

FOOD STANDARDS AGENCY CONSULTATION

Title: The Draft Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:
5 October 2009	2 November 2009

Who will this consultation be of most interest to?

Manufacturers of foods for particular nutritional use, enforcement authorities and lawyers.

What is the subject of this consultation?

Draft Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 which will provide for the execution and enforcement provisions for Commission Regulation (EC) No. xx/2009¹ on substances that may be added for specific nutritional purposes in foods for particular nutritional uses in England and will repeal the following Statutory Instruments:

- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (SI 1817)
- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2004 (SI 649);
- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2006 (SI 3116);
- Regulation 5 of the Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007 (SI 2591).

What is the purpose of this consultation?

To seek comments on the draft Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 in England. Parallel regulations are also being produced in Scotland, Wales and Northern Ireland and consultations on these will be run concurrently.

Responses to this consultation should be sent to:

Name Derek Hampson
Dietetic Foods Branch
Nutrition Division

FOOD STANDARDS AGENCY

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London WC2B 6NH

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¹ This consultation was launched before publication of the Regulation in the Official Journal of the European Communities and is based on the agreed text communicated to the European Council. The Regulation number must be inserted into the SI before it comes into force.

Is an Impact Assessment included with this consultation?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/> See Annex A for reason.
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Draft Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

DETAIL OF CONSULTATION

Introduction

European legislation

1. Commission Regulation (EC) No. xx/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses consolidates and amends current parnuts legislation allowing the addition of certain substances to parnuts foods. This Regulation repeals Directive 2001/15/EC as amended by Directives 2004/5/EC and 2006/34/EC, and also repeals Directive 2004/6/EC as amended by Directive 2007/26/EC with effect from 1 January 2010.
2. A food for a particular nutritional use (a 'parnuts') 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. 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.
4. 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 recast framework Directive 2009/39/EC.
5. Directive 2001/15/EC provides a list of substances for specific nutritional purposes that may be added to certain parnuts foods together with rules on the purity criteria applicable to those substances. Directive 2001/15/EC (as amended) limits the sources of several categories of substances that may be added to certain parnuts foods to those substances listed under each of the relevant categories in the Annex.
6. At the time of adoption of 2001/15/EC and of its amending Directives, 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, the forerunner of the European Food Safety Authority (EFSA). Thus, Commission Directive 2004/6/EC implemented a derogation which permitted their use in parnuts foods until 31st December 2006. Each substance listed in 2004/6/EC would have had to be approved by EFSA and then included in the Annex to 2001/15/EC before 31st December 2006 in order to permit its continued use in parnuts foods within the EC after that date. The

length of the derogation was extended by Directive 2007/26/EC as EFSA had not completed this list by that time. EFSA has now given favourable opinions on some of these substances and they are included in the Annex to this new Regulation.

National legislation

1. Directives 2001/15/EC, 2004/5/EC, 2004/6/EC, 2006/34/EC and 2007/26/EC were implemented into legislation in England by The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (SI 1817); The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2004 (SI 649); The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2006 (SI 3116); Regulation 5 of the Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007 (SI 2591).
2. These SIs will now be replaced by the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009.

Proposals

1. **Do nothing, i.e. fail to implement appropriate execution and enforcement provisions in England for the Commission Regulation**
2. **To introduce the appropriate provisions into law in England to allow for the execution and enforcement of national legislation enforcement of Commission Regulation (EC) No. xx/2009**

Option 2 is preferred, first as it increases the range of sources of vitamins and minerals and of other substances (notably amino acids) that may be added to foods for particular nutritional use; and second as EC regulations are binding in their entirety and are directly applicable in all Member States, and a failure to provide for the execution and enforcement of Commission Regulation (EC) No. xx/2009 could lead to possible infraction proceedings against the UK. In addition, this represents a simplification of current legislation as the provisions will be consolidated into one SI making it easier to read.

Consultation Process

1. In order to achieve a coming-into-force date of 1st January 2010 we are consulting over a four week period instead of conducting a full 12-week public consultation. The Agency has previously consulted all interested parties throughout the duration of EU negotiations on the Commission Regulation and we have received comments broadly supporting the new Regulation. On this basis we consider that a shortened consultation at this stage is appropriate and allows us to update domestic legislation according to the timetable set by the Commission, which is of benefit to all stakeholders.

