STATUTORY INSTRUMENTS

2002 No. 1817

FOOD, ENGLAND

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

Made - - - - 14th July 2002

Laid before Parliament 15th July 2002

Coming into force in accordance with regulation 1(2) and (3)

The Secretary of State, in exercise of the powers conferred by sections 16(1)(f), 17(1), 26(3) and 48(1) of the Food Safety Act 1990(**1**) and now vested in him(**2**), having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council(**3**) 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 and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Title, extent and commencement

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 and extend to England only.

(2) Regulations 1, 5 and 10, and regulations 2 and 6 to 9 in so far as they relate to regulation 5, come into force on 5th August 2002.

(**1**) 1990 c. 16.

(**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 paragraphs 7 and 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), and paragraphs 12 and 21 of that Schedule amend respectively sections 17(1) and 48 of the 1990 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 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. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the Food Safety Act 1990.

(**3**) OJ No. L31, 1.2.2002, p.1.

(3) The remainder of these Regulations comes into force—

(a) on 5th August 2002 in relation to an L-tryptophan food; and

(b) in any other case on 1st April 2004.

Interpretation

2.—(1) In these Regulations—

"the Act" means the Food Safety Act 1990;

"designated PNU food" means any PNU food other than infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children;

"Directive 89/398" means Council Directive 89/398/EEC(**4**) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive 1999/41/EC of the European Parliament and of the Council(**5**);

"Directive 2001/15" means Commission Directive 2001/15/EC(**6**) (as corrected(**7**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

"food authority" does not include—

(a) the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change, or

(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple);

"L-tryptophan food" means any designated PNU food being a food to which L-tryptophan, or any of its sodium, potassium, calcium or magnesium salts or its hydrochloride, has been added for a specific nutritional purpose;

"PNU food" means a food for a particular nutritional use which—

(a) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and

(b) is sold in such a way as to indicate its suitability for its claimed particular nutritional purpose;

"particular nutritional use" means the fulfilment of the particular nutritional requirements of—

(a) certain categories of persons whose digestive processes are, or whose metabolism is, disturbed, or

(b) certain categories of person whose physiological condition renders them able to obtain a special benefit from the controlled consumption of any substance in food, or

(c) infants or young children in good health; and

"sell" includes possess for sale and offer, expose or advertise for sale.

(2) Other expressions used both in these Regulations and in Directive 89/398 or 2001/15 have the same meaning in these Regulations as they have in the Directive concerned.

(**4**) OJ No. L186, 30.6.89, p.27.
(**5**) OJ No. L172, 8.7.1999, p.38.
(**6**) OJ No. L52, 22.2.2001, p.19.
(**7**) OJ No. L253, 21.9.2001, p.34.

Restrictions on sale

3.—(1) No person shall sell any designated PNU food being a food to which a substance falling within one of the categories mentioned in paragraph (2) has been added for a specific nutritional purpose unless that substance—

(a) is listed under that category—

(i) in the case of any food for special medical purposes, in Schedule 1 or 2; and

(ii) in any other case, in Schedule 1; and

(b) complies with the relevant purity criteria referred to in paragraph (3).

(2) For the purposes of paragraph (1), the categories are—

(a) vitamins,

(b) minerals,

(c) amino acids,

(d) carnitine and taurine,

(e) nucleotides, and

(f) choline and inositol.

(3) The relevant purity criteria for the purposes of paragraph (1)(b) are—

(a) the purity criteria, if any, specified by Community legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2001/15, or

(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

(4) No person shall sell any designated PNU food in the manufacture of which any substance has been used for a specific nutritional purpose unless that food—

(a) is safe when used in accordance with the manufacturer's instructions (if any); and

(b) fulfils the particular nutritional requirements of the persons for whom it is intended,

as established by generally accepted scientific data.

Verification of regulation 3(4)

4. The manufacturer or, as the case may be, the importer of a designated PNU food in the manufacture of which a substance has been used for a specific nutritional purpose shall supply to the Food Standards Agency on request—

(a) a copy of the scientific work and data establishing that the use of that substance in the manufacture of that food results in a food which meets the criteria in regulation 3(4), or

(b) if such work and data are contained in a publication which is readily available, a reference to that publication.

Notification requirement

5.—(1) Subject to paragraph (2), the manufacturer or, where appropriate, the importer of any notifiable food shall not sell any such food unless at least 3 months before placing food of that particular type on the market in England for the first time he notified the Food Standards Agency in writing by forwarding to it a model of the label to be used for that food and details of the composition of the food.

(2) Paragraph (1) shall not apply if the manufacturer or, where appropriate, the importer has already notified the Food Standards Agency before placing food of that particular type on the market

elsewhere in the United Kingdom for the first time in accordance with an equivalent provision having effect there.

