SCOTTISH STATUTORY INSTRUMENTS

2003 No. 278

FOOD

The Food Supplements (Scotland) Regulations 2003

Made - - - -	*5th June 2003*
Laid before the Scottish Parliament - - - -	*5th June 2003*
Coming into force - -	*1st August 2005*

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 [M1], and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A) [M2] of that Act to relevant advice given by the Food Standards Agency, and after consultation in accordance with section 48(4) and (4B) [M3] of that Act, hereby make the following Regulations:

Marginal Citations

M1 1990 c. 16; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), **Schedule 9**, paragraph 6 and by the Food Standards Act 1999 (c. 28) ("the 1999 Act"), Schedule 5, paragraph 10(3); sections 16(1) and 48(1) were amended by 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 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c. 46) 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 Scotland Act 1998.

M2 Section 48(4A) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

M3 Section 48(4B) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21.

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Food Supplements (Scotland) Regulations 2003 and shall come into force on 1st August 2005.

(2) These Regulations shall extend to Scotland only.

Interpretation

2.—(1) In these Regulations–

"the Act" means the Food Safety Act 1990;

"catering establishment" means a restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer and is ready for consumption without further preparation;

"Directive 2002/46" means Directive 2002/46/EC of the European Parliament and of the Council [M4] on the approximation of the laws of the Member States relating to food supplements;

"dose form" means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;

"food supplement" means any food the purpose of which is to supplement the normal diet and which–

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form;

"preparation" includes manufacture and any form of processing or treatment and "prepared" shall be construed accordingly;

"sell" includes possess for sale and offer, expose or advertise for sale, and "sold" shall be construed accordingly; and

"ultimate consumer" means any person who purchases otherwise than–

(a) for the purpose of resale;

(b) for the purposes of a catering establishment; or

(c) for the purposes of a manufacturing business.

(2) A food supplement shall be regarded as prepacked for the purposes of these Regulations if–

(a) it is ready for sale to the ultimate consumer or to a catering establishment; and

(b) it is put into packaging before being offered for sale in such a way that the food supplement cannot be altered without opening or changing the packaging.

(3) Other expressions used both in these Regulations and in Directive 2002/46 have the same meaning in these Regulations as they have in that Directive.

Marginal Citations

M4 O.J. No. L 183, 12.7.02, p.51.

Scope of Regulations

3.—(1) These Regulations apply to food supplements sold as food and presented as such.

(2) These Regulations do not apply to medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [M5].

Marginal Citations

M5 O.J. No. L 311, 28.11.01, p.67.

Restriction on form in which food supplements are sold to the ultimate consumer

4. No person shall sell any food supplement to the ultimate consumer unless it is prepacked.

Prohibitions on sale relating to composition of food supplements

5.—(1) Subject to paragraph (3), no person shall sell a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral–

(a) is listed in column 1 of Schedule 1; and

(b) is in a form which–

(i) is listed in Schedule 2; and

(ii) meets the relevant purity criteria.

(2) The relevant purity criteria for the purposes of paragraph (1)(b)(ii) are–

(a) the purity criteria, if any, specified by Community legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2002/46; or

(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

(3) In the case of a vitamin or mineral which is not listed in column 1 of Schedule 1 or is not in a form listed in Schedule 2, the prohibitions in paragraph (1) shall not apply until 1st January 2010 if–

(a) the substance in question was used in the manufacture of a food supplement which was on sale in the European Community on 12th July 2002;

(b) a dossier supporting use of the substance in question was submitted to the European Commission by the Food Standards Agency or a member State other than the United Kingdom by 12th July 2005; and

(c) the European Food Safety Authority has not given an unfavourable opinion in respect of the use of that substance, or its use in that form in the manufacture of food supplements.

Restrictions on sale relating to labelling etc of food supplements

6.—(1) No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement".

(2) Without prejudice to the Food Labelling Regulations 1996 [M6], no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars–

(a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

(b) the portion of the product recommended for daily consumption;

(c) a warning not to exceed the stated recommended daily dose;

(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

(e) a statement to the effect that the product should be stored out of the reach of young children; and

(f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

(3) The information required by paragraph (2)(f) shall–

(a) be given in numerical form;

(b) in the case of a vitamin or mineral listed in column 1 of Schedule 1, be given using the relevant unit specified in column 2 of that Schedule;

(c) be the amount per portion of the product as recommended for daily consumption on the labelling of the product;

(d) be an average amount based on the manufacturer's analysis of the product; and

(e) in the case of a vitamin or mineral listed in the Annex to Council Directive 90/496/EEC on nutrition labelling for foodstuffs [M7], be expressed also as a percentage (which may also be given in graphical form) of the relevant recommended daily allowance specified in that Annex.

