

2002 No. 397

FOOD

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

Made 30th August 2002

Laid before the Scottish Parliament 2nd September 2002

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

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(1)(a) and (f), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(a) and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(b) of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B)(c) of that Act, hereby make the following Regulations:

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002.

(2) This regulation and regulations 4(1) and (2) and 9, and regulations 2 and 5 to 8 in so far as they relate to regulation 4(1) and (2), shall come into force on 23rd September 2002.

(3) The remainder of these Regulations shall come into force—

- (a) on 23rd September 2002 in relation to L-tryptophan food; and
- (b) on 1st April 2004 in any other case.

(4) These Regulations extend to Scotland only.

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;

(a) 1990 c.16; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c.40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c.28) (“the 1999 Act”), Schedule 5, paragraph 10(3); sections 16(1) and 48(1) were amended by the 1999 Act, Schedule 5, paragraph 8; section 17(1) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, Schedule 6; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.

(b) Section 48 (4A) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

(c) Section 48(4B) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

“Directive 89/398” means Council Directive 89/398/EEC^(a) 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^(b);

“Directive 2001/15” means Commission Directive 2001/15/EC^(c) (as corrected^(d)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

“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;

“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);

“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 persons whose special 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.

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 European 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.

(a) O.J. No. L 186, 30.6.89, p.27.

(b) O.J. No. L 172, 8.7.99, p.38.

(c) O.J. No. L 52, 22.2.01, p.19.

(d) O.J. No. L 253, 21.9.01, p.34.

(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.—(1) In the case of any notifiable food, the manufacturer or, where appropriate, the importer of that food–

- (a) shall at least 3 months before placing food of that particular type on the market in Scotland for the first time notify the Food Standards Agency in writing by forwarding to it–
 - (i) a model of the label to be used for that food;
 - (ii) details of the composition of that food; and
 - (iii) 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 if such work and data are contained in a publication which is readily available, a reference to that publication; and
- (b) subject to paragraph (2), shall not sell such notifiable food unless notification has been given in accordance with sub-paragraph (a).

(2) In relation to any notifiable food of a particular type which has been placed on the market for the first time in England, Wales or Northern Ireland, notification in accordance with any provision in legislation having effect in England, Wales or Northern Ireland corresponding to paragraph (1)(a) shall be treated for the purposes of paragraph (1)(b) as if it were notification in accordance with paragraph (1)(a).

(3) In the case of a designated PNU food which is not a notifiable food, 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.

Enforcement

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

Offences and penalties

6. If any person–

- (a) contravenes regulation 3(1) or (4); or
- (b) without reasonable excuse contravenes regulation 4(1) or (3),

that person 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

7. 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

8. The following provisions of the Act shall apply for the purposes of these Regulations and any reference in those provisions to the Act or Part thereof shall be construed for the purposes of these Regulations 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 of the Act;
- (e) section 22 (defence of publication in the course of business);
- (f) section 30(8) (which relates to documentary evidence);
- (g) section 33 (obstruction etc. of officers);
- (h) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (g);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships); and
- (k) section 44 (protection of officers acting in good faith).

Amendment of the Tryptophan in Food (Scotland) Regulations 1990

9.—(1) The Tryptophan in Food (Scotland) Regulations 1990(a) shall be amended in accordance with paragraph (2).

- (2) In regulation 2 (interpretation)—
 - (a) 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) (Scotland) Regulations 2002;”;
 - (b) after the definition of “hospital”, there shall be inserted the following definition:—

““infant formula” and “follow on formula” have the meaning assigned to them the Infant Formula and Follow On Formula Regulations 1995(b);”;
 - (c) after the definition of “hospital”, the word “and” shall be omitted; and
 - (d) after the definition of “pharmacist”, there shall be inserted the following definition:—

“processed cereal-based food” and “baby food” have the meaning assigned to them by Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997(c); and”.
- (3) In regulation 3 (prohibition on sale, etc. of food containing tryptophan)—
 - (a) in paragraphs (1) and (2) for “Subject to paragraph (4)” there shall be substituted “Subject to paragraphs (4) and (4A)”;
 - (b) in paragraph (3) there shall be inserted at the beginning “Subject to paragraph (4A) of this regulation,”; and
 - (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

(a) S.I. 1990/1972, to which there are amendments not relevant to these Regulations.

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

(c) S.I. 1997/2042, to which there are amendments not relevant to these Regulations.

(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^(a) (as corrected^(b)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.”.

MARY MULLIGAN

Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
30th August 2002

^(a) O.J. No. L 52, 22.2.01, p.19.
^(b) O.J. No. L 253, 21.9.01, p.34.

SCHEDULE 1

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 selenite
- 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
- inosine 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

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)

These Regulations, which extend to Scotland only, implement Commission Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.

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)).

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 unless such food is safe and fulfils the particular nutritional requirements of the persons for whom it is intended (regulation 3(4)). The regulations require prior notification of the placing on the market for the first time of certain designated PNU foods to which L-tryptophan has been added for a specific nutritional purpose (notifiable food is defined in regulation 2(1)), and prohibit the sale of such foods where the notification requirement has not been met (regulation 4(1)) in order to enable the Food Standards Agency to verify that the requirements of regulation 3(4) are met. The Regulations also require the manufacturer or importer in the case of all other designated PNU foods to supply the Food Standards Agency with information if the Agency so requests to verify that those requirements of regulation 3(4) are met (regulation 4(3)).

The Regulations make provision as to responsibilities for enforcement (regulation 5); create offences and penalties (regulation 6) and apply certain provisions of the Food Safety Act 1990 (regulation 8). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (O.J. No. L 186, 30.6.89, p.23) on the official control of foodstuffs (regulation 7).

The Regulations also disapply the prohibitions in the Tryptophan in Food (Scotland) Regulations 1990 in so far as they conflict with Directive 2001/15/EC, Article 5 of Commission Directive 91/321/EEC (O.J. No. L 175, 4.7.91, p.35) on infant formulae and follow-on formulae and Article 5 of Commission Directive 96/5/EC (O.J. No. L 49, 28.2.96, p.17) on processed cereal-based foods and baby foods for infants and young children.

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effect which these Regulations would have on business costs has been prepared and has been placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.

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