(3) In this regulation "notifiable food" means any L-tryptophan food which is—

(a) intended for use in energy-restricted diets for weight reduction;

(b) intended to meet the expenditure of intense muscular effort, especially for sportsmen; or

(c) for persons suffering from carbohydrate-metabolism disorders (diabetes).

Enforcement

6. Each food authority shall enforce and execute these Regulations in its area.

Offences and penalties

7. If any person—

(a) contravenes regulation 3(1) or (4), or

(b) without reasonable excuse contravenes regulation 4 or 5(1),

he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence in relation to exports

8. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that the food in respect of which the offence is alleged to have been committed was intended for export to a country (other than a member State) which has legislation analogous to these Regulations and that the food complies with that legislation.

Application of various provisions of the Act

9. 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 2 (extended meaning of "sale" etc.);

(b) section 3 (presumptions that food is intended for human consumption);

(c) section 20 (offences due to fault of another person);

(d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;

(e) section 22 (defence of publication in the course of business);

(f) section 30(8) (which relates to documentary evidence);

(g) section 33(1) (obstruction etc. of officers);

(h) 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 paragraph (g) above;

(i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g) above;

(j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h) above;

(k) section 36 (offences by bodies corporate); and

(l) section 44 (protection of officers acting in good faith).

Amendment of the Tryptophan in Food Regulations 1990

10.—(1) The Tryptophan in Food Regulations 1990(**8**) shall be amended (in so far as they extend to England) in accordance with paragraph (2).

(2) In regulation 2 (prohibition on sale, etc. of food containing tryptophan)—

(a) in paragraphs (1) and (2) for the words "Subject to paragraph (4)" there shall be substituted the words "Subject to paragraphs (4) and (4A)";

(b) in paragraph (3) there shall be inserted at the beginning the words "Subject to paragraph (4A) of this regulation,";

(c) after paragraph (4) there shall be inserted the following paragraph—

"(4A) Paragraphs (1) to (3) of this regulation shall not apply in respect of—

(a) laevorotatory tryptophan added to any infant formula or follow-on formula;

(b) laevorotatory tryptophan added to any processed cereal-based food or baby food; or

(c) laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride, added to any designated PNU food for a specific nutritional purpose in compliance with Commission Directive 2001/15/EC(**9**) (as corrected(**10**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.";

(d) in paragraph (7)—

(i) after the definition of "appropriate medical certificate" there shall be inserted the following definition—

""designated PNU food" has the meaning assigned to it by the Food for Particular Nutritional Uses (Addition of Substances for Particular Nutritional Purposes) (England) Regulations 2002;";

(ii) after the definition of "hospital" the word "and" shall be omitted and there shall be inserted the following definitions—

""infant formula" and "follow-on formula" have the meaning assigned to them by the Infant Formula and Follow-on Formula Regulations 1995(**11**);

"processed cereal-based food" and "baby food" have the meaning assigned to them by the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997(**12**); and".

Signed by authority of the Secretary of State for Health

Hazel Blears
Parliamentary Under Secretary of State,
Department of Health

14th July 2002

(**8**) S.I. 1990/1728, to which there is an amendment not relevant to these Regulations.
(**9**) OJ No. L52, 22.2.2001, p.19.
(**10**) OJ No. L253, 21.9.2001, p.34.
(**11**) S.I. 1995/77, to which there are amendments not relevant to these Regulations.
(**12**) S.I. 1997/2042, to which there are amendments not relevant to these Regulations.

SCHEDULE 1

Regulation 3(1)(a)

SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN DESIGNATED PNU FOODS

Category 1. Vitamins

VITAMIN A:	
—	retinol
—	retinyl acetate
—	retinyl palmitate
—	beta-carotene
VITAMIN D:	
—	cholecalciferol
—	ergocalciferol
VITAMIN E:	
—	D-alpha-tocopherol
—	DL-alpha-tocopherol
—	D-alpha-tocopheryl acetate
—	DL-alpha-tocopheryl acetate
—	D-alpha-tocopheryl acid succinate
VITAMIN K:	
—	phylloquinone (phytomenadione)
VITAMIN B1:	
—	thiamin hydrochloride
—	thiamin mononitrate
VITAMIN B2:	
—	riboflavin
—	riboflavin 5'-phosphate, sodium
NIACIN:	
—	nicotinic acid
—	nicotinamide
PANTOTHENIC ACID:	
—	D-pantothenate, calcium
—	D-pantothenate, sodium
—	dexpanthenol
VITAMIN B6:	