(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the labelling, presentation or advertising of that food supplement includes any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

Marginal Citations

M6 S.I. 1996/1499.

M7 O.J. No. L 276, 06.10.90, p.40.

Manner of marking or labelling

7.—(1) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or is ready for delivery to a catering establishment and is prepacked, unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) appear–

(a) on the packaging;

(b) on a label attached to the packaging; or

(c) on a label which is clearly visible through the packaging:

Provided that where the sale is otherwise than to the ultimate consumer such particulars may, alternatively, appear only on the commercial documents relating to the food supplement where it can be guaranteed that such documents, containing all such particulars, either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement, and provided that the particulars required by regulation 5(a), (c) and (e) of the Food Labelling Regulations 1996 are also marked or labelled on the outermost packaging in which that food supplement is sold.

(2) No person shall sell any food supplement which is ready for delivery to a catering establishment and is not prepacked, unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) appear–

(a) on a label attached to the food supplement;

(b) on a ticket or notice which is readily discernible by the intending purchaser at the place where the purchaser chooses the food supplement; or

(c) in commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.

(3) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) are easy to understand, clearly legible and indelible and, when a food

is sold to the ultimate consumer, those particulars are marked in a conspicuous place in such a way as to be easily visible.

(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) are in any way hidden, obscured or interrupted by any other written or pictorial matter.

Enforcement

8. Each food authority shall enforce and execute these Regulations in its area.

Offences and penalties

9. If any person contravenes regulation 4, 5, 6 or 7 that person shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence in relation to exports

10. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove–

(a) that the food in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that the food complies with that legislation; and

(b) in the case of export to a member State, that the legislation complies with the provisions of Directive 2002/46.

Application of various provisions of the Act

11. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations–

(a) section 2 (extended meaning of "sale" etc.);

(b) section 3 (presumptions that food is intended for human consumption);

(c) section 20 (offences due to fault of another person);

(d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;

(e) section 22 (defence of publication in the course of business);

(f) section 30(8) (which relates to documentary evidence);

(g) section 33 (obstruction etc. of officers);

(h) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) or (2) as applied by paragraph (g) above;

(i) section 36 (offences by bodies corporate);

(j) section 36A (offences by Scottish partnerships); and

(k) section 44 (protection of officers acting in good faith).

St Andrew's House, Edinburgh
5th June 2003

TOM McCABE
Authorised to sign by the Scottish Ministers

SCHEDULE 1

Regulations 5(1) and (3) and 6(3)(b)

VITAMINS AND MINERALS WHICH MAY BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

Column 1 ***Vitamins and minerals***	***Column 2*** ***Unit***
1. Vitamins	
Vitamin A	µg RE
Vitamin D	µg
Vitamin E	mg α–TE
Vitamin K	µg
Vitamin B1	mg
Vitamin B2	mg
Niacin	mg NE
Pantothenic acid	mg
Vitamin B6	mg
Folic acid	µg
Vitamin B12	µg
Biotin	µg
Vitamin C	mg
2. Minerals	
Calcium	mg
Magnesium	mg
Iron	mg
Copper	µg
Iodine	µg
Zinc	mg
Manganese	mg
Sodium	mg
Potassium	mg
Selenium	µg
Chromium	µg
Molybdenum	µg
Fluoride	mg
Chloride	mg
Phosphorus	mg

SCHEDULE 2

Regulation 5(1) and (3)

FORM OF VITAMIN AND MINERAL SUBSTANCES WHICH MAY BE USED IN THE MANUFACTURE OF FOOD SUPPLEMENTS

A. Vitamins

1. VITAMIN A
- (a) retinol
- (b) retinyl acetate
- (c) retinyl palmitate
- (d) beta–carotene

2. VITAMIN D
- (a) cholecalciferol
- (b) ergocalciferol

3. VITAMIN E
- (a) D–alpha–tocopherol
- (b) DL–alpha–tocopherol
- (c) D–alpha–tocopheryl acetate
- (d) DL–alpha–tocopheryl acetate
- (e) D–alpha–tocopheryl acid succinate

