

**2009 No. 3251**

**FOOD, ENGLAND**

**The Food Supplements (England) and Addition of Vitamins,  
Minerals and Other Substances (England) (Amendment)  
Regulations 2009**

<i>Made</i> - - - -	<i>8th December 2009</i>
<i>Laid before Parliament</i>	<i>11th December 2009</i>
<i>Coming into force</i> - -	<i>1st January 2010</i>

The Secretary of State makes 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(a) and now vested in him(b), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(c).

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has had regard to relevant advice given by the Food Standards Agency.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State 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(d) to be construed as a reference to that Annex as amended from time to time.

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

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- (a) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), “the 1999 Act”. Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act, S.I. 2004/2990 and S.I. 2004/3279.
- (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 1999 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 thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.
- (c) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51).
- (d) OJ No. L183, 12.7.2002, p.51, as last amended by Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36).

European Food Safety Authority and laying down procedures in matters of food safety<sup>(a)</sup> there has been open and transparent public consultation during the preparation of the following Regulations.

### **Title and commencement**

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

### **Amendment of the Food Supplements (England) Regulations 2003**

2.—(1) The Food Supplements (England) Regulations 2003<sup>(b)</sup> are amended in accordance with the following paragraphs.

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

““Directive 90/496” means Council Directive 90/496/EEC on nutrition labelling for foodstuffs<sup>(c)</sup> 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<sup>(d)</sup>;

“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<sup>(e)</sup> 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<sup>(f)</sup>;

“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 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements<sup>(g)</sup>”.

(3) Immediately after paragraph (3) of regulation 2 (interpretation) there is inserted the following paragraph—

“(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) In regulation 3 (scope of Regulations), for paragraph (2) there is substituted the following paragraph—

“(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) at paragraph (1), omit the words ‘subject to paragraph (3)’;

(b) at sub-paragraph (a) of paragraph (1), for the words ‘column 1 of Schedule 1’ there is substituted the words “Annex I to Directive 2002/46”;

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(a) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468 with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

(b) S.I. 2003/1387, amended by S.I. 2005/2759 and S.I. 2007/330; there is another amending instrument but it is not relevant.

(c) OJ No. L276, 6.10.1990, p.40.

(d) OJ No. L285, 29.10.2008, p.9.

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

(f) OJ No. L168, 30.6.2009, p.33.

(g) OJ No. L314, 1.12.2009, p.36.

- (c) at sub-paragraph (b)(i) of paragraph (1), for the words “Schedule 2” there is substituted the words “Annex II to Directive 2002/46”; and
  - (d) paragraph (3) is omitted.
- (6) In regulation 6 (restrictions on sale relating to labelling etc of food supplements)—
- (a) for sub-paragraph (b) of paragraph (3) there is substituted the following sub-paragraph—
    - “(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;”;
  - (b) for sub-paragraph (e) of paragraph (3) there is substituted the following sub-paragraph—
    - “(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) Immediately after regulation 11 (application of various provisions of the Act) add the following regulation—

#### **“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 the 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 (England) and Addition of Vitamins, Minerals and Other Substances (England) (Amendment) 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 (England) Regulations 2007**

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

(2) In paragraph (1) of regulation 2 (interpretation), for the definition “the EC Regulation”, there is substituted 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(b) as last amended by Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.” .

Signed by authority of the Secretary of State for Health

*Gillian Merron*  
Minister of State,  
Department of Health

8th December 2009

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(a) S.I. 2007/1631.

(b) OJ No. L404, 30.12.2006, p.26.

## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

1. These Regulations, which apply in relation to England only, amend the Food Supplements (England) Regulations 2003 (S.I. 2003/1387 as already amended by S.I. 2005/2626, S.I. 2005/2759 and S.I./2007/330) and the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 (S.I. 2007/1631) in order to provide for the execution and enforcement of Commission Regulation (EC) No. 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36). These Regulations also update the references to directives referred to in the Food Supplements (England) Regulations 2003.

2. These Regulations amend the Food Supplements (England) Regulations 2003 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 amendments to them (*regulation 2(4) and (6)(b)*);
- (d) removing those provisions which implemented a derogation from Directive 2002/46 which lapses on 1 January 2010 (*regulation 2(5)(a) and (d)*);
- (e) providing that those Regulations refer to the Annexes to Directive 2002/46 (vitamins and minerals and vitamin and mineral substances which may be used in the manufacture of food supplements) 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)*).

3. These Regulations amend the Addition of Vitamins, Minerals and Other Substances (England) Regulations 2007 substituting a revised definition of Regulation (EC) No.1925/2006 (*regulation 3(2)*).

4. A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Nutrition Division of the Food Standards Agency, Aviation House, 125 Kingsway, London, WC2B 6NH and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

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£4.00