2003 No. 1387

FOOD, ENGLAND

The Food Supplements (England) Regulations 2003

Made - - - -	*9th May 2003*
Laid before Parliament	*2nd June 2003*
Coming into force	*1st August 2005*

The Secretary of State, in exercise of the powers conferred by sections 16(1)(a) and (e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990**(a)** and now vested in him**(b)**, 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**(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 section 48(4) and (4B) of that Act, makes the following Regulations:

Title, commencement and extent

1. These Regulations may be cited as the Food Supplements (England) Regulations 2003; they come into force on 1st August 2005 and extend to England 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**(d)** 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;

(a) 1990 c. 16.

(b) 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 (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 (c. 46) as read with section 40(2) of the 1999 Act.

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

(d) OJ No. L183, 12.7.2002, p.51.

"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;

"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.

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**(a)** on the Community code relating to medicinal products for human use.

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 Commission by the Food Standards Agency or a member State other than the United Kingdom by 12th July 2005; and

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(a) OJ No. L311, 28.11.2001, p.67.

(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**(a)**, 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**(b)** on nutrition labelling for foodstuffs, 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.

Manner of marking or labelling

7.—(1) No person shall sell any food supplement which—

(a) is ready for delivery to the ultimate consumer, or

(b) 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—

(i) on the packaging;

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

(iii) on a label which is clearly visible through the packaging,

save 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

(a) S.I. 1996/1499, amended by S.I. 1998/141, 1398, 2424, 1999/747, 1136, 1483, 1540, 1603, 2000/768, 2254, 3323, 2001/2294, 3442, 3775, 2002/379, 2003/474.

(b) OJ No. L276, 6.10.90, p.40.

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 always 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 he 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.—(1) Each food authority shall enforce and execute these Regulations in its area.

(2) In this regulation "food authority" does not include—

(a) the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change; or

(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple).

Offences and penalties

9. If any person contravenes regulation 4, 5, 6 or 7 he 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(1) (obstruction etc. of officers);

(h) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (g) above;

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

(j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h) above;

(k) section 36 (offences by bodies corporate); and

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

Signed by authority of the Secretary of State for Health

Hazel Blears
Parliamentary Under Secretary of State,
Department of Health

9th May 2003

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)

1. These Regulations implement in England 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.

2. 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)).

3. With effect from 1st August 2005 the Regulations—

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

(b) 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),

(c) 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).

4. 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 (regulation 40(1) and Schedule 6, Part I, paragraph 2).

5. 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 (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 10).

6. A regulatory impact assessment 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 2002/46/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.

STATUTORY INSTRUMENTS

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