—	pyridoxine hydrochloride
—	pyridoxine 5'-phosphate
—	pyridoxine dipalmitate
FOLIC ACID:	
—	pteroylmonoglutamic acid
VITAMIN B12:	
—	cyanocobalamin
—	hydroxocobalamin
BIOTIN:	
—	D-biotin
VITAMIN C:	
—	L-ascorbic acid
—	sodium-L-ascorbate
—	calcium-L-ascorbate
—	potassium-L-ascorbate
—	L-ascorbyl 6–palmitate

Category 2. Minerals

CALCIUM:	
—	carbonate
—	chloride
—	salts of citric acid
—	gluconate
—	glycerophosphate
—	lactate
—	salts of orthophosphoric acid
—	hydroxide
—	oxide
MAGNESIUM:	
—	acetate
—	carbonate
—	chloride
—	salts of citric acid
—	gluconate
—	glycerophosphate

—	salts of orthophosphoric acid
—	lactate
—	hydroxide
—	oxide
—	sulphate
IRON:	
—	ferrous carbonate
—	ferrous citrate
—	ferric ammonium citrate
—	ferrous gluconate
—	ferrous fumarate
—	ferric sodium diphosphate
—	ferrous lactate
—	ferrous sulphate
—	ferric diphosphate (ferric pyrophosphate)
—	ferric saccharate
—	elemental iron (carbonyl + electrolytic + hydrogen reduced)
COPPER:	
—	cupric carbonate
—	cupric citrate
—	cupric gluconate
—	cupric sulphate
—	copper lysine complex
IODINE:	
—	potassium iodide
—	potassium iodate
—	sodium iodide
—	sodium iodate
ZINC:	
—	acetate
—	chloride
—	citrate
—	gluconate
—	lactate

—	oxide
—	carbonate
—	sulphate
MANGANESE:	
—	carbonate
—	chloride
—	citrate
—	gluconate
—	glycerophosphate
—	sulphate
SODIUM:	
—	bicarbonate
—	carbonate
—	chloride
—	citrate
—	gluconate
—	lactate
—	hydroxide
—	salts of orthophosphoric acid
POTASSIUM:	
—	bicarbonate
—	carbonate
—	chloride
—	citrate
—	gluconate
—	glycerophosphate
—	lactate
—	hydroxide
—	salts of orthophosphoric acid
SELENIUM:	
—	sodium selenate
—	sodium hydrogen selentine
—	sodium selenite
CHROMIUM (III) and their hexahydrates:	
—	chloride

—	sulphate
MOLYBDENUM (VI):	
—	ammonium molybdate
—	sodium molybdate
FLUORINE:	
—	potassium fluoride
—	sodium fluoride

Category 3. Amino acids

—	L-alanine
—	L-arginine
—	L-cysteine
—	Cystine
—	L-histidine
—	L-glutamic acid
—	L-glutamine
—	L-isoleucine
—	L-leucine
—	L-lysine
—	L-lysine acetate
—	L-methionine
—	L-ornithine
—	L-phenylalanine
—	L-threonine
—	L-tryptophan
—	L-tyrosine
—	L-valine

For amino acids, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used

Category 4. Carnitine and taurine

—	L-carnitine
—	L-carnitine hydrochloride
—	taurine

Category 5. Nucleotides

—	adenosine 5'-phosphoric acid (AMP)
—	sodium salts of AMP
—	cytidine 5'-monophosphoric acid (CMP)
—	sodium salts of CMP
—	guanosine 5'-phosphoric acid (GMP)
—	sodium salts of GMP
—	insosine 5'-phosphoric acid (IMP)
—	sodium salts of IMP
—	uridine 5'-phosphoric acid (UMP)
—	sodium salts of UMP

Category 6. Choline and inositol

—	choline
—	choline chloride
—	choline bitartrate
—	choline citrate
—	inositol

SCHEDULE 2

Regulation 3(1)(a)

ADDITIONAL SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN FOODS FOR SPECIAL MEDICAL PURPOSES

Category 3. Amino acids

—	L-aspartic acid
—	L-citrulline
—	glycine
—	L-proline

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

2. These Regulations concern food for most particular nutritional uses (definition of "designated PNU food" in regulation 2(1) which excludes infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children) where there has been added to that food for a specific nutritional purpose a substance falling within one of the following categories: vitamins; minerals; amino acids; carnitine and taurine; nucleotides; choline and inositol. The Regulations prohibit the sale of such food 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)).

3. The Regulations also impose general restrictions on the sale of 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). The Regulations 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).

4. The Regulations 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).

5. The Regulations also 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).

6. A regulatory impact assessment has been prepared and placed in the Library of each House of Parliament together with a Transposition Note setting out how the main elements of Directive 2001/15/EC are transposed in these Regulations. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.