. 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.

Costs

21. Option 1 – 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.

22. Option 2 – There are no costs to consumers, businesses, enforcement authorities or Government associated with implementation of this new Regulation apart from costs to Government to administer this legislation.

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

Administrative Burden

24. 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 cost to read and understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

25. 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.

Impact on the Regions

26. Any regional differences due to the new legislation would depend upon the location of the relevant businesses. We are not aware of any differential impact.

Competition assessment

27. 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.

Enforcement, sanctions and monitoring

28. Local food authorities are responsible for enforcing the Regulations. The amending Regulations bring no new enforcement responsibilities.

Post-implementation review

29. 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.

Summary and Recommendations

30. 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 would attract infraction proceedings by the Commission against the UK and the possibilty of heavy fines.

31. 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 (Miscellaneous Amendments) (England) Regulations 2007.

Declaration:

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

Signed by the responsible Minister: Ben Bradshaw.....

Date:.3rd September 2007.....……

Contact point

Bindiya Shah
Food Standards Agency
Aviation House, Room 115B
125 Kingsway
London WC2B 6NH
Nutrition Division

Telephone: 0207-276-8169
Fax: 0207-276-8193

E-mail: bindiya.shah@foodstandards.gsi.gov.uk

Regulatory Impact Assessment

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007
(Regulatory Impact Assessment for regulation 3 to allow the used of 'reduced hunger' and 'increased satiety' claims on foods intended for use in energy restricted diets for weight reduction)

Purpose and intended effect of the measure

Objective

2. The proposed Regulations will, in England -

- 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 Medical Food (England) 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) (England) 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 (England) Regulations 2003 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6).

Devolution

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

Scope of this RIA

4. 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, a 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)

5. 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.

6. 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.

7. 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

8. Regulation 3 implements, in England, 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

9. 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 enable continued consumer choice.

CONSULTATION (regulation 3)

10. 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.

11. 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.

12. The Agency received 5 responses in total to the formal consultation. 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 offered any comments on the drafting of the Regulations so no changes were made to the text of the SI as a result of the consultation.

Options for transposing regulation 3

13. 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.

Flexibility

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

Costs and benefits associated with regulation 3

15. This section aims to identify the costs and benefits associated with option 1 and 2 noted above.

Business sectors

16. 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 worth 32 million pounds with one company accounting for 60% of the market share.

Consumers

17. 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

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

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

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

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

[4] 2006 Mintel report on slimming foods

Costs associated with regulation 3

22. 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.

23. 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 relabel their products in light of this change in legislation but this would normally be done as part of normal label redesign.

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

Administrative Burden on businesses affected by regulation 3

25. 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 cost to read and understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

26. Small businesses have been consulted informally and have not indicated that they will be put at any disadvantage as a result of the Regulation.

Impact on the Regions of regulation 3

27. Any regional differences due to the new legislation would depend upon the location of the relevant businesses. We are not aware of any differential impact.

Competition assessment as related to regulation 3

28. As Option Two 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.

Enforcement, sanctions and monitoring as related to regulation 3

29. Local food 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.

Post-implementation review as related to regulation 3

30. 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.

Summary and Recommendations

31. 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 would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

32. 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 (Miscellaneous Amendments) (England) Regulations 2007.

Declaration:

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

Signed by the responsible Minister: Ben Bradshaw.....

Date:3rd September 2007.....……

Contact point

Bindiya Shah

Food Standards Agency
Aviation House, Room 115B
125 Kingsway
London WC2B 6NH
Nutrition Division

Telephone: 0207-276-8173
Fax: 0207-276-8193

E-mail: bindiya.shah@foodstandards.gsi.gov.uk

Regulatory Impact Assessment

The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007
(Regulatory Impact Assessment for regulation 5 to implement the extension of the period of derogation for addition of substances that may be added to foods for particular nutritional uses).

Purpose and intended effect of the measure

Objective

33. The proposed Regulations will, in England -

- 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 Medical Food (England) 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) (England) 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 (England) Regulations 2003 so that it refers to the Directive 2006/125/EC instead of Directive 96/5/EC as amended (regulation 6).

