
WELSH STATUTORY INSTRUMENTS

2004 No. 1012 (W.109)

FOOD, WALES

**The Food for Particular Nutritional Uses
(Addition of Substances for Specific Nutritional
Purposes) (Wales) (Amendment) Regulations 2004**

Made - - - - *31st March 2004*
Coming into force - - *1st April 2004*

The National Assembly for Wales, 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 it(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, commencement and interpretation

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) (Amendment) Regulations 2004.

(2) These Regulations come into force on 1st April 2004.

(3) In these Regulations “the principal Regulations” means the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002(4).

Amendment of the principal Regulations

2. The principal Regulations shall be amended in accordance with regulations 3 to 7.

3. In regulation 2(1) (interpretation), in the definition of “Directive 2001/15” there shall be inserted at the end the words “, as amended by Commission Directive 2004/5/EC(5) and as read

(1) 1990 c. 16.

(2) Functions of the Secretary of State 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.

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

(4) S.I. 2002/2939 (W 280).

(5) OJ No. L14, 21.1.2004, p.19.

with Commission Directive [2004/6/EC](#)(6) derogating from Directive [2001/15/EC](#) to postpone the application of the prohibition of trade to certain products”.

4. In regulation 3 (restrictions on sale) —

(a) for paragraph (1) there shall be substituted the following paragraph —

“(1) Subject to paragraph (5), 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 —

(a) that substance 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;

(b) that substance complies with the relevant purity criteria referred to in paragraph (3); and

(c) in the case of a substance listed in Schedule 2, the conditions of use (if any) set out in that Schedule relating to that substance are met.”; and

(b) there shall be inserted at the end the following paragraph —

“(5) The restrictions in paragraph (1) shall not apply until 1st January 2007 in the case of a substance falling within one of the categories mentioned in paragraph (2) and listed under that category in Schedule 3 if —

(a) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance in the manufacture of any designated PNU food; and

(b) that substance was used in the manufacture of a food for a particular nutritional use which was on sale in the European Community on 11th February 2004.”.

5. In Schedule 1 (substances which may be added for specific nutritional purposes in designated PNU foods) —

(a) there shall be inserted in Category 2 (Minerals) under the heading “CALCIUM” after the entry “— oxide”, the entry “— sulphate”; and

(b) there shall be inserted in Category 4 (Carnitine and taurine) after the entry “L-carnitine hydrochloride” the entry “L-carnitine-L-tartrate”.

6. For Schedule 2 (additional substances which may be added for specific nutritional purposes in foods for special medical purposes) there shall be substituted the contents of Schedule 1 to these Regulations.

7. After Schedule 2 there shall be inserted as Schedule 3 the contents of Schedule 2 to these Regulations.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(7).

31st March 2004

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

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

SCHEDULE 1

Regulation 6

REVISED SCHEDULE 2 TO BE SUBSTITUTED IN THE PRINCIPAL REGULATIONS

“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

<i>Substance</i>	<i>Conditions of use</i>
L-arginine-L-aspartate	
L-aspartic acid	
L-citrulline	
Glycine	
L-lysine-L-aspartate	
L-lysine-L-glutamate	
L-proline	
L-serine	
N-acetyl-L-cysteine	
N-acetyl-L-methionine	Shall not be used except in foods intended for persons over 1 year of age.

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

SCHEDULE 2

Regulation 7

NEW SCHEDULE 3 TO BE INSERTED IN THE PRINCIPAL REGULATIONS

“SCHEDULE 3

Regulation 3(5)

SUBSTANCES WHICH MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN DESIGNATED PNU FOODS IN ACCORDANCE WITH THE DEROGATION IN REGULATION 3(5)

Category 1. Vitamins

VITAMIN E:

- D-alpha tocopheryl polyethylene glycol 1000 succinate

Category 2. Minerals

BORON:

— boric acid

— sodium borate

CALCIUM:

— amino acid chelate

— pidolate

MAGNESIUM:

— amino acid chelate

— pidolate

IRON:

— ferrous hydroxide

— ferrous pidolate

— amino acid chelate

COPPER:

— amino acid chelate

ZINC:

— amino acid chelate

MANGANESE:

— amino acid chelate

SELENIUM:

— enriched yeast

CHROMIUM:

— amino acid chelate”

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in Wales, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2002 (“the principal Regulations”).

2. These Regulations implement —

- (a) Commission Directive [2004/5/EC](#) (OJ No. L.14, 21.1.2004, p.19) amending Directive [2001/15/EC](#) to include certain substances in the Annex; and
- (b) Commission Directive [2004/6/EC](#) (OJ No. L.15, 22.1.2004, p.31) derogating from Directive [2001/15/EC](#) to postpone the application of the prohibition of trade to certain products.

3. The principal Regulations apply to food for most particular nutritional uses (definition of “designated PNU foods” in regulation 2(1) of those Regulations). Where there has been added to

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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, those Regulations prohibit (in most cases from 1st April 2004) 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, Schedule 1 or 2.

4. These Regulations —

- (a) allow until 1st January 2007, subject to conditions, the sale of designated PNU foods to which there has been added a substance listed in new Schedule 3 to the principal Regulations (regulations 4(b) and 7 and Schedule 2);
- (b) add another substance to the list of substances in the category minerals and in the category carnitine and taurine which may be added for specific nutritional purposes in designated PNU foods (regulation 5);
- (c) add six substances to the list of substances in the category amino acids which may be added for specific nutritional purposes in foods for specific medical purposes (regulation 6 and Schedule 1); impose a condition of use in the case of one of these substances (regulation 4(a) and Schedule 1); and in implementation of the Annex to Directive [2001/15/EC](#) (OJ No. L52, 22.2.2001, p.19) provide that for amino acids also the sodium, potassium, calcium and magnesium salts, as well as their hydrochlorides may be used (Schedule 1);
- (d) update the definition of “Directive 2001/15” (regulation 3).

5. A regulatory appraisal pursuant to section 65 of the Government of Wales Act 1998 has been prepared and placed in the Library of the National Assembly for Wales together with a Transposition Note setting out how the main elements of Directives [2004/5/EC](#) and [2004/6/EC](#) are transposed in these Regulations. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Cardiff, CF10 1EW.