In addition, we do not expect the coming-into-force date to pose a problem to manufacturers of parnuts foods as the date coincides with the expiration of the derogation.

2. All responses received as part of this consultation will be given careful consideration. These will be summarised and published on the Agency's website in due course.

Questions asked in this consultation:

Q1: Do you have any comments on the drafting of this SI? If so, please let us have them.

Q2: Do you have any comments on the draft sustainability assessment at Annex D

We welcome comments from all stakeholders. Please send your response by email or post using the contact details on page 1.

Other relevant documents

3. Council Directive 2009/39/EC on foodstuffs intended for particular nutritional uses: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:124:0021:0029:EN:PDF>

4. Commission Regulation (EC) No. xx/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses

Responses

5. **Responses are required by close 2 November 2009.** Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours faithfully,

**Derek Hampson
Dietetic Foods Branch
Nutrition Division**

Enclosed

Annex A: Standard Consultation Information

Annex B: List of interested parties

Annex C: The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009

Annex D: Draft sustainability assessment

Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at <http://www.food.gov.uk/multimedia/pdfs/dataprotection.pdf> Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.
7. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.
8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: <http://www.berr.gov.uk/files/file47158.pdf>
The Consultation Criteria are available at <http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44458.html>
9. Criterion 2 of HM Government Code of Practice on Consultation states Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

10. The purpose of an impact assessment is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, consumers and enforcement bodies. It is not expected that the proposed Regulation will impose any additional burdens or costs to manufacturers or enforcement authorities.
11. Therefore, an impact assessment has not been prepared to accompany these Regulations at this stage. However, if you consider that these Regulations will impose additional costs on businesses or the public sector, please provide evidence and estimated costs in your response to this consultation and we will consider preparing an impact assessment.
12. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 2C, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 0207 276 8630.

Comments on the consultation process itself

13. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at:
<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc>
14. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at:
<http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc> the questionnaire can also be used to update us about your existing contact details.

List of Interested Party

4CHILDREN
A.G. BARR PLC
ABBOT LABORATORIES LIMITED
ADDENBROOKES HOSPITAL
ADVERTISING ASSOCIATION
ADVERTISING STANDARDS AUTHORITY
ADVISORY CENTRE FOR EDUCATION
AGAINST THE GRAIN LTD.
AGRICULTURAL INDUSTRIES CONFEDERATION
ALCONTROL LABORATORIES
ALFA CHEMICALS
ALLCHEM INTERNATIONAL
ALLERGY UK
ALLIED BAKERIES LID
ALLSPORTS INTERNATIONAL LTD
ALPRO UK LTD
AMATEUR ATHLETICS ASSOCIATION
AMERICAN MAIZE-PRODUCTS COMPANY (USA)
AMICUS
ANAPHYLAXIS CAMPAIGN UK
ANIMAL MEDICINES INSPECTORATE
ANIMAL PHARMACY
APCO EUROPE
ASDA STORES LIMITED
ASHWELL ASSOCIATES
ASSICURAZIONE QUALITÀ
ASSOCIATION FOR BREASTFEEDING MOTHERS
ASSOCIATION OF CEREAL FOOD MANUFACTURERS
ASSOCIATION OF CONVENIENCE STORES
ASSOCIATION OF FROZEN FOOD PRODUCERS & ICE CREAM FEDERATION
ASSOCIATION OF PORT HEALTH AUTHORITIES (APHA)
ASSOCIATION OF PUBLIC ANALYSTS
ASSOCIATION OF RADICAL MIDWIVES
AVILTON FOODS LTD
BABY MILK ACTION
BABYLICIOUS LIMITED
BAPEN OFFICE
BARBOUR INDEX PLC
BARRY ATWOOD
BERNARD MATTHEWS FARMS LTD
BERRY OTTAWAYAND ASSOCIATES LIMITED
BIO BAMBINI
BIRD & BIRD
BODYCOTE LAW LABS
BOND PEARCE LLP
BOOKER LTD
BOOTH SMITH
BOOTS UK LIMITED
BOWMAN INGREDIENTS
BPEX AND EBLEX