Devolution

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

Scope of this RIA

35. 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, a 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) (England) Regulations 2002. Two separate RIAs accompany this one to cover each of regulations 2 and 3.

Background (regulation 5)

36. Directive 2001/15/EC, which is implemented in England by The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (SI 2002/1817) (referred to as the '2002 Regulations' for the purposes of this PRIA), lays down certain requirements regarding substances that may be added for specific nutritional purposes to certain foods for particular nutritional uses.

37. 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.

38. 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. 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.

39. 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.

40. 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.

41. 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.

42. 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) (England) (Amendment) Regulations 2004 (SI 2004/649).

43. 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) (England) (Amendment) Regulations 2004 (SI 2004/649) and The Food for Particular Nutritional uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2006 (SI 2006/3116) respectively.

Provisions in the proposed regulation 5

44. The key proposal of regulation 6 is to implement, in England, 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.

Rationale for government intervention

45. 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.

CONSULTATION (regulation 5)

46. 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 informal consultation, from the Infant and Dietetic Foods Association, who supported the proposed amendment to the European Directive.

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

48. The Agency received 5 responses in total to the formal consultation. 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 offered any comments on the drafting of the Regulations so no changes were made to the text of the SI as a result of the consultation.

Options for transposing regulation 5

49. 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.

Flexibility

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

Costs and benefits associated with regulation 5

51. This section aims to identify the costs and benefits associated with option 1 and 2 noted above.

Sectors and groups affected by regulation 5

Business sectors

52. Businesses 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

53. 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

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

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

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

57. 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 associated with regulation 5

58. Option 1: Failure to implement would bring risks and disbenefits to consumers, industry and Government. 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 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.

59. 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 costs to 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".

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

Administrative Burden on businesses affected by regulation 5

61. 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 cost to read and understand this Regulation. There would be no other additional administrative costs.

Small Firms Impact Test

62. The new regulations will allow companies to continue using certain products in these foods. This will allow small business, along with larger business, 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.

Impact on the Regions of regulation 5

63. Any regional differences due to the new legislation would depend upon the location of the relevant businesses. We are not aware of any differential impact.

Competition assessment as related to regulation 5

64. 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).

Enforcement, sanctions and monitoring for regulation 5

65. Local food authorities are responsible for enforcing The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002. Responsibilities for enforcement, sanctions and monitoring are the same as those set out in the RIA for the original legislation (Appendix 1).

Post-implementation review for regulation 5

66. 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.

Summary and Recommendations

67. 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 would attract infraction proceedings by the Commission against the UK and the possibility of heavy fines.

68. 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 (Miscellaneous Amendments) (England) Regulations 2007.

Declaration:

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

Signed by the responsible Minister: Ben Bradshaw.....

Date:3rd September 2007.....……

Contact point

Bindiya Shah
Food Standards Agency
Aviation House, Room 115B
125 Kingsway
London WC2B 6NH
Nutrition Division

Telephone: 0207-276-8173
Fax: 0207-276-8193

E-mail: bindiya.shah@foodstandards.gsi.gov.uk

Appendix1

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSED MEASURE

The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002

1. The Regulations implement, in England, Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

2(i) The issue

2. As defined in the Regulations a food for a particular nutritional use (a PNU 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.

3. PNU foods include, but are not limited to, infant formulae and follow-on formulae; processed cereal-based foods and baby foods for infants and young children (weaning foods); foods intended for use in energy restricted diets for weight reduction (certain weight reduction products); and foods for special medical purposes (including special products such as tube feeds mainly used in a hospital setting).

4. 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, 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.

5. Currently under UK law there are no specific restrictions on the substances that may be added for specific nutritional purposes to PNU foods during their manufacture except that the addition of tryptophan is prohibited by the Tryptophan in Foods Regulations 1990. PNU foods, like other foods, are subject to the general provisions of the Food Safety Act 1990.

