Changes to legislation: *The Food Supplements (Wales) Regulations 2003 is up to date with all changes known to be in force on or before 27 August 2020. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

WELSH STATUTORY INSTRUMENTS

2003 No. 1719 (W.186)

FOOD, WALES

The Food Supplements (Wales) Regulations 2003

Made - - - -	*9th July 2003*
Coming into force - -	*1st August 2005*

In exercise of the powers conferred by sections 16(1)(a) and (e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 [F1], and now vested in the National Assembly for Wales [F2], having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation both as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council [F3] 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 and in accordance with section 48(4) and (4B) of that Act, the National Assembly for Wales makes the following Regulations:

F1 1990 c. 16.

F2 Functions of the Secretary of State under the Food Safety Act 1990, 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 in conjunction with Section 40(3) of the Food Safety Act 1990.

F3 OJ No. L31, 1.2.2002, p.1.

Citation, application and commencement

1. These Regulations may be cited as the Food Supplements (Wales) Regulations 2003; they come into force on 1st August 2005 and apply to Wales only.

Interpretation

2.—(1) In these Regulations —

"the Act" ("*y Ddeddf*") means the Food Safety Act 1990;

"catering establishment" ("*sefydliad arlwyo*") means a restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer and is ready for consumption without further preparation;

[F4][F5]...

"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 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;

"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;**]**

"dose form" ("*ffurf dogn*") means a form such as capsules, pastilles, tablets, pills, and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids or powders designed to be taken in measured small unit quantities;

"food supplement" ("*ychwanegyn bwyd*") means any food the purpose of which is to supplement the normal diet and which —

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form;

"preparation" ("*paratoi*") includes manufacture and any form of processing or treatment,

[[F6]"Regulation (EU) No 1169/2011" ("*Rheoliad (EU) Rhif 1169/2011*") means Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004;**]**

"sell" ("*gwerthu*") includes possess for sale and offer, expose or advertise for sale; and

"ultimate consumer" ("*defnyddiwr Olaf*") means any person who purchases otherwise than —

(a) for the purpose of resale;

(b) for the purposes of a catering establishment; or

(c) for the purposes of a manufacturing business.

(2) A food supplement shall be regarded as prepacked for the purposes of these Regulations if —

(a) it is ready for sale to the ultimate consumer or to a catering establishment, and

(b) it is put into packaging before being offered for sale in such a way that the food supplement, cannot be altered without opening or changing the packaging.

(3) Other expressions used both in these Regulations and in Directive 2002/46 have the same meaning in these Regulations as they have in that Directive.

[[F7](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.**]**

F4 Words in reg. 2(1) omitted (13.12.2014) by virtue of The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 25(a)**

F5 Words in reg. 2(1) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(2)**

F6 Words in reg. 2(1) inserted (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 25(b)**

F7 Reg. 2(4) inserted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(3)**

Scope of Regulations

3.—(1) These Regulations apply to food supplements sold as food and presented as such.

[F8(2) These Regulations do not apply to medicinal products as defined by Directive 2001/83.**]**

F8 Reg. 3(2) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(4)**

Restriction on form in which food supplements are sold to the ultimate consumer

4. No person shall sell any food supplement to the ultimate consumer unless it is prepacked.

Prohibitions on sale relating to composition of food supplements

5.—(1) F9... No person shall sell a food supplement in the manufacture of which a vitamin or mineral has been used unless that vitamin or mineral —

(a) is listed in **[**F10Annex I to Directive 2002/46**]**; and

(b) is in a form which —

(i) is listed in **[**F11Annex II to Directive 2002/46**]**, and

(ii) meets the relevant purity criteria.

(2) The relevant purity criteria for the purposes of paragraph (1)(b)(ii) are —

(a) the purity criteria, if any, specified by **[**F12EU**]** legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2002/46; or

(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

F13(3) . . . . . .

F9 Words in reg. 5(1) omitted (1.1.2010) by virtue of The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(5)(a)**

F10 Words in reg. 5(1)(a) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(5)(b)**

F11 Words in reg. 5(1)(b)(i) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(5)(c)**

F12 Word in reg. 5(2)(a) substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **8-10**

F13 Reg. 5(3) omitted (1.1.2010) by virtue of The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(5)(d)**

Restrictions on sale relating to labelling etc of food supplements

6.—(1) No person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the name under which it is sold is "food supplement"..

