

**2007 No.**

**FOOD, ENGLAND**

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

<i>Made</i>	- - - -	2007
<i>Laid before Parliament</i>		2007
<i>Coming into force</i>	- -	1st October 2007

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup> and now vested in him<sup>(2)</sup>.

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

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<sup>(3)</sup>, there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title, application and commencement**

1. These Regulations may be cited as the Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007; they apply in relation to England only and come into force on 1st October 2007.

---

(1) 1990 c.16 section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

(2) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.

(3) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

### **Amendment of the Infant Formula and Follow-on Formula Regulations 1995**

2.—a) The Infant Formula and Follow-on Formula Regulations 1995(4) are amended in accordance with paragraph (2) in so far as they apply in relation to England.

(1) In paragraph (1) of regulation 22 (offences and enforcement), insert at the beginning the words –

“Subject to the derogation set out in Article 1 of Commission Regulation (EC) No. 1609/2006 authorising the placing on the market of infant formulae based on hydrolysates of whey protein derived from cows’ milk protein for a two-year period 9(5),”.

### **Amendment of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997**

3.—b) The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997(6) are amended in accordance with paragraph (2) in so far as they apply in relation to England.

(1) In regulation 4 (labelling, advertising and presentation) omit the words “or to a reduction in the sense of hunger or an increase in the sense of satiety”.

### **Amendment of the Medical Food (England) Regulations 2000**

4.—c) The Medical Food (England) Regulations 2000(7) are amended in accordance with paragraph (2).

(1) In regulation 2 (interpretation), for the definition of “the Directive” substitute the following definition—

“the Directive” means Commission Directive 1999/21/EC on dietary foods for special medical purposes(8) as amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded(9) and Commission Directive 2006/82/EC adapting Directive 91/321 on infant formulae and follow-on formulae and Directive 1999/21/EC on dietary foods for special medical purposes, by reason of the accession of Bulgaria and Romania(10);”.

### **Amendment of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003**

5.—d) The Processed Cereal-based-Foods for Infants and Young Children (England) Regulations 2003(11) are amended in accordance with paragraph (2).

(1) In paragraph (1) of regulation 2 (interpretation), for the definition of “the Directive” substitute the following definition –

““the Directive” means Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children(12);”.

---

(4) S.I. 1995/77, to which there are amendments not relevant to these Regulations.

(5) OJ No. L299, 28.10.2006, p.9.

(6) S.I. 1997/2182, to which there is an amendment not relevant to these Regulations.

(7) S.I. 2000/845; relevant amendment instrument is S.I. 2004/2145.

(8) OJ No. L91, 7.4.99, p.29.

(9) OJ No. L236, 23.9.2003, p.33.

(10) OJ No. L362, 20.12.2006, p.94.

(11) S.I. 2003/3207, to which there is an amendment not relevant to these Regulations.

(12) OJ No. L339, 6.12.2006, p.16.

**Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002**

6.—e) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002<sup>(13)</sup> are amended in accordance with paragraph (2).

(1) In paragraph (5) of regulation 3 (restrictions on sale) for the words “1st January 2007” substitute the words “1st January 2010”.

Signed by authority of the Secretary of State for Health

2007

Minister of State,  
Department of Health

---

<sup>(13)</sup>S.I. 2002/1817, amended by S.I. 2004/649; there are other amending instruments but none is relevant.

