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WELSH STATUTORY INSTRUMENTS

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**2019 No. 179 (W. 45)**

**EXITING THE EUROPEAN UNION, WALES  
FOOD, WALES**

The Nutrition (Miscellaneous Amendments)  
(Wales) (EU Exit) Regulations 2019

<i>Sift requirements satisfied</i>	<i>28 January 2019</i>
<i>Made - - - -</i>	<i>4 February 2019</i>
<i>Laid before the National Assembly for Wales - -</i>	<i>6 February 2019</i>
<i>Coming into force in accordance with regulation 1(2)</i>	

The Welsh Ministers make these Regulations in exercise of the powers conferred by paragraph 1(1) of Schedule 2 and paragraph 21(b) of Schedule 7 to the European Union (Withdrawal) Act 2018<sup>(1)</sup>.

The requirements of paragraph 4(2) of Schedule 7 to that Act (relating to the appropriate scrutiny procedure for these Regulations) have been satisfied.

There has been consultation 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<sup>(2)</sup>.

**Title, commencement and application**

1.—(1) The title of these Regulations is the Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

(2) The Regulations come into force on exit day.

(3) These Regulations apply in relation to Wales.

**Amendment of the Medical Food (Wales) Regulations 2000**

2.—(1) The Medical Food (Wales) Regulations 2000<sup>(3)</sup> are amended as follows.

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(1) 2018 c. 16.

(2) OJ No. L 31, 1.2.2002, p. 1, last amended by Commission Regulation (EC) No. 596/2009 (OJ No. L 188, 18.7.2009, p. 14).

(3) S.I. 2000/1866 (W. 125) as amended by S.I. 2005/3254 (W. 247), S.I. 2008/2602 (W. 228), S.I. 2014/1102 (W. 110), S.I. 2016/639 (W. 175) and S.I. 2018/806 (W. 162).

- (2) Regulation 2 (interpretation) is renumbered as paragraph (1) of that regulation.
- (3) After paragraph (1) as so renumbered, insert—
- “(2) In these Regulations, any reference to compliance with a provision of the Directive is to be read as a reference to complying with that provision as would be required if the provision formed part of domestic law.
- (3) For the purposes of these Regulations, Articles 4 to 5 of, and the Annex to, the Directive are to be read subject to the modifications set out in Schedule 2 to these Regulations.”
- (4) In regulation 5A(4) (application of the improvement notice provisions of the Act), in each place where it occurs, for “Schedule” substitute “Schedule 1”.
- (5) The Schedule is renumbered as Schedule 1.
- (6) After Schedule 1 as so renumbered, insert—

“SCHEDULE 2

Regulation 2(3)

Modifications to the Directive

1. The modifications of the Directive are as follows.
2. Article 4(2) is to be read as if for “Article 3 of [Directive 79/112/EEC](#)” there were substituted “Article 9 of Regulation (EU) No 1169/2011.”
3. Article 5 is to be read as if—
  - (a) in paragraph 1—
    - (i) for “where a product is manufactured in a third country” there were substituted “where a product is manufactured outside of the United Kingdom”;
    - (ii) for the first reference to “Member States” there were substituted “territories within the United Kingdom”;
    - (iii) the words “Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation” were omitted.
  - (b) in paragraph 2, for “are those referred to in Article 9(4) of [Directive 89/398/EEC](#).” there were substituted—
 

“are—

    - (a) in respect of England, the Secretary of State,
    - (b) in respect of Wales, the Welsh Ministers,
    - (c) in respect of Scotland, Food Standards Scotland,
    - (d) in respect of Northern Ireland, the Food Standards Agency.”
4. In the Annex, paragraph 4 is to be read as if for “[Directive 91/321/EEC](#) and its subsequent modifications” there were substituted “[Directive 2006/141/EC](#)(5)

**Amendment of the Food Supplements (Wales) Regulations 2003**

- 3.—(1) The Food Supplements (Wales) Regulations 2003(6) are amended as follows.