BRADFORD ROYAL INFIRMARY
BRAKES GROUP
BREASTFEEDING NETWORK
BRITANNIA HEALTH PRODUCTS LTD
BRITISH ASSOCIATION OF SPORTS & EXERCISE MEDICINE (BASEM)
BRITISH BAKERS LTD
BRITISH BEEKEEPER'S ASSOCIATION
BRITISH BEER AND PUB ASSOCIATION
BRITISH COFFEE ASSOCIATION
BRITISH DENTAL ASSOCIATION
BRITISH DIETETIC ASSOCIATION
BRITISH EGG INDUSTRY COUNCIL
BRITISH FERMENTATION PRODUCTS
BRITISH HOSPITALITY ASSOCIATION
BRITISH INDEPENDENT GROCERS ASSOCIATION
BRITISH MEDICAL ASSOCIATION
BRITISH NUTRITION FOUNDATION
BRITISH OLYMPIC ASSOCIATION
BRITISH POULTRY COUNCIL
BRITISH RETAIL CONSORTIUM
BRITISH SOCIETY OF GASTROENTEROLOGY
BRITISH SOFT DRINKS ASSOCIATION LTD
BRITISH SUGAR PLC
BRITISH WEIGHTLIFTERS ASSOCIATION (BWLA)
BROMLEY CENTRAL LIBRARY
BRUNEL HEALTHCARE MANUFACTURING LTD
BUCKINGHAMSHIRE NHS TRUST
BUSINESS IN SPORT AND LEISURE
CAMBRIDGE MANUFACTURING COMPANY LTD
CAMEDICA
CAMPDEN BRI
CANTOX HEALTH SCIENCES INTERNATIONAL
CARGILL FLAVOR SYSTEMS/DUCKWORTH GROUP
CATALENT PHARMA SOLUTIONS
CAVAGHAN & GRAY
CENTRAL LOBBY CONSULTANTS LTD
CENTRE FOR PUBLIC HEALTH EXCELLENCE, NATIONAL INSTITUTE FOR
HEALTH AND CLINICAL EXCELLENCE
CHARTERED INSTITUTE OF ENVIRONMENTAL HEALTH
CHEMICAL BUSINESS ASSOCIATION
CHEMISTRY & INDUSTRY MAGAZINE
CHRISTIAN HANSEN UK LTD
CHRISTCHURCH
CHRISTIAN HANSON
CIVO-INSTITUTES TNO
CLEARSPRING LTD
COCA-COLA GREAT BRITAIN & IRELAND
COELIAC UK
COMMUNITY FOODS LTD
COMMUNITY NUTRITION GROUP
COMMUNITY PRACTITIONERS AND HEALTH VISITORS ASSOCIATION
CONFEDERATION OF INDIAN FOOD TRADE AND INDUSTRY
CONFOCO INTERNATIONAL LIMITED
CONSENSUS ACTION ON SALT & HEALTH