6. Directive 2001/15/EC has been adopted pursuant to article 4(2) of Directive 89/398/EC which provides for the future adoption of a Directive containing a list of substances for specific nutritional purposes intended for addition to PNU 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. A statutory instrument is required to implement Directive 2001/15/EC in England. Parallel legislation will also be made in Scotland, Wales and Northern Ireland.

7. After the coming into force of the new Regulations, substances that may be added for specific nutritional purposes to the PNU foods covered by this Directive during their manufacture will be limited to those listed in the Schedules 1 and 2 of the Regulations. The list of substances in these Schedules is identical to the list of substances in the Annex to Directive 2001/15/EC. At present, the Annex to the Directive, hence Schedules 1 and 2 to the Regulations, exclude a number of substances currently used in the manufacture of PNU foods on the market. However, there are procedures for adding substances to the list and the list may yet be expanded before 1st April 2004. The Directive requires that trade in products not complying with the Directive be prohibited with effect from 1 April 2004.

2(ii) The objectives

8. The purpose of Commission Directive 2001/15/EC is to ensure that the use of nutritional substances in most PNU foods results in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are

intended. Substances added for nutritional purposes to infant formulae and baby foods are controlled in separate legislation that covers their composition and labelling.

9. The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 concern food for most particular nutritional purposes where there has been added to that food a substance falling within one of the following categories: vitamins, minerals, amino acids, carnitine and taurine; nucleotides, choline and inositol. Other substances not belonging to one of these categories may be used subject to the general provisions laid down. The Regulations are not relevant to infant formulae and baby foods except in so far as the Regulations amend the Tryptophan in Food Regulations 1990 as mentioned below.

10. The new Regulations introduce measures to meet the following objectives:

- to prohibit the sale of most PNU foods to which a substance listed in paragraph 9 above has been added unless the substance is listed under the relevant category in Schedule 1 or, in the case of foods for special medical purposes, is listed under the relevant category in either Schedule 1 or 2. Relevant purity criteria must be met for the substance. (Regulation 3(1) to (3))

- to impose general restrictions on the sale of most designated PNU foods in the manufacture of which any substances have been used for specific nutritional purposes (regulation 3(4)); and require the manufacturer or importer to supply the Food Standards Agency with information on request to verify that those restrictions are met (regulation 4)

- to make provision as to responsibilities for enforcement (regulation 6); create offences and penalties (regulation 7) and apply certain provisions of the Food Safety Act 1990 (regulation 9). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 8)

- to disapply the prohibitions in the Tryptophan in Food Regulations 1990 (in their application to England) in so far as they conflict with Directive 2001/15/EC, Article 5 of Commission Directive 91/321/EEC (OJ No. L175, 4.7.91, p.35) on infant formulae

and follow–on formulae and Article 5 of Commission Directive 96/5/EC (OJ No. L49, 28.2.96, p.17) on processed cereal–based foods and baby foods for infants and young children (regulation 10)

- to prohibit the sale by the manufacturer or importer of certain designated PNU foods to which L-tryptophan has been added for a specific nutritional purpose, unless prior notification has been given to the Food Standards Agency before the first marketing of food of that particular type (regulation 5).

2(iii) Risk Assessment

11. The Directive addresses the risk that substances added for specific nutritional purposes to PNU foods could result in the production of unsafe products if those substances did not meet relevant purity criteria. This is particularly important given that PNU foods may be manufactured to meet the particular nutritional needs of groups of vulnerable consumers. The implementing Regulations also address this risk. To this end, the Annex to the Directive lists substances that may be added and states that relevant purity criteria must be met. The list of substances is based on advice from the EU Scientific Committee on Food which has evaluated their safety and bioavailability.