(2) Without prejudice to **[**F14Regulation (EU) No 1169/2011**]**, no person shall sell a food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless it is marked or labelled with the following particulars —

(a) the name of the category of any vitamin or mineral or other substance with a nutritional or physiological effect which characterises the product or an indication of the nature of that vitamin or mineral or other substance;

(b) the portion of the product recommended for daily consumption;

(c) a warning not to exceed the stated recommended daily dose;

(d) a statement to the effect that food supplements should not be used as a substitute for a varied diet;

(e) a statement to the effect that the product should be stored out of the reach of young children; and

(f) the amount of any vitamin or mineral or other substance with a nutritional or physiological effect which is present in the product.

(3) The information required by paragraph (2)(f) shall —

(a) be given in numerical form;

[F15(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;**]**

(c) be the amount per portion of the product as recommended for daily consumption on the labelling of the product;

(d) be an average amount based on the manufacturer's analysis of the product; and

[F16(e) in the case of a vitamin or mineral listed in **[**F17point 1 of Part A of Annex XIII to Regulation (EU) No 1169/2011**]**, be expressed also as a percentage (which may also be given in graphical form) of the **[**F18relevant reference value specified in that point**]**.**]**

(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the labelling, presentation or advertising of which includes any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of vitamins or minerals in general.

F14 Words in reg. 6(2) substituted (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 26(a)**

F15 Reg. 6(3)(b) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(6)(a)**

F16 Reg. 6(3)(e) substituted (1.1.2010) by The Food Supplements (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 (S.I. 2009/3252), regs. 1, **2(6)(b)**

F17 Words in reg. 6(3)(e) substituted (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 26(b)(i)**

F18 Words in reg. 6(3)(e) substituted (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 26(b)(ii)**

Manner of marking or labelling

7.—(1) No person shall sell any food supplement which —

(a) is ready for delivery to the ultimate consumer, or

(b) is ready for delivery to a catering establishment and is prepacked,

unless the particulars with which it is required to be marked or labelled by regulation 6(2) shall appear —

(i) on the packaging;

(ii) on a label attached to the packaging; or

(iii) on a label which is clearly visible through the packaging,

save that where the sale is otherwise than to the ultimate consumer such particulars may, alternatively, appear only on the commercial documents relating to the food supplement where it can be guaranteed that such documents, containing all such particulars, either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement, and provided always that the particulars required by **[**F19points (a), (f), (g) and (h) of Article 9(1) Regulation (EU) No 1169/2011**]** shall also be marked or labelled on the outermost packaging in which that food supplement is sold.

(2) No person shall sell any food supplement which is ready for delivery to a catering establishment and is not prepacked unless the particulars with which it is required to be marked or labelled by regulation 6(2) appear —

(a) on a label attached to the food supplement;

(b) on a ticket or notice which is readily discernible by the intending purchaser at the place where he or she chooses the food supplement; or

(c) in commercial documents relating to the food supplement where it can be guaranteed that such documents either accompany the food supplement to which they relate or were sent before, or at the same time as, delivery of the food supplement.

(3) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment unless the particulars with which a food supplement is required to be marked or labelled by regulation 6(2) shall be easy to understand, clearly legible and indelible and, when a food is sold to the ultimate consumer, those particulars shall be marked in a conspicuous place in such a way as to be easily visible.

(4) No person shall sell any food supplement which is ready for delivery to the ultimate consumer or to a catering establishment if the particulars with which it is required to be marked or labelled by virtue of regulation 6(2) are in any way be hidden, obscured or interrupted by any other written or pictorial matter.

F19 Words in reg. 7(1) substituted (13.12.2014) by The Food Information (Wales) Regulations 2014 (S.I. 2014/2303), reg. 1(3), **Sch. 7 para. 27**

Enforcement

8. Each food authority shall enforce and execute these Regulations in its area.

Offences and penalties

9. Any person who contravenes regulation 4, 5, 6 or 7 shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.