CONSTELLATION EUROPE (HOLDINGS) LTD
CONSUMER EDUCATION & RESEARCH CENTRE
CONSUMER FOCUS
CONSUMERS FOR HEALTH CHOICE
CONTRACT FOOD LTD
COUNCIL FOR RESPONSIBLE NUTRITION
COUNTRYSIDE ALLIANCE
COUTRELIS & ASSOCIES
COVINGTON & BURLING
CROP PROTECTION ASSOCIATION
CULLINANE ASSOCIATES LTD
CUMBRIA COUNTY COUNCIL
D & T ASSOCIATION
D F ANSTEAD LTD
DABUR RESEARCH FOUNDATION
DAILYCER LTD
DAIRY COUNCIL
DAIRY CREST GROUP PLC
DAIRY UK LTD
DBC FOODSERVICE
DELICIOUS ALCHEMY
DEPARTMENT FOR AGRICULTURE AND RURAL DEVELOPMENT
DEPARTMENT FOR BUSINESS, ENTERPRISE AND REGULATORY REFORM
DEPARTMENT FOR CULTURE, MEDIA AND SPORT
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS
DEPARTMENT OF GASTROENTEROLOGY & NUTRITION
DEPARTMENT OF HEALTH
DEPARTMENT OF TRADING STANDARDS
DEPT OF AGRICULTURE & RURAL DEVELOPMENT FOR NORTHE
DEPT OF PHYSICAL EDUCATION, SPORTS SCIENCE
DERRISFORD HOSPITAL
DIABETES UK
DIAGNOSTIC INNOVATIONS LTD
DIETETIC DEPT
DIETITIANS IN SPORT & EXERCISE NUTRITION
DOVES FARM FOODS LTD
DROSSA
DURHAM COUNTY COUNCIL
EALING COUNCIL
EAST & NORTH EAST HERTFORDSHIRE PTC
EAST AND NORTH HERTS. NHS TRUST
ECLIPSE SCIENTIFIC GROUP
ENGLISH GRAINS LTD
ENGLISH INSTITUTE OF SPORT
ENVIRONMENTAL DATA SERVICES
ESSENTIAL TRADING CO-OPERATIVE LTD
ETHICS COMMITTEE'S
EURODIET DISTRIBUTION AND WHOLESALE LIMITED
EUROPEAN FEDERATION OF HEALTH PRODUCT MANUFACTURERS
ASSOCIATION
EUROPEAN SNACKS ASSOCIATION / SNACMA
EUROPEAN SPECIALIST SPORTS NUTRITION ALLIANCE
F I DATA SERVICES
FACULTY OF PUBLIC HEALTH

FEDERATION INTERNATIONALE DE FOOTBALL ASSOCIATION (FIFA)
FEDERATION OF DANISH PIG PRODUCERS & SLAUGHTERHOUSES
FEDERATION OF SYNAGOGUES
FITNESS INDUSTRY ASSOCIATION
FOCUS ON FOOD
FOOD ADDITIVES AND INGREDIENTS ASSOCIATION
FOOD AND DRINK FEDERATION
FOOD BRAND GROUP
FOOD COMMISSION UK LTD
FOOD SCIENCE AUSTRALIA
FOOD STANDARDS AUSTRALIA NEW ZEALAND
FOODCHAIN EUROPE LTD
FOODLINKS LIMITED
FOOTBALL ASSOCIATION
FORESIGHT
FORUM OF PRIVATE BUSINESS
FORUM PRODUCTS LIMITED
FRENSENIUS KABI LTD
FSA NORTHERN IRELAND
FTSE
G F DIETARY GROUP LTD
G R LANE HEALTH PRODUCTS LTD
GADSBY'S BAKERY
GALACTOSAEMIA SUPPORT GROUP
GARNELL CORPORATION LTD
GASTROENTEROLOGY UNIT
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GOVERNMENT OFFICE FOR THE EAST MIDLANDS
GRACE EUROPE HOLDING GMBH
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HARTWELL FOOD RESEARCH LTD
HEALTH FOOD MANUFACTURERS' ASSOCIATION
HEALTH PROMOTION AGENCY
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HIPP NUTRITION UK LIMITED
HIPP UK LIMITED
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HUNTINGDON LIFE SCIENCES
HUSH (HAEMOLYTIC URAEMIC SYNDROME HELP)
ICEFRESH FOODS LIMITED
ILS LTD
IMPERIAL COLLEGE
INFANT AND DIETETIC FOODS ASSOCIATION

