

2004 No. 105

FOOD

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Amendment) Regulations (Northern Ireland) 2004

Made - - - - - *11th March 2004*

Coming into operation *1st April 2004*

The Department of Health, Social Services and Public Safety^(a) in exercise of the powers conferred on it by Articles 15(1)(f), 16(1), 25(3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991^(b) and of all other powers enabling it in that behalf, having had regard in accordance with Article 47(3A) of the said Order 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^(c) 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 Article 47(3) and (3B) of the said Order, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Amendment) Regulations (Northern Ireland) 2004 and shall come into operation on 1st April 2004.

(2) In these Regulations “the principal Regulations” means the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2002^(d).

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, “as amended by Commission Directive 2004/5/EC^(e) and as read with Commission Directive 2004/6/EC^(f) 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) in paragraph (1) there shall be inserted at the beginning “Subject to paragraph (5),”;

(a) Formerly the Department of Health and Social Services; *see* S.I. 1999/283 (N.I. 1), Article 3
(b) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12) and paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c. 28
(c) O.J. No. L31, 1.2.2002, p. 1
(d) S.R. 2002 No. 264
(e) O.J. No. L14, 21.1.2004, p. 19
(f) O.J. No. L15, 22.1.2004, p. 31

- (b) in paragraph (2), for “paragraph (1)” there shall be substituted “this regulation”; and
- (c) 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.

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

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 11th March 2004.

(L.S.)

Deirdre Kenny

A senior officer of the Department of Health, Social Services and Public Safety

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.)

These Regulations, which amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2002 (“the principal Regulations”), implement –

- (a) Commission Directive 2004/5/EC (O.J. 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 (O.J. 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.

The principal Regulations apply to food for most particular nutritional uses (*see* the 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: 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.

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 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 (O.J. 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).

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