12. The Regulations also prohibit the sale by the manufacturer or importer of certain designated PNU foods to which L-tryptophan has been added for a specific nutritional purpose, unless prior notification has been given to the Food Standards Agency before the first marketing of food of that particular type. The national Tryptophan in Food Regulations 1990 have prohibited the addition of tryptophan to foods, with certain exemptions. This prohibition was brought into effect in 1990 following a series of serious food incidents in the USA and UK. A number of individuals fell seriously ill after taking dietary supplements containing artificially-produced tryptophan and there were a number of fatalities. There have been no further problems since the introduction of this precautionary measure. Directive 2001/15/EC (and Directives 91/321/EEC and 96/5/EC) allow the use of L-tryptophan in PNU foods. With the implementation of the Directive it became necessary to remove this conflict but at the same time it is considered appropriate to monitor the use of L-tryptophan in order to protect public health. For this reason the new Regulations contain a notification requirement in regulation 5 in order to assist in effective enforcement of the substantive requirements of the Directive as implemented in regulations 3 and 4.

3 Benefits and options

13. The benefit of these Regulations is that they will contribute to consumer protection by ensuring that substances added for specific nutritional purposes in foods for particular nutritional uses have been evaluated for safety and bioavailability. The EU Scientific Committee on Food has previously given its opinion that addition of such substances may be appropriate in order that these products fulfil the particular nutritional requirements of the people for whom they are intended.

3(i) Options

14. The UK is obliged to implement Commission Directive 200115/EC and to prohibit trade in products that do not comply with the Directive with effect from 1st April 2004; the Directive does not allow for any flexibility in timing. Failure to implement would risk infraction proceedings from the Commission. In implementing the Directive, it is also necessary to deal with the conflict between the Tryptophan in Food Regulations 1990 and Directive 2001/15/EC and also, incidentally, with the conflict between the Tryptophan in Food Regulations 1990 and Article 5 of Commission Directive 91/321/EEC (on infant formulae and follow–on formulae) and Article 5 of Commission Directive 96/5/EC (on processed cereal–based foods and baby foods for infants and young children).

The options are:

Option 1: do nothing i.e. fail to implement Commission Directive 2001/15/EC.

Option 2: implement Directive 2001/15/EC and leave the Tryptophan in Food Regulations 1990 unamended, thereby retaining the previous national prohibition on the addition of tryptophan (including L-tryptophan which features in the list of amino acids in the Annex to the Directive) to PNU foods as well as to other foods. This would result, necessarily, in incomplete implementation of the Directive.

Option 3: implement Directive 2001/15/EC and, at the same time, amend the Tryptophan in Food Regulations 1990 to disapply the prohibitions as far as they apply to certain Directives. At the same time, introduce a requirement prohibiting the manufacturer or importer from selling certain PNU foods to which L-tryptophan has been added for a specific nutritional purpose unless the Food

Standards Agency has been notified at least three months prior to the placing on the market of food of that particular type.

Option 4: implement Directive 200115/EC and revoke the Tryptophan in Food Regulations 1990.

3(iii) Benefits and disbenefits of options

15. Option 1: failure to implement the Directive would mean that the UK would risk infraction proceedings from the Commission.
16. Option 2: while, on the face of it, this would allow the UK to maintain the national safety measure in its entirety it would lead to the UK running the risk of being subject to infraction proceedings from the Commission. This option would result in two inconsistent legislative provisions and the courts would give effect to the provisions implementing the Directive, effectively overruling the national Tryptophan in Food Regulations 1990 and reducing the level of consumer protection.

17. Option 3: this would remove the risk of the UK incurring infraction proceedings from the Commission while at the same time allowing the UK to maintain national safety controls on other foods containing added tryptophan.

18. In the case of certain PNU foods containing added L-tryptophan the Food Standards Agency would have the opportunity to assess the safety of any such product before it was put on the market. If, after examination of the scientific work and data submitted, the Agency considered that the company had failed to demonstrate the safety of a particular product then any company selling that product would be guilty of an offence under regulation 7(a) and would be liable to prosecution by a local authority.

19. Option 4: this would remove the national provisions prohibiting the addition of tryptophan to foodstuffs. While this would remove a constraint on food manufacturing practice and would be the least restrictive option it would carry the greatest risk to public health. It also goes further than required by the Directive.

4 Compliance costs estimates

20. Businesses affected by the Regulation will be food businesses manufacturing PNU foods to which substances for specific nutritional purposes have been added. The legislation could also have knock-on effects on importers and suppliers of such foods including charities and voluntary organisations.