INNOVATION ADVERTISING
INSTITUTE OF CHEMICAL ENGINEERS
INSTITUTE OF CHILD HEALTH
INSTITUTE OF FOOD SCIENCE & TECHNOLOGY (IFST)
INSTITUTE OF HOSPITALITY
INTERNATIONAL FOOD INFORMATION SERVICE
INTERNATIONAL SOFT DRINK COUNCIL
INTERNATIONAL SWEETENERS ASSOCIATION
ISS MEDICLEAN LIMITED
J RALPH BLANCHFIELD CONSULTANCY
J SAINSBURY PLC
JOHNSTON CONSULTING
KELLER & HECKMAN LLP
KELLOGG EUROPE TRADING LIMITED
KING'S COLLEGE LONDON
KREGLINGER EUROPE
L HEPNER & ASSOCIATES LTD
LA LECHE LEAGUE (GREAT BRITAIN)
LABORATORY OF THE GOVERNMENT CHEMIST (LGC)
LACTATION CONSULTANTS OF GREAT BRITAIN (LCGB)
LANCASHIRE COUNTY COUNCIL
LAWDATA LTD
LEATHERHEAD FOOD INTERNATIONAL
LEEDS METROPOLITAN UNIVERSITY
LEGOLAND WINDSOR PARK LTD
LEICESTERSHIRE COUNTY COUNCIL
LGC (TEDDINGTON) LTD
LGC LIMITED
LIFE TREE SHOP
LINCOLN CO-OP CHEMIST LTD
LIVWELL LTD
LOCAL AUTHORITIES CO-ORDINATORS OF REGULATORY SERVICES
LONDON BOROUGH OF BRENT (ENVIRONMENTAL HEALTH)
LONDON CHAMBER OF COMMERCE AND INDUSTRY
LONDON FIRE BRIGADE - CROYDON TRAINING CENTRE
LONDON FIRE BRIGADE - HARROW TRAINING CENTRE
LONDON FIRE BRIGADE - SHOREDITCH TRAINING CENTRE
LONDON FIRE BRIGADE - SOUTHWARK TRAINING CENTRE
LONDON FOOD CENTRE
LONDON METROPOLITAN UNIVERSITY
LOVELL WHITE DURRANT SOLICITORS
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LYSI HS
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MCCAMBRIDGE GROUP
MCDONALD'S RESTAURANTS LTD
MEAD JOHNSON NUTRITIONALS
MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY
MERIDIAN FOODS - TECHNICAL DEPARTMENT
METROPOLITAN POLICE SERVICE
MIDWIVES INFORMATION AND RESOURCE SERVICE

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MITCHELLS & BUTLERS PLC
MJSR ASSOCIATES
MOILAS OY
MORELANDS LTD/MH FOODS LTD
MRC HUMAN NUTRITION RESEARCH
MYGOODNESS LTD
NAIRN'S OATCAKES LIMITED
NAT ASSOC OF LOCAL GOVT OFFICIALS
NATIONAL AMATEUR BODYBUILDERS ASSOCIATION (NABBA)
NATIONAL ASSOCIATION OF BRITISH AND IRISH MILLERS
NATIONAL ASSOCIATION OF HEALTH STORES
NATIONAL ASSOCIATION OF MASTER BAKERS
NATIONAL ASSOCIATION OF WOMEN'S CLUBS
NATIONAL CHILDBIRTH TRUST
NATIONAL CONSUMER FEDERATION
NATIONAL COUNCIL OF WOMEN OF GREAT BRITAIN
NATIONAL FAMILY & PARENTING INSTITUTE
NATIONAL FARMERS UNION (NFU)
NATIONAL FEDERATION OF WOMEN'S INSTITUTES
NATIONAL HEART FOUNDATION OF AUSTRALIA
NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE
NATIONAL INSTITUTE OF MEDICAL HERBALISTS
NATIONAL PHARMACY ASSOCIATION
NATIONAL WOMEN'S REGISTER
NATURALLY GOOD FOOD LTD
NATURE'S OWN LIMITED
NCH ACTION FOR CHILDREN
NESTLE CONFECTIONERY (UK)
NEVILLE CRADDOCK ASSOCIATES
NEWCASTLE UPON TYNE CITY LIBRARY
NEWHAM COMMUNITY COLLEGE
NHS PURCHASING AND SUPPLY AGENCY
NMB CONSULTING
NORTON ROSE
NOVARTIS CONSUMER HEALTH UK LTD
NUTRAGEN LTD
NUTRICIA CLINICAL CARE
NUTRILICIOUS
NUTRITECH CONSULTANCY LTD
NUTRITIONAL HEALTHCARE R & D
OFFICE OF COMMUNICATIONS
OLYMPIC MEDICAL INSTITUTE
ORANGINA GROUP
ORGANIX BRANDS
OXFORDSHIRE COUNTY COUNCIL
PATIENTS ON INTRAVENOUS & NASOGASTRIC NUTRITION THERAPY
PEPSICO UK
PERRIGO UK
PESTICIDE ACTION NETWORK UK
PHARMACEUTICAL SOCIETY OF GB
PIONEERING FOODS
PIZZA HUT (UK) LIMITED
PORTER FOODS CO. LTD

