
SCOTTISH STATUTORY INSTRUMENTS

2009 No. 438

FOOD

The Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009

Made - - - - *10th December 2009*
Laid before the Scottish Parliament - - - - *11th December 2009*
Coming into force - - - - *1st January 2010*

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(1)(a) and (e), 17(1) and (2), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990⁽¹⁾ as read with paragraph 1A of Schedule 2 to the European Communities Act 1972⁽²⁾, and all other powers enabling them to do so.

In accordance with section 48(4A) of the Food Safety Act 1990, the Scottish Ministers have had regard to relevant advice given by the Food Standards Agency⁽³⁾.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for any reference to an Annex to 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⁽⁴⁾ to be construed as a reference to that Annex as amended from time to time.

There has been consultation 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⁽⁵⁾.

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- (1) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; sections 16(1) and 48(1) were amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraph 8; section 17(2) was amended by the 1999 Act, section 40(1) and Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, section 40(4) and Schedule 6; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) inserted by S.I. 2004/2990; 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) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. Insofar as not transferred and insofar as relating to food (including drink) including the primary production of food, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc) Order 2005 (S.I. 2005/849).
- (2) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51).
- (3) Section 48(4A) was inserted by the Food Standards Act 1999, Schedule 5, paragraph 21. Section 48(4) was disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by regulation 5(b) of the Food Safety Act 1990 (Amendment) Regulations 2004 S.I. 2004/2990.
- (4) O.J. No. L 183, 12.7.2002, p.51, as amended by Commission Directive 2006/37/EC (O.J. L 94, 1.4.2006, p. 32), Regulation (EC) No 1137/2008 of the European Parliament and of the Council (O.J. L 311, 21.11.2008, p.1) and Commission Regulation (EC) No. 1170/2009 (O.J. No. L 314, 1.12.2009, p.36).
- (5) O.J. No. L 31, 1.2.02, p.1 as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.2003, p.4), Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 8.4.2006, p.3), Commission Regulation (EC) No. 202/2008 (O.J. No. L 60, 5.3.2008, p.17) and Regulation (EC) No. 596/2009 of the European Parliament and of the Council (O.J. No. L 188, 18.7.2009, p.14).

Citation and commencement

1. These Regulations may be cited as the Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 and come into force on 1st January 2010.

Amendment of the Food Supplements (Scotland) Regulations 2003

2.—(1) The Food Supplements (Scotland) Regulations 2003⁽⁶⁾ are amended in accordance with the following paragraphs.

(2) In regulation 2(1) (interpretation), for the definition of “Directive 2002/46” substitute the following definitions—

““Directive 90/496” means Council Directive [90/496/EEC](#) on nutrition labelling for foodstuffs⁽⁷⁾ as amended by Commission Directive [2008/100/EC](#) amending Council Directive [90/496/EEC](#) on nutrition labelling for foodstuffs as regards recommended daily allowances, energy conversion factors and definitions⁽⁸⁾;

“Directive 2001/83” means Directive [2001/83/EC](#) of the European Parliament and of the Council on the Community code relating to medicinal products for human use⁽⁹⁾ as last amended by Directive [2009/53/EC](#) of the European Parliament and of the Council amending Directive [2001/82/EC](#) and Directive [2001/83/EC](#), as regards variations to the terms of marketing authorisations for medicinal products⁽¹⁰⁾;

“Directive 2002/46” means 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 as last amended by [Commission Regulation \(EC\) No. 1170/2009](#)⁽¹¹⁾ amending Directive [2002/46/EC](#) and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements⁽¹²⁾”.

(3) After regulation 2(3) (interpretation) insert—

“(4) In these Regulations any reference to an Annex to Directive 2002/46 is a reference to that Annex as amended from time to time.”

(4) For regulation 3(2) (scope of Regulations) substitute—

“(2) These Regulations do not apply to medicinal products as defined by Directive 2001/83.”.

(5) In regulation 5 (prohibitions on sale relating to composition of food supplements)—

- (a) in paragraph (1) omit the words “Subject to paragraph (3),”;
- (b) in paragraph (1)(a) for the words “column 1 of Schedule 1” substitute the words “Annex I to Directive 2002/46”;
- (c) in paragraph (1)(b)(i) for the words “Schedule 2” substitute the words “Annex II to Directive 2002/46”; and
- (d) omit paragraph (3).