4. VITAMIN K
- (a) phylloquinone (phytomenadione)

5. VITAMIN B1
- (a) thiamin hydrochloride
- (b) thiamin mononitrate

6. VITAMIN B2
- (a) riboflavin
- (b) riboflavin 5'–phosphate, sodium

7. NIACIN
- (a) nicotinic acid
- (b) nicotinamide

8. PANTOTHENIC ACID
- (a) D–pantothenate, calcium
- (b) D–pantothenate, sodium
- (c) dexpanthenol

9. VITAMIN B6
- (a) pyridoxine hydrochloride
- (b) pyridoxine 5'–phosphate

10. FOLIC ACID

(a) pteroylmonoglutamic acid

11. VITAMIN B12

(a) cyanocobalamin

(b) hydroxocobalamin

12. BIOTIN

(a) D–biotin

13. VITAMIN C

(a) L–ascorbic acid

(b) sodium–L–ascorbate

(c) calcium–L–ascorbate

(d) potassium–L–ascorbate

(e) L–ascorbyl 6–palmitate

B. Minerals

Calcium carbonate

Calcium chloride

Calcium salts of citric acid

Calcium gluconate

Calcium glycerophosphate

Calcium lactate

Calcium salts of orthophosphoric acid

Calcium hydroxide

Calcium oxide

Magnesium acetate

Magnesium carbonate

Magnesium chloride

Magnesium salts of citric acid

Magnesium gluconate

Magnesium glycerophosphate

Magnesium salts of orthophosphoric acid

Magnesium lactate

Magnesium hydroxide

Magnesium oxide

Magnesium sulphate

Ferrous carbonate

Ferrous citrate

Ferric ammonium citrate

Ferrous gluconate

Ferrous fumarate

Ferric sodium diphosphate

Ferrous lactate

Ferrous sulphate

Ferric diphosphate (ferric pyrophosphate)

Ferric saccharate

Elemental iron (carbonyl+electrolytic+hydrogen reduced)

Cupric carbonate

Cupric citrate

Cupric gluconate

Cupric sulphate

Copper lysine complex

Sodium iodide

Sodium iodate

Potassium iodide

Potassium iodate

Zinc acetate

Zinc chloride

Zinc citrate

Zinc gluconate

Zinc lactate

Zinc oxide

Zinc carbonate

Zinc sulphate

Manganese carbonate

Manganese chloride

Manganese citrate

Manganese gluconate

Manganese glycerophosphate

Manganese sulphate

Sodium bicarbonate

Sodium carbonate

Sodium chloride

Sodium citrate

Sodium gluconate

Sodium lactate

Sodium hydroxide

Sodium salts of orthophosphoric acid

Potassium bicarbonate

Potassium carbonate

Potassium chloride

Potassium citrate

Potassium gluconate

Potassium glycerophosphate

Potassium lactate

Potassium hydroxide

Potassium salts of orthophosphoric acid

Sodium selenate

Sodium hydrogen selenite

Sodium selenite

Chromium (III) chloride

Chromium (III) sulphate

Ammonium molybdate (molybdenum (VI))

Sodium molybdate (molybdenum (VI))

Potassium fluoride

Sodium fluoride

EXPLANATORY NOTE

(This note is not part of the Regulations)
These Regulations implement Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements ("the Directive").
The Regulations concern the sale (as defined in regulation 2(1)) of food supplements which are sold as food and presented as such (regulation 3). A food supplement is defined as a food sold in dose form whose purpose is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination (regulation 2(1)).
With effect from 1st August 2005, the Regulations–

(i) prohibit the sale of a food supplement to the ultimate consumer unless it is prepacked (regulations 4 and 2(2));

(ii) prohibit the sale of a food supplement in the manufacture of which a vitamin or mineral has been used, unless certain compositional requirements are met, subject to a transitional provision (regulation 5 and Schedules 1 and 2);

(iii) prohibit the sale of a food supplement which is ready for delivery to the ultimate consumer or a catering establishment unless certain requirements as to labelling, presentation and advertising of the product are met (regulations 6 and 7).

The prohibition in Article 6(2) of the Directive (labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties) is already implemented in the Food Labelling Regulations 1996 (S.I. 1996/1499) (regulation 40(1) and Schedule 6, Part I, paragraph 2).

The Regulations make provision as to responsibilities for enforcement (regulation 8); create offences and penalties (regulation 9) and apply certain provisions of the Food Safety Act 1990 (regulation 11). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (O.J. No. L 186, 30.6.89, p.23) on the official control of foodstuffs (regulation 10).

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, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.

Status:
Point in time view as at 01/08/2005.

Changes to legislation:
The Food Supplements (Scotland) Regulations 2003 is up to date with all changes known to be in force on or before 30 May 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.