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

AG BARR	Berkshire Healthcare NHS Foundation Trust
Abbott Laboratories	Bernard Matthews Foods Limited
Addenbrookes Hospital	Berry Ottaway Associates
Academy of Culinary Arts (ACA)	BIBRA Information Services Limited
Advertising Association	Bird & Bird
Advertising Standards Authority (ASA)	Birmingham Childrens Hospital
Advisory Body for Social Services	Biscuit, Cake, Chocolate and Confectionery Association (BCCCA)
Catering (ABSSC)	Booker PLC
Advisory Centre for Education	Booth Smith & Associates
Agricultural Industries Confederation (AIC)	Boots PLC
Agricultural Supply Industry	Borough of Reigate and Banstead
Ajinmoto Co Limited	Bradford Royal Infirmary
Alan Turner Consultancy	Bristol City Council Scientific Services
Alcontrol Food Laboratories	Britannia Health Products Limited
Alfa Chemicals	British Association of Sports & Exercise Medicine (BASEM)
Allchem International	British Bakels Limited
Allied Domecq Retailing Limited	British Beekeepers Association
Allied Technical Centre (ATC)	British Beer and Pub Association
Allsports International	British Chemical Distributors & Traders Association
Amateur Athletics Association (AAA)	British Coffee Association
American Maize – Products Company (USA)	British Dental Association
Amicus	British Diabetic Society
Anglia Bioscience Consultancy Limited	British Dietetic Association
Animal Medicines Inspectorate	British Essence Manufacturers Association
ANZFA	British Egg Industry Council
APCO Europe	British Fermentation Products
Arkarius Limited	British Glass Manufacturers Confederation
ASDA Stores Limited	British Hospitality Association (BHA)
Ashurst Morris Crisp	British Independent Grocers Association
Ashwell Associates	British Medical Association (BMA)
Association of British Paediatric Nurses	British Nutrition Foundation (BNF)
Associated British Agriculture	British Oat and Barley Millers Association
Association of the British Pharmaceutical Industry	British Olympic Association
Associate Parliamentary Food and Health Forum	British Pasta Product Association
Association for Breastfeeding Mothers	British Pharmaceutical Nutrition Group
Association of Convenience Stores	British Poultry Council
Association of Malt Product Manufactures	British Retail Consortium (BRC)
Association of Port Health Authorities	British Society of Gastroenterology
Association of Public Analysts	British Soft Drinks Association (BSDA)
Association of Radical Midwives	British Sugar PLC
Baby Milk Action Group	British Tennis Coaches Association
Babylicious Limited	British Weightlifters Association (BWLA)
Bakers Delight	Bromley Central Library
BAPEN	Burson Marsteller
Barbour Index PLC	
Beam Global Spirits and Wine	

Business in Sport and Leisure	Crookes Healthcare Limited
Buckinghamshire NHS Trust	Crop Protection Association
Cadbury Schwepps PLC	Cumbria County Council
Cambridge Manufacturing Company Limited	D&T Association
CAMedica	Dabur Research Foundation
Campden and Chorleywood Food Research Association	Dairy Council
Campbells Grocery Products Limited	Dairy Crest Group Limited
Cantox Health Sciences International	Dairy UK Limited
Cardinal Health	Danish Bacon Company PLC
Cargill Flavour Systems	Dennis T Gordon
Clover Corp	Department of Agriculture & Rural
Consensus Action on Health and Salt (CASH)	Derbyshire County Primary care Trust
Copeland Borough Council	Development for Northern Ireland
Countrelis & Associes	Department of Local Government and the Environment for the Isle of Man
Cavaghan & Gray	Derrisford Hospital
Central Laboratories	DHSS/NI
Central Lobby Consultants	Diabetes UK
Central Middlesex Hospital NHS Trust– Department of Gastroenterology and Nutrition	Dieticians in Sport and Exercise Nutrition
Chartered Institute of Environmental Health	Duckworth Group PLC
Chemistry and Industry Magazine	Durham County Council
Child Action Prevention Trust	Eclipse Scientific Group Company Limited
Christan Hansen UK Limited	EHPM Secretariat
Christchurch Borough Council	Embassy of the Federal Republic of Germany
Christian Hanson	English Institute of Sport
City of York Council	Environmental Data Services
CIVO-Institutes TNO	Essential Trading Co-operative
Clinic 5	Ethics Committees
Cocoa Cola Company	Eurofins Laboratory Limited
Coeliac Society	European Economic and Social Committee
Coeliac UK	European Federation of Health Product Manufacturers Association
Coffee Trade Federation	European Malt Product Manufacturers Association
Community foods Limited	European Specialist Sports Nutrition Alliance (ESSNA)
Community Practitioners and Health Visitors Association	F1 Data Services
Confederation of Indian Trade and Industry	Federal Office of Public Health
CONFOCO UK Limited	Federation Internationale de Football Association (FIFA)
Consumer Education and Research Centre	Federation of Danish Pig Producers and Slaughterhouses
Consumers for Health Choice	Federation of Small Businesses
Co-Operative Group (CWS) Limited	Federation of Synagogues
Contract Foods	Fitness Industry Association
Copeland Borough Council	Food Standards Australia New Zealand (FSANZ)
Cumbria County Council – Department of Trading Standards	Food and Drink Federation
Council for Responsible Nutrition	
Courage Limited	
Coutrelis & Associes	
Covington and Burling	

