

## 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 <sup>F1</sup>, and now vested in the National Assembly for Wales <sup>F2</sup>, 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 <sup>F3</sup> 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;

<sup>F4</sup><sup>F5</sup>...

**Changes to legislation:** The Food Supplements (Wales) Regulations 2003 is up to date with all changes known to be in force on or before 29 June 2023. 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

F6  
...

“Directive 2002/46” (“*Cyfarwydddeb 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 dogyn*”) 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,

[<sup>F7</sup>“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.

<sup>F8</sup>(3) .....

<sup>F8</sup>(4) .....

**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) omitted (31.12.2020) by virtue of [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/179), regs. 1(2), **3(2)(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

**F7** 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)**

**F8** [Reg. 2\(3\)\(4\)](#) omitted (31.12.2020) by virtue of [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/179), regs. 1(2), **3(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## Scope of Regulations

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

[<sup>F9</sup>(2) These Regulations do not apply to medicinal products [<sup>F10</sup>as defined by regulation 2(1) of the Human Medicines Regulations 2012].]

- F9** 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)**
- F10** Words in [reg. 3\(2\)](#) substituted (31.12.2020) by [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019 \(S.I. 2019/179\)](#), regs. 1(2), **3(3)**; 2020 c. 1, Sch. 5 para. 1(1)

## 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) <sup>F11</sup>... 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 [<sup>F12</sup>Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019]; and
- (b) is in a form which —

- (i) is listed in [<sup>F13</sup>Schedule 2 to the Nutrition (Amendment) (EU Exit) Regulations 2019], and
- (ii) meets the relevant purity criteria.

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

- [<sup>F14</sup>(a) the purity criteria, if any, specified in retained EU law or in regulations applying in relation to Wales made by the Secretary of State or by the Welsh Ministers under regulation 3 of the Nutrition (Amendment) (EU Exit) Regulations 2019; or]
- (b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

<sup>F15</sup>(3) .....

- F11** 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)**
- F12** Words in [reg. 5\(1\)\(a\)](#) substituted (31.12.2020) by [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019 \(S.I. 2019/179\)](#), regs. 1(2), **3(4)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Words in [reg. 5\(1\)\(b\)\(i\)](#) substituted (31.12.2020) by [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019 \(S.I. 2019/179\)](#), regs. 1(2), **3(4)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** [Reg. 5\(2\)\(a\)](#) substituted (31.12.2020) by [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019 \(S.I. 2019/179\)](#), regs. 1(2), **3(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** [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”..

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(2) Without prejudice to <sup>F16</sup>Regulation (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;
- <sup>F17</sup>(b) in the case of a vitamin or mineral listed in <sup>F18</sup>Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019] 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
- <sup>F19</sup>(e) in the case of a vitamin or mineral listed in <sup>F20</sup>point 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 <sup>F21</sup>relevant 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.

- F16** 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\(a\)](#)
- F17** 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\(6\)\(a\)](#)
- F18** Words in [reg. 6\(3\)\(b\)](#) substituted (31.12.2020) by [The Nutrition \(Miscellaneous Amendments\) \(Wales\) \(EU Exit\) Regulations 2019 \(S.I. 2019/179\)](#), [regs. 1\(2\), 3\(5\)](#); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)
- F19** 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\(6\)\(b\)](#)
- F20** 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\(b\)\(i\)](#)
- F21** 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 <sup>F22</sup>points (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.

**F22** 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.

## Defence in relation to exports

<sup>F23</sup>10. ....

**F23** Reg. 10 revoked (1.1.2006) by [The Official Feed and Food Controls \(Wales\) Regulations 2005 \(S.I. 2005/3254\)](#), reg. 1, [Sch. 6 Pt. 2](#)

## Application of various provisions of the Act

**11.** The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations —

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 3 (presumptions that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
- (e) section 22 (defence of publication in the course of business);
- (f) section 30(8) (which relates to documentary evidence);
- (g) section 33(1) (obstruction etc. of officers);
- (h) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (g) above;
- (i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g) above;
- (j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h) above;
- (k) section 36 (offences by bodies corporate); and
- (l) section 44 (protection of officers acting in good faith).

