WELSH STATUTORY INSTRUMENTS

2009 No. 3252 (W.282)

FOOD, WALES

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

Made - - - -	*8 December 2009*
Laid before the National Assembly for Wales - -	*10 December 2009*
Coming into force - -	*1 January 2010*

The Welsh 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**).

In accordance with section 48(4A) of the Food Safety Act 1990, the Welsh Ministers have 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(**2**) and it appears to the Welsh 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(**3**) 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(**4**) there has been open and transparent public consultation during the preparation of the following Regulations.

(**1**) 1990 c. 16. Functions of the Secretary of State under the Food Safety Act 1990, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c. 32).

(**2**) 1972 c. 68.

(**3**) 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).

(**4**) 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).

Title and commencement

1. The title of these Regulations is The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 and they come into force on 1 January 2010.

Amendment of the Food Supplements (Wales) Regulations 2003

2.—(1) The Food Supplements (Wales) Regulations 2003(**5**) 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" ("*Cyfarwyddeb 90/496*") means Council Directive 90/496/EEC on nutrition labelling for foodstuffs(**6**) 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(**7**);
>
> "Directive 2001/83" ("*Cyfarwyddeb 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(**8**) 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(**9**);
>
> ""Directive 2002/46" ("*Cyfarwyddeb 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(**10**);".

(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";

(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)—

(**5**) S.I. 2003/1719 (W.186), amended by S.I. 2005/2759, S.I. 2005/3254 (W.247) and S.I. 2007/1076 (W.114).
(**6**) OJ No. L276, 6.10.1990, p.40.
(**7**) OJ No. L285, 29.10.2008, p.9.
(**8**) OJ No. L311, 28.11.2001, p.67.
(**9**) OJ No. L168, 30.6.2009, p.33.
(**10**) OJ No. L314, 1.12.2009, p.36.