Food and Health Research Association	Huntingdon Life Sciences
Food Additives and Ingredients Association (FAIA)	Haemolytic Uraemic Syndrome Help (HUSH)
Food Additives Industry Association Limited	Ice Fresh Foods Limited
Food Links UK	IDFA (Infant and Dietetic Food Association)
Food Brand Group	ILS limited
Food Commission Limited	Imperial College
Food Law Group	Institute of Chemical Engineers
Food Processors Association	Institute of Child Health
Food Science Australia Library	Institute of Food Science and Technology (IFST)
Foodaware – The Consumer’s Food Group	Institute of Grocery Distribution (IGD)
Foresight	International Association for the Study of Obesity
Forum of Private Businesses	International Food Information Service
Forum Products	International Laboratory Service
Fresenius Kabi Limited	International Soft Drinks Council
FTSE Group	J Ralph Blanchfield Consultancy
Functional Foods Magazine	J Sainsbury PLC
G F Dietary Group Limited	John Russell Associates
G R Lane Health Products Limited	Johnston Consulting
Garnell Corporation	Juvela, SHS International
General Dietary Limited	Keller and Heckman
Genuine Empowerment of Mothers in Society	Kellogg Company (GB) Limited
Gin and Vodka Association of Great Britain	Kings College London
GIRACT	Kreglinger Europe
Glaxo-Smith Kline	L B Croydon Food Team
Glisten Confectionery	L Hepner & Associates Limited
Gluten Free Foods Limited	La Leche League (GB)
Government Office for the East Midlands	Laboratory of the Government Chemist (LGC)
Grace GmbH	Lactation Consultants of Great Britain (LCGB)
Grampian Country Food Group	Lancashire County Council
Harrods Limited	Law Laboratories Limited
Health Food Manufacturers Association	Law Data Limited
Health Promotion Agency	Lawrence Graham
Heather Paine Associates	Leatherhead Food International
HERBISON	Leeds Metropolitan University
Hereford and Worcester Scientific Services	Leicestershire County Analysts Laboratories
Hipp Nutrition Limited	Leicester General Hospital – Dietetic Department
Hipp – Werk Georg Hipp OHG	Life Tree Shop
H J Heinez Company Limited	LACORS
Hobbelink	London Borough of Brent
Holland and Barrett	London Borough of Ealing Council
Honeyrose Products Limited	London Chamber of Commerce
Horticultural Research International	London Fire Brigade – Croydon Training Centre
Hotel and Catering Institutional Management Association	London Fire Brigade – Harrow Training Centre
Howard Foundation Research Group - LIPOTRIM	London Fire Brigade – Shoreditch Training Centre