## [<sup>F24</sup>Transitional provision

**12.—[**

<sup>F25</sup>(1)] 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 (Wales) and Addition of Vitamins, Minerals and Other Substances (Wales) (Amendment) Regulations 2009 had not been in operation when the food was sold.]

[<sup>F26</sup>(2) 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)(b), it shall be a defence to prove that—

- (a) zinc was used in the manufacture of the food supplement and the food supplement was marked or labelled before 10th February 2023; and
- (b) the matters constituting the alleged offence would not have constituted an offence under these Regulations as they had effect immediately before 10th February 2023.]

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- F24** Reg. 12 added (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(7)**
- F25** Reg. 12 renumbered as reg. 12(1) (10.2.2023) by [The Food Supplements and Food for Specific Groups \(Miscellaneous Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/131\)](#), regs. 1(2), **5(2)**
- F26** Reg. 12(2) inserted (10.2.2023) by [The Food Supplements and Food for Specific Groups \(Miscellaneous Amendments\) \(No. 2\) Regulations 2023 \(S.I. 2023/131\)](#), regs. 1(2), **5(3)**

<sup>F27</sup> Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998 .

*D. Elis-Thomas*  
The Presiding Officer of the National Assembly

**F27** 1998 c. 38.



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## F28 SCHEDULE 1

Regulations 5(1) and (3) and 6(3)(b)

**VITAMINS AND MINERALS WHICH MAY BE USED  
IN THE MANUFACTURE OF FOOD SUPPLEMENTS**

**F28** Sch. 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(8)**

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## F29 SCHEDULE 2

Regulation 5(1) and (3)

**F29** Sch. 2 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(8)**

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**EXPLANATORY NOTE**

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

**1.** These Regulations implement in Wales 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.

**2.** The Regulations concern the sale (as defined in regulation 2(1)) of food supplements which are sold as food and presented as such (regulation 3). A food supplement is defined as a food sold in dose form whose purpose is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination (regulation 2(1)).

**3.** The Regulations — with effect from 1st August 2005 —

- (a) prohibit the sale of a food supplement to the ultimate consumer unless it is prepacked (regulations 4 and 2(2)),
- (b) prohibit the sale of a food supplement in the manufacture of which a vitamin or mineral has been used, unless certain compositional requirements are met, subject to a transitional provision (regulation 5(3) and Schedules),
- (c) prohibit the sale of a food supplement which is ready for delivery to the ultimate consumer or a catering establishment unless certain requirements as to labelling, presentation and advertising of the product are met (regulations 6 and 7).

**4.** Article 6(2) of the Directive (labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties) is already implemented in the Food Labelling Regulations 1996 (regulation 40(1) and Schedule 6, Part I, paragraph 2).



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5. The Regulations make provision as to responsibilities for enforcement (regulation 8); create offences and penalties (regulation 9) and apply certain provisions of the Food Safety Act 1990 (regulation 11). The Regulations provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive [89/397/EEC](#) (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 10).

6. A Regulatory appraisal for these Regulations has been prepared and placed in the Library of the National Assembly for Wales. Copies may be obtained from the Food Standards Agency, 1st Floor, Southgate House, Cardiff CF10 1EW.

**Changes to legislation:**

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**Changes and effects yet to be applied to :**

- reg. 12(1) reg. 12 renumbered as reg. 12(1) by [S.I. 2023/131 reg. 6\(2\)](#) (Amendment to Welsh text only)
- reg. 12(2) inserted by [S.I. 2023/131 reg. 6\(3\)](#) (Amendment to Welsh text only)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- reg. 12(3) inserted by [S.I. 2023/131 reg. 5\(4\)](#) (Amendment to English text only)
- reg. 12(3) inserted by [S.I. 2023/131 reg. 6\(4\)](#) (Amendment to Welsh text only)