
STATUTORY INSTRUMENTS

2004 No. 649

FOOD, ENGLAND

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

<i>Made</i>	- - - -	<i>8th March 2004</i>
<i>Laid before Parliament</i>		<i>9th March 2004</i>
<i>Coming into force</i>	- -	<i>31st March 2004</i>

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, commencement and interpretation

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

(2) These Regulations come into force on 31st March 2004.

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

(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 paragraph 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.

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

(4) S.I. 2002/1817.

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 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-arnitine—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.

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

(6) OJ No. L15, 22.1.2004, p.31.

Signed by authority of the Secretary of State for Health

8th March 2004

Melanie Johnson
Parliamentary Under Secretary of State,
Department of Health

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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 relation to England, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 (“the principal Regulations”).
2. These Regulations implement —
 - (a) Commission Directive [2004/5/EC](#) (OJ No. L14, 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. L15, 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 that food for a specific nutritional purpose a substance falling within one of the following categories:

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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 full regulatory impact assessment of the effect that these Regulations will have on the costs of business 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 Directives [2004/5/EC](#) and [2004/6/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.