London Fire Brigade –Southwark Training Centre	National Heart Foundation of Australia
London International Group PLC	National Institute of Clinical Excellence
London Southbank University	National Institute of Medical Herbalists Limited
LONZA	National Pharmaceutical Association
Lovell White Durrant Solicitors	National Association of Master Bakers
Lyons Tetley Limited	Natures Own Limited
LYSI HS	NMB Consulting Limited
Macfarlanes	NCH Action for Children
Manchester Metropolitan University	Nestle Rowntree UK Limited
Marks and Spencer PLC	Nestle UK Limited
MARS Confectionery	Neville Craddock Associates
Martlet Health Food	Newcastle upon Tyne City Library
Maternity Alliance	North Herfordshire NHS Trust
Matthew Clarke Limited	Norton Rose
MCC Public Relations Limited	Novartis Medical Nutrition
McDonalds Restaurants Limited	Novartis Consumer Health UK Limited
Mead Johnson	Nutragen Limited
Meat and Livestock Commission (MLC)	Nutricia Dietary Care
Medical Research Council (MRC)	Nutritech Consultancy
Medicines and Healthcare Regulatory Agency (MHRA)	Nutrition Society
Meridian Foods – Technical Department	OFCOM
Merrydown PLC	Olympic Medical Institute
Metropolitan Police Service	OMYA UK Limited
Midwives Information and Resource Service	Optima Foods
Mills and Reeve	Orangina Group
Milupa Limited	Organix Brands Limited
MJSR Associates	PAGB
NABIM	Parliamentary Food and Health Forum
NCH Action for Children	Patients on Intravenous and Nasogastric Nutrition Therapy
National Association of Local Government Officials	Pepsico International
National Amateur Bodybuilders Association (NABBA)	Perrigo UK
National Association of Health Stores (NAHS)	Pesticide Action Network UK
National Association of British and Irish Millars	Pharmaceutical Society of Great Britain
National Association of Master Bakers, Confectioners and Caterers	Pharmacy and Prescriptions Branch
National Association of Women's Clubs	Phytopharm
National Childbirth Trust (NCT)	Pioneering Foods
National Consumer Council (NCC)	Pizza Hut UK
National Consumer Federation (NCF)	Plymouth Consumer Group
National Council of Women	Poole Trading Standards Department
National Dairy Council	Power Health Products Limited
National Family and Parenting Institute	Premier Foods Limited
National Farmers Union (NFU)	Premier Grocery Products
National Federation of Women's Institutes	Premier Training International
	Princes Foundation for Integrated Health
	Protein Factory
	Protein Technology International
	Provision Trade Federation
	Quest International
	Queens Medical Centre – Department of Gastroenterology
	Reading Scientific Services Limited

Reference and Information Library	Somerfield Stores Limited
RHM Group	Sanofi-Aventis
RHM Technology Limited	Solgar
Rhodia Consumer Specialities Limited	Sovereign Publications Limited
Rio Trading Company (Health) Limited	Sport England
Roche Diagnostics UK and Ireland Limited	St Bartholomew's and the Royal London Hospital – Department of Human Nutrition
Ross Youngs International Limited	St George's Medical Hospital School
Rotherham Health Authority	St Ivel Limited (Dairy Crest)
Royal College of Midwives	Stoke Mandeville Hospital - Dieticians Department
Royal College of Nursing	Stute Foods Limited
Royal College of Paediatric and Child Health	Sure Start Breastfeeding Project
Royal College of Physicians – Faculty of Public Health	Sure Start Centre
Royal College of Physicians – Information Centre	Surrey County Council
Royal Institute of Public Health and Hygiene	Surrey Trading Standards
Royal Free Hospital	Sustain – The Alliance for Better Food and Farming
Royal Pharmaceutical Society of Great Britain	Sustainable Development Commission
Royal Society of Health	Syngenta
Royal Society of Chemistry	Table Jellies Association
Ruddock and Sherratt	Tate and Lyle Sweeteners
Rugby Football League	Tesco Stores PLC
Rugby Football Union	The Boots Company PLC
Safepharm Laboratories Limited	The Breastfeeding Network
Salt Manufacturers Association	The British Dietetic Association
Salford Primary Care Trust	The British Egg Industry Council
Sandwell Information Service	The British Retail Consortium
Sanofi-Aventis	The Centre for Public Health Excellence, National Institute for Health and Clinical Excellence
School of Sport and Exercise Sciences SCI	The Environment Council
Scottish Breastfeeding Group	The Football Association
Scottish Executive Rural Affairs Department	The Jacobs Bakery Limited
Seale-Hayne College	The National Childbirth Trust
Seven Seas Limited	The National Food Authority
Sheffield City Libraries	The Nutrition Society
Shoosmith	The Royal College of Paediatrics and Child Health
SHS International Limited	The Royal Society for the Promotion of Health
Simkins Partnership	The Vegan Society
Simply Organic	The Vegetarian Society of the UK Limited
SiS (Science in Sport) Limited	The National Pharmacy Association
SMA Nutrition	Thompson and Capper Limited
SMH Consultancy	Townswomen's Guild
Small Business Service	Trading Standards Institute
Small Independent Brewers Association	Transport and General Workers Union
SmithKline Beecham Consumer Care Snack, Nut and Crisps Manufacturers Association	Truuuly Scrumptious Baby Food Limited
Soil Association Certification Limited	UCB Pharma Limited
Solway Foods	UK Association of Frozen Food Producers