POWER HEALTH PRODUCTS LTD
PREMIER FOODS PLC
PREMIER GROCERY PRODUCTS LTD
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PROFESSIONAL, MANAGERIAL AND HEALTHCARE PUBLICATIO
PROPRIETARY ASSOCIATION OF GREAT BRITAIN
PROTEIN TECHNOLOGY INTERNATIONAL
PROVISION TRADE FEDERATION
QUEENSWOOD NATURAL FOODS LTD
QVIST FOOD SCIENCE CONSULTING
RASPBERRY CREEK FOODS
READING SCIENTIFIC SERVICES LTD
REGULATORY SOLUTIONS
RIO TRADING COMPANY (HEALTH) LTD
ROTHERHAM NHS FOUNDATION TRUST
ROYAL COLLEGE OF MIDWIVES
ROYAL COLLEGE OF NURSING
ROYAL COLLEGE OF PAEDIATRICS AND CHILD HEALTH
ROYAL COLLEGE OF PHYSICIANS
ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN
ROYAL SOCIETY FOR THE PROMOTION OF HEALTH
ROYAL SOCIETY OF HEALTH
RUGBY FOOTBALL UNION
SALT ASSOCIATION
SCHOOL FOOD TRUST
SCHOOL OF SPORT & EXERCISE SCIENCES
SCI - WHERE SCIENCE MEETS BUSINESS
SCOTTISH GOVERNMENT RURAL DIRECTORATE, ANIMAL HEALTH
SEVEN SEAS LTD
SHEFFIELD CITY COUNCIL
SHOOSMITH & HARRISON SOLICITORS
SHS INTERNATIONAL LIMITED
SIMKINS PARTNERSHIP
SIMPLY ORGANIC - SERIOUS FOOD COMPANY
SIS (SCIENCE IN SPORT) LTD
SMA NUTRITION
SMALL INDEPENDENT BREWERS ASSOCIATION
SMH CONSULTANCY
SNACK, NUT & CRISPS MANUFACTURERS ASSOCIATION
SOLGAR
SOLWAY FOODS
SOMERFIELD STORES LIMITED
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SOUTHBANK UNIVERSITY
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SURE START BREASTFEEDING PROJECT
SURE START CENTRE
SURREY TRADING STANDARDS
SUSTAIN: THE ALLIANCE FOR BETTER FOOD AND FARMING
TABLE JELLIES ASSOCIATION

TATE & LYLE PLC
TEPNEL BIOSYSTEMS LTD
TESCO STORES PLC
THE BRITISH MEDICAL ASSOCIATION
THE CO-OPERATIVE GROUP
THE FOOD COMMISSION
THE NUTRITION SOCIETY
THE RAYNE INSTITUTE
THE VEGAN SOCIETY
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THOMPSON & CAPPER LTD
TNO QUALITY OF LIFE
TOXICOLOGY ADVICE AND CONSULTING
TRANSPORT AND GENERAL WORKERS' UNION
UCB PHARMA LIMITED
UGO FOODS GROUP LTD
UK SPORTS
UK VLCD INDUSTRY GROUP
ULTRAPHARM LTD
UNICEF
UNIGREG LIMITED
UNILEVER PLC
UNITED BISCUITS (UK) LTD
UNIVERSITY COLLEGE & MIDDLESEX
UNIVERSITY GLYNDWR
UNIVERSITY OF BIRMINGHAM
UNIVERSITY OF LEEDS
UNIVERSITY OF NEW SOUTH WALES
UNIVERSITY OF PLYMOUTH
UNIVERSITY OF READING
UNIVERSITY OF SOUTHAMPTON
UNIVERSITY OF SUSSEX
VEGAN SOCIETY
VEGETARIAN ECONOMY AND GREEN AGRICULTURE
VEGETARIAN SOCIETY OF THE UNITED KINGDOM
VETERINARY SCIENCE LIBRARY
VILLAGE BAKERY MELMERBY
VINEGAR BREWERS' FEDERATION
VITACARE LIMITED
VITAFLO INTERNATIONAL LIMITED
W.A. TURNER LIMITED
WAITROSE LIMITED
WALSALL METROPOLITAN BOROUGH COUNCIL
WARBURTONS LTD
WEBER SHANDWICK
WEETABIX LIMITED
WEIDER PUBLISHING LTD
WELLFOODS LTD
WELSH ASSEMBLY GOVERNMENT
WHICH?
WHITEHOUSE CONSULTANCY LTD
WM MORRISON SUPERMARKETS PLC
WYETH CONSUMER HEALTHCARE
YOUNG'S SEAFOOD LIMITED