4(i) Compliance costs for a typical business

21. The PNU food sector is dominated by a relatively small number of large companies that manufacture medical foods. Each of these companies was given the opportunity to comment on the Regulations but only two chose to respond. Other PNU foods on sale in England (such as many sports foods) are manufactured in the United States thus the impacts of the new Regulations are most likely to be felt, in this country, by businesses importing and supplying such foods.

22. As it stands, the Annex to Directive 2001/15/EC excludes a number of nutritional substances (primarily amino acids) that are added to PNU foods currently on the market. The Directive requires that trade in products not complying with the Directive be prohibited with effect from 1 April 2004. The Commission recognises that the list of permitted substances in the Annex requires updating and has stated its intention to expand the list before 1 April 2004. Since the adoption of framework Directive 89/398/EEC in 1989 industry has been aware that this Directive (2001/15/EC) would eventually be drafted and has already submitted some dossiers to the Scientific Committee on Food for assessment with a view to getting those substances included in the Annex. However, at the level of the European Commission, there is slow progress on work to expand the list in the Annex.

23. With the help of the Infant and Dietetic Food Association (IDFA), the main trade association in the field which sent out questionnaires to its members, businesses were consulted on the potential financial impacts of the Regulations. IDFA carried out active liaison with its members and allowed considerable time for response.

24. Two companies returned completed questionnaires. Both were large companies, each with several hundred employees. Company ‘A’ produces a wide range of dietetic foods (infant formulae, baby foods, medical foods, dietary supplements, sports foods); Company ‘B’ produces medical foods and gluten-free foods. Both

companies based their estimates of costs on the assumption that the Directive would be implemented without amendment of the Annex.

25. Company 'A' estimated that implementation of the Directive would result in one-off costs of £1,005,000 (approximately 2% of turnover). Company 'B' estimated implementation costs of £1,081,000 (approximately 1.3% of turnover) together with annual costs of £10,000 covering the purchase of raw materials and other inputs. The labelling element of these costs will be offset by the fact that during the transition period (between the date of coming into force of these Regulations and 1st April 2004 when trade in products not complying with the Directive is prohibited) companies are likely to have made voluntary labelling changes anyway. Company 'B' estimated that, if implemented with the Annex to the Directive in its present state, the new Regulations would result in the need to reformulate approximately 103 products and change 600 product labels throughout Europe. Company 'B' specializes in the development and marketing of a wide range of amino acid-based products with small sales volume and high production costs. Since a number of amino acid sources are currently absent from the Annex to the Directive, this company is particularly sensitive to the impact of the Directive. Both companies indicated that implementation of the Directive was likely to have a disadvantageous effect on competitiveness and profitability.

26. Costs to this sector of industry as a whole will largely depend upon the state of the list in the Annex to the Directive on 1 April 2004. If the Annex remains unamended on 1 April 2004 or if it has been amended but still excludes some nutritional substances currently used in the manufacture of PNU foods then companies will have to reformulate certain products or remove them from the market; either of these outcomes would result in considerable costs. If the Annex is expanded to include more substances currently in use then costs to industry will be less.

27. For companies that do not currently use substances excluded from the Annex there will be no implementation costs. Based on the limited amount of information received through consultation we estimate the upper limit for implementation costs across the sector as a whole to be around 2% of turnover. These costs would be significantly reduced if the list of permitted substances in the Annex to the Directive were amended appropriately before 1 April 2004.

28. The new arrangement permitting the addition of L-tryptophan to PNU foods would only have an impact on those companies that choose to do this. In the event that any company voluntarily chose to take advantage of this and decided to reformulate products or produce completely new products with added L-tryptophan, costs would include those associated with reformulation and, under Option 3 of section 3(i) above; costs, in appropriate cases, of notifying the Food Standards Agency prior to placing on the market in the UK; and costs of complying with any requests to demonstrate safety that the Agency would be likely to make. Costs associated with notification and demonstrating safety would largely be administrative costs: the notification procedure will involve filling in a two-page form and posting it, together with a model of the product label, to the Agency; demonstrating safety will involve assembling data that should already be in a company's files.

