
STATUTORY INSTRUMENTS

2006 No. 3116

FOOD, ENGLAND

The Food for Particular Nutritional Uses (Addition
of Substances for Specific Nutritional Purposes)
(England) (Amendment) Regulations 2006

<i>Made</i>	- - - -	<i>20th November 2006</i>
<i>Laid before Parliament</i>		<i>28th November 2006</i>
<i>Coming into force</i>	- -	<i>31st December 2006</i>

The Secretary of State makes the following Regulations 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 her(2). She has had regard to relevant advice given by the Food Standards Agency as required by section 48(4A) of that Act.

There has been open and transparent public consultation during the preparation of the Regulations as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(3).

Title, commencement, application 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 2006.
- (2) These Regulations come into force on 31st December 2006.
- (3) These Regulations apply in relation to England only.

(1) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; section 53(2) was amended by Schedule 6 to the Food Standards Act 1999 (1999 c.28) and S.I. 2004/2990.

(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 and paragraphs 12 and 21 of that Schedule amend respectively sections 17(1) and 48 of the 1990 Act. Section 48 was also amended by S.I. 2004/2990. 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. That Regulation was last amended by Regulation (EC) No. 575/2006 (OJ No. L100, 8.4.2006, p.3).

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

Amendment of the principal Regulations

2. The principal Regulations are amended in accordance with regulations 3 to 5.
3. In regulation 2(1) (interpretation), in the definition of “Directive 2001/15”, after “Directive 2004/5/EC” insert “and Commission Directive 2006/34/EC(5)”.
4. In Schedule 1 (substances which may be added for specific nutritional purposes in designated PNU foods)—
 - (a) in the Section concerning Category 1 (vitamins), for the heading “FOLIC ACID” substitute “FOLATE”, and under that (revised) heading insert at the end “— calcium-L-methylfolate”;
 - (b) in the Section concerning Category 2 (minerals), under the heading “IRON” insert at the end “— ferrous bisglycinate”.
5. In Schedule 2 (additional substances which may be added for specific nutritional purposes in foods for special medical purposes) insert at the beginning—

“**Category 2. Minerals**
magnesium L-aspartate”.

Amendment of the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002.

6.—(1) In so far as they apply in relation to England, the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002(6) are amended as specified in paragraph (2).

(2) In regulation 6 (application of various provisions of the Food Safety Act 1990) omit the words “, unless the context otherwise requires,”.

Signed by authority of the Secretary of State

20th November 2006

Caroline Flint
Minister of State,
Department of Health

(4) S.I. 2002/1817, amended by S.I. 2004/649; there are other amending instruments but none is relevant.
(5) OJ No. L83, 22.3.2006, p.14.
(6) S.I. 2002/333.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England only, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2002 as amended (“the principal Regulations”).

2. These Regulations implement Commission Directive [2006/34/EC](#) (OJ No. L83, 22.3.2006, p.14) amending the Annex to Directive [2001/15/EC](#) as regards the inclusion of certain substances.

3. The principal Regulations apply to food for most particular nutritional uses (definition of “designated PNU food” in regulation 2(1) of those Regulations). Those Regulations restrict the sale of such food where there has been added to it for a specific nutritional purpose a substance falling within one of the following six categories: vitamins; minerals; amino acids; carnitine and taurine; nucleotides; choline and inositol. In such a case the substance must be listed under the relevant category in Schedule 1 or, as regards foods for special medical purposes, Schedule 1 or 2. There is a time-limited derogation as respects substances listed in Schedule 3 (regulation 3(5) of those Regulations).

4. These Regulations—

- (a) add certain substances to the list in the categories vitamins and minerals which may be added for specific nutritional purposes in designated PNU foods (without any time limit) (regulation 4);
- (b) add a substance in the category minerals to the list of substances which may be added for specific nutritional purposes in foods for special medical purposes (without any time limit) (regulation 5);
- (c) update the definition of “Directive 2001/15” (regulation 3).

5. These Regulations also amend the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 in so far as they apply in relation to England to remove unnecessary wording from regulation 6 of those Regulations (regulation 6).

6. 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 Directive [2006/34/EC](#) are transposed in these Regulations. Copies may be obtained from the Nutrition Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.