

---

WELSH STATUTORY INSTRUMENTS

---

**2002 No. 2939 (W.280)**

**FOOD, WALES**

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

*Made - - - - 27th November 2002  
Coming into force in accordance with regulation 1(2)  
and (3)*

In exercise of the powers conferred by sections 16(1)(f), 17(1), 26(3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup> and now vested in the National Assembly for Wales<sup>(2)</sup>, the National Assembly 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<sup>(3)</sup> 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:

**Citation, application and commencement**

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 and extend to Wales 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 31 December 2002.

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

- (a) on 31 December 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” (“*y Ddeddf*”) means the Food Safety Act 1990;

---

(1) 1990 c. 16.

(2) Functions of the Secretary of State under the Food Safety Act 1990, 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).

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

“designated PNU food” (“*bwyd DMN dynodedig*”) 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” (“*Cyfarwyddeb 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” (“*Cyfarwyddeb 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;

“L - tryptophan food” (“*bwyd L-tryptoffan*”) 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” (“*bwyd DMN*”) 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” (“*defnydd maethol neilltuol*”) 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 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” (“*gwerthu*”) 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,

(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.

- (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 Wales for the first time the manufacturer or, where appropriate, the importer 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” (“*bwyd hysbysadwy*”) 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),

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**

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 Wales) 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,”;

---

(8) S.I. 1990/1728, to which there is an amendment not relevant to these Regulations.

- (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](#)<sup>(9)</sup> (as corrected<sup>(10)</sup>) 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) (Wales) 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<sup>(11)</sup>;

“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<sup>(12)</sup>; and”.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998<sup>(13)</sup>

27th November 2002

*D. Elis-Thomas*  
The Presiding Officer of the National Assembly

---

(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.

(13) [1998 c. 38](#).

**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

**Status:** This is the original version (as it was originally made).

- 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

*Status: This is the original version (as it was originally made).*

- 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

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 Wales 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 Wales) 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).

**Status:** *This is the original version (as it was originally made).*

**6.** A Regulatory appraisal for these Regulations has been prepared pursuant to section 65 of the Government of Wales Act 1998 and placed in the Library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff CF10 1EN.