SCOTTISH STATUTORY INSTRUMENTS

2004 No. 90

FOOD

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

Made - - - -	*8th March 2004*
Laid before the Scottish Parliament	*9th March 2004*
Coming into force - -	*31st March 2004*

The Scottish Ministers, in exercise of the powers conferred by sections 16(1)(a) and (f), 17(1), 26(3) and 48(1) of the Food Safety Act 1990(**a**), and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)(**b**) of that Act to relevant advice given by the Food Standards Agency and after consultation in accordance with section 48(4) and (4B)(**c**) of that Act, hereby make the following Regulations:

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Amendment Regulations 2004 and shall come into force on 31st March 2004.

(2) These Regulations extend to Scotland only.

(3) In these Regulations "the principal Regulations" means the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002(**d**).

Amendment of the principal Regulations

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

3. In regulation 2(1) (interpretation), in the definition of "Directive 2001/15" insert 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".

(**a**) 1990 c.16; sections 16(1) and 48(1) were amended by the Food Standards Act 1999 (c.28) ("the 1999 Act"), Schedule 5, paragraph 8; section 17(1) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, Schedule 6; amendments made by Schedule 5 of the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) ("the 1998 Act") by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act.
(**b**) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
(**c**) Section 48(4B) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
(**d**) S.S.I. 2002/397.
(**e**) O.J. No. L 14, 21.1.04, p.19.
(**f**) O.J. No. L 15, 22.1.04, p.31.

4. In regulation 3 (restrictions on sale)–

(a) for paragraph (1) substitute–

"(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.";

(b) in paragraph (2) for "paragraph (1)" substitute "this regulation"; and

(c) at the end insert–

"(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) in Category 2 (Minerals) under the heading "CALCIUM", after "- oxide" insert "- sulphate"; and

(b) in Category 4 (Carnitine and taurine) after "L-carnitine hydrochloride" insert "L-carnitine-L-tartrate".

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

7. After Schedule 2 insert as Schedule 3 the content of Schedule 2 to these Regulations.

TOM McCABE
Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
8th March 2004

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

Substance	*Conditions of use*
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 extend to Scotland only, amend the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Scotland) Regulations 2002 ("the principal Regulations").

These Regulations implement–

(a) Commission Directive 2004/5/EC (O.J. No. L 14, 21.1.04, p.19) amending Directive 2001/15/EC to include certain substances in the Annex; and

(b) Commission Directive 2004/6/EC (O.J. No. L 15, 22.1.04, 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 ("designated PNU foods"). Such foods are defined in regulation 2(1) of the principal Regulations but do not include infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children. Where there has been added to a designated PNU food a substance falling within one of the following categories: vitamins; minerals; amino acids; carnitine and taurine; nucleotides; choline and inositol for a specific nutritional purpose, the principal 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(c) and 7 and Schedule 2);

(b) add another substance to the list of substances 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);

(d) in implementation of the Annex to Directive 2001/15/EC (O.J. No. L 52, 22.2.01, p.19) provide that for amino acids also the sodium, potassium, calcium and magnesium salts, as well as their hydrochlorides may be used (regulation 6 and Schedule 1); and

(e) update the definition of "Directive 2001/15" (regulation 3).

A Regulatory Impact Assessment which includes a compliance cost assessment of the effect which these Regulations would have on business costs has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.

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