2009 No.

FOOD, ENGLAND

**The Food for Particular Nutritional Uses (Addition of
Substances for Specific Nutritional Purposes) (England)
Regulations 2009**

<i>Made</i>	- - - -	2009
<i>Laid before Parliament</i>		2009
<i>Coming into force</i>	- -	1 January 2010

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(1)(e), 17(2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972(c) and it appears to the Secretary of State that it is expedient for any reference to the Annex to Commission Regulation (EC) No. []/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses(d) to be construed as a reference to that Annex as amended from time to time.

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(e) there

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- (a) 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.
- (b) 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. Functions of “the Ministers”, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (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.
- (c) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).
- (d) OJ No. L[].
- (e) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty of Council

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 (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009, apply in relation to England only and come into force on 1 January 2010.

Interpretation

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“the Commission Regulation” means Commission Regulation (EC) No. []/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

“food authority” has the meaning that it bears by virtue of section 5(1) of the Act, except that it does not include the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and Middle Temple); and

“specified provision” means any provision of the Commission Regulation that is specified in Column 1 of the Schedule and whose subject-matter is described in Column 2 of the Schedule.

(2) Subject to paragraph (3), any expression other than one defined in paragraph (1) that is used both in these Regulations and in the Act has the meaning it bears in the Act.

(3) Notwithstanding paragraph (2), any expression used both in these Regulations and in the Commission Regulation has the meaning that it bears in the Commission Regulation.

(4) Where any functions under the Act are assigned—

(a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(a), to a port health authority;

(b) by an order under section 6 of the Public Health Act 1936(b), to a joint board for a united district; or

(c) by an order under paragraph 15(6) of Schedule 8 to the Local Government Act 1985(c), to a single authority for a metropolitan county,

any reference in these Regulations to a food authority shall be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

(5) In these Regulations any reference to the Annex to the Commission Regulation is a reference to that Annex as amended from time to time.

Offences, penalties and execution and enforcement

3.—(1) Any person who contravenes any of the specified provisions shall be guilty of an offence.

(2) A person guilty of an offence under paragraph (1) shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

(3) Each food authority shall execute and enforce these Regulations within its area.

Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

(a) 1984 c.22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990.

(b) 1936 c.49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

(c) 1985 c.51; paragraph 15(6) was amended by paragraph 31(b) of Schedule 3 to the Food Safety Act 1990.

Application of various sections of the Food Safety Act 1990

4. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence)(a), as it applies for the purpose of section 14 or 15;
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 33(1) (obstruction etc. of officers);
- (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences)(b), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2) and (3)(c), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships)(d); and
- (k) section 44 (protection of officers acting in good faith).

Amendment to the Tryptophan in Food (England) Regulations 2005

5.—(1) The Tryptophan in Food (England) Regulations 2005(e) are amended in accordance with the following paragraphs.

(2) In paragraph (1) of regulation 2 (interpretation), for the definition “Directive 2001/15/EC” there is substituted the following definition—

““Regulation [] /2009” means Commission Regulation (EC) No. []/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;”.