(6) In regulation 6 (restrictions on sale relating to labelling etc of food supplements)—

- (a) for paragraph (3)(b) substitute—

⁽⁶⁾ [S.S.I. 2003/278](#), amended by [S.I. 2005/2759](#), [S.S.I. 2005/616](#) and [S.S.I. 2007/78](#).

⁽⁷⁾ O.J. No. L 276, 6.10.1990, p.40.

⁽⁸⁾ O.J. No. L 285, 29.10.2008, p.9.

⁽⁹⁾ O.J. No. L 311, 28.11.2001, p.67.

⁽¹⁰⁾ O.J. No. L 168, 30.6.2009, p.33.

⁽¹¹⁾ O.J. No. L 314, 1.12.2009, p.36.

⁽¹²⁾ O.J. No. L 404, 30.12.2006, p.26.

- “(b) in the case of a vitamin or mineral listed in Annex I to Directive 2002/46, be given using the relevant unit specified in brackets after the name of that vitamin or mineral;” and
- (b) for paragraph (3)(e) substitute—
- “(e) in the case of a vitamin or mineral listed in the Annex to Directive 90/496, be expressed also as a percentage (which may also be given in graphical form) of the relevant recommended daily allowance specified in that Annex.”
- (7) After regulation 11 (application of various provisions of the Act) insert—

“Transitional provision

- 12.** In any proceedings for an offence under regulation 9 relating to a breach of regulation 6 or 7 consisting of a contravention of or a failure to comply with regulation 6(3)(e), it shall be a defence to prove that—
- (a) the food supplement concerned was sold before 31st October 2012; and
- (b) the matters constituting the alleged offence would not have constituted an offence under those regulations if the amendments made by regulation 2(2) and (6)(b) of the Food Supplements, Vitamins, Minerals and Other Substances (Scotland) Regulations 2009 had not been in operation when the food was sold.”
- (8) Schedule 1 (vitamins and minerals which may be used in the manufacture of food supplements) and Schedule 2 (form of vitamin and mineral substances which may be used in the manufacture of food supplements) are omitted.

Amendment of the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007

3.—(1) The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007(**13**) are amended in accordance with the following paragraph.

(2) In regulation 2(1) (interpretation) for the definition “the EC Regulation” substitute the following definition—

““the EC Regulation” means Regulation (EC) No. 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods, as last amended by Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC and Regulation (EC) No. 1925/2006 as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements(**14**).”

St Andrew’s House, Edinburgh
10th December 2009

SHONA ROBISON
Authorised to sign by the Scottish Ministers

(13) S.S.I. 2007/325.

(14) O.J. No. L 404, 30.12.2006, p.26.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, amend the Food Supplements (Scotland) Regulations 2003 (“the 2003 Regulations”) and the Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (“the 2007 Regulations”) in order to provide for the execution and enforcement of [Commission Regulation \(EC\) No. 1170/2009](#) amending Directive [2002/46/EC](#) and Regulation [\(EC\) No. 1925/2006](#) as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements. These Regulations also update the references to Directives referred to in the 2003 Regulations.

These Regulations amend the 2003 Regulations by—

- (a) substituting a revised definition of Directive 2002/46 and inserting definitions of Directive 90/496 and Directive 2001/83 (*regulation 2(2)*);
- (b) providing that a reference to an Annex to Directive 2002/46 is a reference to that Annex as amended from time to time (*regulation 2(3)*);
- (c) revising references to directives to refer to the definitions of those directives (*regulation 2(4) and (6)(b)*);
- (d) removing those provisions which implemented a part of Directive 2002/46 which lapses on 1st January 2010 (*regulation 2(5)(a) and (d)*);
- (e) providing that those Regulations refer to the Annexes to Directive 2002/46 rather than the Schedules to those Regulations and making consequential amendments (*regulation 2(5)(b) and (c), (6)(a) and (8)*); and
- (f) providing a transitional period for the phasing in of the new provisions relating to Directive 90/496 (*regulation 2(7)*).

These Regulations amend the 2007 Regulations by substituting a revised definition of Regulation [\(EC\) No. 1925/2006](#) (*regulation 3(2)*).

A full regulatory impact assessment, which includes a compliance cost assessment of the effect which these Regulations would have on business costs, has been prepared for these Regulations and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.