4(ii) Small business litmus test

29. With the help of the Small Business Service we identified and contacted four small businesses involved in supplying sports foods; of these, two were micro businesses (1 employee and two employees respectively). Only one business responded and stated that the implications of any controls on manufacturing would not affect the business in any way other than that it would pass on any increased costs to its own customers.

4(iii) Enforcement

30. Local food authorities will be responsible for enforcing the Regulations. They will also provide advice to businesses on compliance with these Regulations. The Food Standards Agency will produce guidance notes on the Regulations for businesses and Local Authorities.

31. The Local Authority Co-ordinators of Regulatory Services (LACORS, formerly LACOTS) has advised that the Regulation will result in a marginal increase in local food authority resource commitment in order to ensure effective enforcement. LACORS has not requested allocation of additional funds to deal with these Regulations.

32. There could be some new implications for resources in the Food Standards Agency as a result of the introduction of these Regulations. This will depend upon whether the Agency receives any notifications of intention to market PNU foods with added L-tryptophan. In this case, there would be an investment of time and personnel in assessing the incoming information in order for the Agency to assess the safety of such products. We consider it unlikely that companies will suddenly begin to manufacture PNU foods that must be notified therefore it is unlikely that the Agency will receive any such notifications.

5 Securing compliance and available sanctions

33. The Regulations will be enforced by local food authorities. The Food Standards Agency will also play a role with regard to the notification requirement in regulation 5(1). IDFA, the major trade association in this area has indicated its willingness to support the Agency and emphasise the importance of this requirement to its members. Any person that contravenes regulation 3(1) or (4) or, without reasonable excuse, contravenes regulation 4 or 5(1) will be guilty of an offence and liable, on summary conviction, to a fine not exceeding level 5 on the standard scale (currently £5000); the Lord Chancellor's Department is content with this level of fine.

5 RESULTS OF CONSULTATIONS

34. During the course of negotiations on Directive 2001/15/EC and subsequently while drafting these implementing Regulations, Food Standards Agency officials have maintained close contact with interested parties including consumer organisations, health professional groups, food manufacturers, trade organisations, enforcement authorities and other government departments through a number of formal consultation exercises. Overall, more than 260 organisations were contacted; 35 written responses were received. Examples of compliance costs for businesses quoted in section 4(i) above have been based on information provided by industry during consultation. Some companies may incur significant implementation costs while for other companies costs will be minimal. Costs will depend upon the list of substances included in the Annex to the Directive and the extent to which companies are sensitive to that list.

35. In response to consultation consumers' organisations generally welcomed the new Regulations and their contribution to ensuring the safety of PNU foods. The main concern expressed by businesses was that the list of permitted substances was too restrictive and that the use of such a list would stifle innovation. Enforcement authorities supported the proposals and requested clarification on some details in order to aid enforcement.

6 SUMMARY AND RECOMMENDATIONS

36. It is recommended that **option 3** (section 3(i) above) **is supported**. This will allow the UK to fulfil its Community obligation to implement the provisions of Directive 2001/15/EC while still allowing the retention of national safety measures relating to the addition of tryptophan to most foods. The SI attached to this Regulatory Impact Assessment implements option 3.

7 MONITORING AND REVIEW

37. No specific review date is provided for within the Directive. However, officials will maintain close and regular contact with LACORS and the relevant trade associations to monitor compliance with the Regulations, in particular compliance with the requirement of prior notification provided for in Regulation 5. LACORS and trade associations are aware of the importance of this new requirement and support it.

Declaration:

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

Signed by the responsible Minister: Ben Bradshaw.....

Date:3rd September 2007.....

Contact point

Rosemary Hignett
Food Standards Agency

Aviation House, Room 125
125 Kingsway
London WC2B 6NH

Division: Food Labelling and Standards, Branch A

Telephone: 0207-276-8178

E-mail: rosemary.hignett@foodstandards.gsi.gov.uk