(3) In regulation 5 (exceptions from prohibitions), for sub-paragraph (c) of paragraph (2) there is substituted the following sub-paragraph—

“(c) laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride, added in compliance with Regulation []/2009 to any food for a particular nutritional use referred to in the Annex to that Regulation;”.

Revocation

6. The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002(f) are revoked.

Signed by authority of the Secretary of State for Health

(a) Section 21 was amended by S.I. 2004/3279.
(b) Section 35(1) is amended by the Criminal Justice Act 2003 (2003 c. 44), Schedule 26, paragraph 42, from a date to be appointed.
(c) Section 35(3) was amended by S.I. 2004/3279.
(d) Section 36A was inserted by the Food Standards Act 1999 (1999 c.28), Schedule 5, paragraph 16.
(e) S.I. 2005/2630.
(f) S.I. 2002/1817.

Date

Minister of State,
Department of Health

THE SCHEDULE

Regulations 2(1) and 3(1)

Specified Provisions of the Commission Regulation

<i>Provision of the Commission Regulation</i>	<i>Subject-matter</i>
Article 2(1)	Requirement that among the substances belonging to the categories appearing in the Annex to the Commission Regulation, only those listed in that Annex, complying with the relevant specifications as necessary may be added for specific nutritional purposes in the manufacture of foodstuffs for particular nutritional uses covered by Directive 2009/39 of the European Parliament and the Council on foodstuffs intended for particular nutritional uses(a).
Article 3(1)	Requirement that the use of substances added for specific nutritional purposes shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended, as established by generally accepted scientific data.
Article 3(2)	Requirement that upon request by the Food Standards Agency, the manufacturer or, where appropriate, the importer shall produce the scientific work and the data establishing that the use of the substances complies with Article 3(1) of the Commission Regulation. If such work and data are contained in a readily available publication, a mere reference to that publication shall suffice.
Article 4(2)	Requirement that purity criteria established by Community legislation which apply to the substances listed in the Annex to the Commission Regulation when they are used in the manufacture of foodstuffs for purposes other than those covered by the Commission Regulation shall also apply to those substances when they are used for purposes covered by the Commission Regulation.
Article 4(3)	Requirement that for substances listed in the Annex to the Commission Regulation for which purity criteria are not established by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

(a) OJ No. L124, 20.5.2009, p.21.

Sustainable development

A preliminary sustainability assessment has been carried out in relation to introducing the execution and enforcement provisions for Commission Regulation (EC) No. XX/2009 in England and to repeal the following SIs:

- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (SI 1817);
- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2004 (SI 649);
- The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) (Amendment) Regulations 2006 (SI 3116);
- Regulation 5 of The Food for Particular Nutritional Uses (Miscellaneous Amendments) (England) Regulations 2007 (SI 649).

Implementing these provisions does not create any new economic or social costs. The new regime will bring more legal certainty for manufacturers, consumers and enforcement authorities as the list of substances permitted is a positive list rather than some substances being listed on a time-limited derogation list. In addition, this represents a simplification of current legislation as the provisions will be consolidated into one SI making it easier to read. Based on information obtained during informal consultation on this Regulation, there are no cost implications for the industry and no labelling changes will be required as a result of the new Regulation so there will not be any significant amounts of wasted products, packaging or labelling. It is unlikely that there will be any considerable implications for greenhouse gas emissions or negative impacts on natural resources.

Not implementing these new provisions may create legal uncertainty as the EC Regulation and the UK law would not be synchronised. This could lead to new economic and social costs due to possible reformulation and/or relabelling and have implications for trade across the EU. This may also be more costly for enforcement authorities as the law will be unclear. In addition, this may bring economic disadvantages to the Government which may be subject to infraction proceedings for not implementing appropriate enforcement sanctions related to the Regulation.

Given that the negative economic, social and legal impacts of not implementing these provisions are outweighed by the benefits of implementation, we conclude that introducing the execution and enforcement provisions for Commission Regulation (EC) No. xx/2009 is the more sustainable option.

The Agency would welcome comments on this sustainability assessment.