UK Sport  
UK VLCD Industry Group  
Ultraparm Limited  
UNICEF  
UNIGATE Dairies Limited  
UNILEVER Central Resources Limited  
UNILEVER Research  
UNILEVER UK Limited  
United Biscuits (UK) Limited  
University College and Middlesex  
University of Birmingham  
University Central Lancashire  
University of Dundee  
University of Hertfordshire  
University of Leeds  
University Of Liverpool  
University of Loughborough –  
Department of Physical Education and  
Sports Science  
University of New South Wales  
University of Plymouth  
University of Reading  
University of Southampton  
University of Sussex  
University of Teeside  
Van Den Bergh Foods limited  
VEGA Research  
Vegetarian Society  
Vegan Society  
Ventress Technical Services Limited  
Veterinary Science Library  
Vinegar Brewers Federation  
Vitacare Limited  
Waitrose Limited  
Walsall Metropolitan Borough Council  
Warburtons Limited  
Weetabix Limited  
Weider Publishing Limited  
Which?  
Whitehouse Consultancy Limited  
WM Supermarkets PLC  
Worcestershire County Council  
Scientific Services  
WYETH Laboratories

## Partial Regulatory Impact Assessment

### The Food for Particular Nutritional Uses (Miscellaneous Amendments)

#### (England) Regulations 2007

(Partial 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

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 in 2007 (regulation 4),
  - 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 5),
  - 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 1<sup>st</sup> January 2010 (regulation 6).

##### Devolution

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

##### Scope of this RIA

3. The Agency has already consulted on the regulations 2, 4 and 5 of these draft Regulations (<http://www.food.gov.uk/consultations/consulteng/2007/parnutsenconsult07>). Should you wish to provide further evidence and estimated costs in relation to these Regulations please provide them in your response to this consultation. The finalised RIA will estimate 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. A separate RIA accompanies this one to cover regulation 6.

### **Background (Regulation 3)**

4. 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.
5. 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.
6. 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**

7. Regulation 3 will implement, 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**

8. 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)**

9. 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.
10. Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments are being consulted on these draft Regulations and this PRIA is part of the formal consultation.

### **Options for transposing regulation 3**

11. 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**

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

### **Costs and benefits associated with regulation 3**

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

### **Business sectors**

14. The businesses which benefit by the amending Directives, and hence the new Regulations, are food businesses producing/distributing slimming foods. According to Mintel<sup>14</sup>, 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**

15. 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

---

<sup>14</sup> insert full reference 2006 Mintel report

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**

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

***We welcome comments from charities and the voluntary sector about the impact that implementing regulation 3 may have on their work.***

### **Public sector**

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

***We welcome comments from enforcement bodies about the impact that implementing regulation 3 may have on their work.***

### **Benefits of regulation 3**

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

19. 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.

### **Costs associated with regulation 3**

20. 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.

21. 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.

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

***We welcome views from all stakeholders on the costs and benefits of the proposed Regulation.***

### **Administrative Burden on businesses affected by regulation 6**

23. 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.

***We welcome views on the administrative burdens to business of the proposed Regulation. If stakeholders consider that there would be additional administrative costs we would welcome evidence of these costs over and above those that would be incurred during the normal course of business.***

### **Small Firms Impact Test**

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

***We welcome views from any small businesses that may be affected by the proposed Regulations.***

### **Impact on the Regions of regulation 3**

25. 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.

