
SCOTTISH STATUTORY INSTRUMENTS

2009 No. 438

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

Amendment of the Food Supplements (Scotland) Regulations 2003

2.—(1) The Food Supplements (Scotland) Regulations 2003⁽¹⁾ 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⁽²⁾ 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⁽³⁾;

“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⁽⁴⁾ 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⁽⁵⁾;

“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](#)⁽⁶⁾ 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⁽⁷⁾”.

(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

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

(2) O.J. No. L 276, 6.10.1990, p.40.

(3) O.J. No. L 285, 29.10.2008, p.9.

(4) O.J. No. L 311, 28.11.2001, p.67.

(5) O.J. No. L 168, 30.6.2009, p.33.

(6) O.J. No. L 314, 1.12.2009, p.36.

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

- (d) omit paragraph (3).
- (6) In regulation 6 (restrictions on sale relating to labelling etc of food supplements)—
 - (a) for paragraph (3)(b) substitute—
 - “(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.