## STATUTORY RULES OF NORTHERN IRELAND

## 2009 No. 407

## FOOD

# The Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 2009

Made	-	-	-	-	10th December 2009
Coming	into	oper	ation	1st January 2010	

The Department of Health, Social Services and Public Safety(1) makes the following Regulations in exercise of the powers conferred by Articles 15(1)(a) and (e), 16(1) and (2), 25(1)(a) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(2), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(3).

In accordance with Article 47(3A) of that Order, it 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 Department of Health, Social Services and Public Safety 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.

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) there has been open and transparent public consultation during the preparation of the following Regulations.

<sup>(1)</sup> Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.1) Article 3(6)

<sup>(2)</sup> S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R. 2004 Nos. 482 and 505

<sup>(3) 1972</sup> c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51)

<sup>(4)</sup> 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 vitamins and minerals and their forms that can be added to foods, including food supplements (OJ No. L314, 1.12.2009, p.36)

<sup>(5)</sup> 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)

#### Citation, commencement and interpretation

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

(2) The Interpretation Act (Northern Ireland) 1954(6) shall apply to these Regulations as it applies to an Act of the Assembly.

#### Amendment of the Food Supplements Regulations (Northern Ireland) 2003

**2.**—(1) The Food Supplements Regulations (Northern Ireland) 2003(7) are amended in accordance with the following paragraphs.

(2) In regulation (2)(1) (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(8) 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(9);

"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(10) 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(11);

"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 the Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements;"(12).

(3) Immediately after regulation 2(3) (interpretation) there is inserted—

"(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), there is substituted—

"(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 paragraph (1)(a), for the words 'column 1 of Schedule 1' there is substituted "Annex I to Directive 2002/46";
  - (c) at paragraph (1)(b)(i), for the words "Schedule 2" there is substituted "Annex II to Directive 2002/46"; and
  - (d) paragraph (3) is omitted.

<sup>(6) 1954</sup> c.33

<sup>(7)</sup> S.R. 2003 No.273, as amended by S.R. 2007 No.116; there is another amending Statutory Rule but it is not relevant

<sup>(8)</sup> OJ No. L276, 6.10.1990, p.40

<sup>(9)</sup> OJ No. L285, 29.10.2008, p.9
(10) OJ No. L311, 28.11.2001, p.67

<sup>(11)</sup> OJ No. L168, 30.6.2009, p.33

<sup>(12)</sup> OJ No. L314, 1.12.2009, p.36

- (6) In regulation 6 (restrictions on sale relating to labelling etc of food supplements)-
  - (a) for paragraph (3)(b) there is substituted—
    - "(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) there is substituted—
    - "(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 Order) 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 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 these Regulations if the amendments made by regulation 2(2) and (6)(b) of the Food Supplements and the Addition of Vitamins, Minerals and Other Substances (Amendment) Regulations (Northern Ireland) 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 manufacturer of food supplements) are omitted.

# Amendment of the Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007

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

(2) In regulation 2(1) (interpretation), for the definition "the EC Regulation" there is substituted—

""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 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.".

(13) S.R. 2007 No.301

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Sealed with the official seal of the Department of Health, Social Services and Public Safety on 10th December 2009.



Sean Donaghy A senior officer of the Department of Health, Social Services and Public Safety

### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations amend the Food Supplements Regulations (Northern Ireland) 2003 (S.R. 2003 No. 273 as already amended by S.R. 2007 No. 116) and the Addition of Vitamins, Minerals and Other Substances Regulations (Northern Ireland) 2007 (S.R. 2007 No. 301) 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 the Council and Regulation (EC) No. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and their forms that can be added to foods, including food supplements (OJNo. L314 1.12.2009, p.36). These Regulations also update the references to Directives referred to in the Food Supplements Regulations (Northern Ireland) 2003.

These Regulations amend the Food Supplements Regulations (Northern Ireland) 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)*).

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