***We welcome views from any stakeholders on any potential differential regional impact brought about by this regulation.***

### Competition assessment as related to regulation 3

26. 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.

**We would welcome views from stakeholders on how this regulation may affect competition in the manufacture or retail of slimming foods.**

### Enforcement, sanctions and monitoring as related to regulation 3

27. 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.

**We would welcome views from enforcement authorities on how this regulation may affect the enforcement of slimming foods.**

### Post-implementation review as related to regulation 3

28. 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

29. This section will be completed as part of the full RIA, after the consultation is complete.

**The Agency would welcome comments from stakeholders in any aspect of the draft Regulations, the proposed options or the draft RIA not addressed above.**

## Partial Regulatory Impact Assessment

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

(Partial Regulatory Impact Assessment for regulation 6 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

30. 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 in 2007 (regulation 4),
  - 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 5),
  - 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 1<sup>st</sup> January 2010 (regulation 6).

##### Devolution

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

##### Scope of this RIA

32. The Agency has already consulted on the regulations 2, 4 and 5 of these draft Regulations (<http://www.food.gov.uk/consultations/consulteng/2007/parnutsenconsult07>). Should you wish to provide further evidence and estimated costs in relation to

these Regulations please provide them in your response to this consultation. The finalised RIA will estimate the cost and impact of implementing regulation 6 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. A separate RIA accompanies this one to cover regulation 3.

### Background (regulation 6)

33. 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.
34. 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.
35. 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.
36. 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.
37. 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.
38. 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.

39. 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).
40. 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 6**

41. 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 1<sup>st</sup> January 2010.

### **Rationale for government intervention**

42. 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 6)**

43. 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.

44. Consumer and health professional groups, manufacturers and industry bodies, enforcement bodies, individuals and other government departments are being consulted on these draft Regulations and this PRIA is part of the formal consultation.

### **Options for transposing regulation 6**

45. 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**

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

### **Costs and benefits associated with regulation 6**

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

### **Sectors and groups affected by regulation 6**

#### **Business sectors**

48. 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**

49. 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**

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

***We welcome comments from charities and the voluntary sector about the impact that implementing regulation 6 may have on their work.***

#### **Public sector**

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

***We welcome comments from enforcement bodies about the impact that implementing regulation 6 may have on their work.***

#### **Benefits of regulation 6**

52. Option 1: failure to implement would not bring any benefits to consumers, industry, enforcement authorities or Government.
53. 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 6**

54. 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.
55. 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".
56. The environmental impact of either option is likely to be negligible.

***We welcome views from all stakeholders on the costs and benefits of the proposed Regulation.***

#### **Administrative Burden on businesses affected by regulation 6**

57. 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.

***We welcome views on the administrative burdens to business of the proposed Regulation. If stakeholders consider that there would be additional administrative costs we would welcome evidence of these costs over and above those that would be incurred during the normal course of business.***

#### **Small Firms Impact Test**

58. 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.

***We welcome views from any small businesses that may be affected by the proposed Regulations.***

#### **Impact on the Regions of regulation 6**

59. 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.

***We welcome views from any stakeholders on any potential differential regional impact brought about by this regulation.***

#### **Competition assessment as related to regulation 6**

60. 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).

**We would welcome views from stakeholders on how this Regulation may affect competition in the manufacture or retail of parnuts foods.**

#### **Enforcement, sanctions and monitoring for regulation 6**

61. 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 6**

62. 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**

63. This section will be completed as part of the full RIA, after the consultation is complete.

**The Agency would welcome comments from stakeholders in any aspect of the draft Regulations, the proposed options or the draft RIA not addressed above.**

**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 1<sup>st</sup> 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 2001/15/EC and to prohibit trade in products that do not comply with the Directive with effect from 1<sup>st</sup> 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 2001/15/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 1<sup>st</sup> 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.

<p>Declaration:</p> <p>I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.</p> <p>Signed by the responsible Minister:.....</p> <p style="text-align: right;">Date:.....</p>
--

**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](mailto:rosemary.hignett@foodstandards.gsi.gov.uk)**