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- (4) Regulation 5A was inserted by [S.I. 2016/639 \(W. 175\)](#).
- (5) OJ No L 401, 30.12.2006, p. 1, last amended by Commission Delegated Regulation (EU) 2016/127 (OJ No L 25, 2.2.2016, p. 1).
- (6) [S.I. 2003/1719 \(W. 186\)](#) as amended by [S.I. 2005/3254 \(W. 247\)](#), [S.I. 2009/3252 \(W. 282\)](#), [S.I. 2011/1043](#) and [S.I. 2014/2303 \(W. 227\)](#).

- (2) In regulation 2 (interpretation) omit—
  - (a) the definition of “Directive 2001/83”;
  - (b) paragraphs (3) and (4).
- (3) In regulation 3(2) (scope of regulations) , for “as defined by Directive 2001/83” substitute “as defined by regulation 2(1) of the Human Medicines Regulations 2012(7)”.
- (4) In regulation 5(8) (prohibitions on sale relating to composition of food supplements)—
  - (a) in paragraph (1)—
    - (i) in sub-paragraph (a) for “Annex I to Directive 2002/46” substitute “Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019(9)”;
    - (ii) in sub-paragraph (b)(i) for “Annex II to Directive 2002/46” substitute “Schedule 2 to the Nutrition (Amendment) (EU Exit) Regulations 2019”.
  - (b) for paragraph (2)(a) substitute—
    - “(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”.
- (5) In regulation 6(3)(b)(10) (restrictions on sale relating to labelling etc of food supplements) , for “Annex I to Directive 2002/46” substitute “Schedule 1 to the Nutrition (Amendment) (EU Exit) Regulations 2019”.

#### **Amendment of the Kava-kava in Food (Wales) Regulations 2006**

- 4.—(1) The Kava-kava in Food (Wales) Regulations 2006(11) are amended as follows.
- (2) In regulation 2 (interpretation)—
  - (a) omit the definitions of “EEA State” and “free circulation in member States”;
  - (b) after the definition of “port health authority”, insert—
    - ““third country” (“*trydedd wlad*”) means a country other than the United Kingdom.”
- (3) In regulation 3 (prohibition on sales etc. of food consisting of or containing Kava-kava) for paragraph (2), substitute—
  - “(2) The prohibition imposed by paragraph (1) does not apply where the food consisting of or containing Kava-kava is imported from a third country if the food is being, or is to be, exported to a third country.”

#### **Amendment of the Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007**

- 5. In regulation 4(2)(a) of the Addition of Vitamins, Minerals and Other Substances (Wales) Regulations 2007(12) (offences and penalties), omit the words “as read with Article 17(1) (transitional application of national rules)”.

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(7) [S.I. 2012/1916](#).

(8) Regulation 5 was amended by [S.I. 2009/3252 \(W. 282\)](#).

(9) [S.I. 2019/xx](#)

(10) Regulation 6 was amended by [S.I. 2009/3252 \(W. 282\)](#) and [S.I. 2014/2303 \(W. 227\)](#).

(11) [S.I. 2006/1851 \(W. 194\)](#) as amended by [S.I. 2012/1809](#).

(12) [S.I. 2007/1984 \(W. 165\)](#) as amended by [S.I. 2014/2303 \(W. 227\)](#) and [S.I. 2018/806 \(W. 162\)](#).

**Amendment of the Infant Formula and Follow-on Formula (Wales) Regulations 2007**

6.—(1) The Infant Formula and Follow-on Formula (Wales) Regulations 2007<sup>(13)</sup> are amended as follows.

(2) In regulation 2 (interpretation), after paragraph (6) insert—

“(7) In these Regulations any reference to compliance with a provision of the Directive is to be read as a reference to complying with that provision as would be required if the provision formed part of domestic law.”

(3) In regulation 12(3)(a) (listed substances and their purity criteria (infant formula and follow-on formula)), for “EU legislation” substitute “retained EU law”.

**Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009**

7.—(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (Wales) Regulations 2009<sup>(14)</sup> are amended as follows.

(2) In Schedule 1, in the “subject matter” column of the table—

- (a) in the entry relating to Article 2(1), for “covered by Directive 2009/39 of the European Parliament and the Council on foodstuffs intended for particular nutritional uses” substitute “(foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability)”;
- (b) in the entry relating to Article 3(2), for “the Food Standards Agency” substitute “the Secretary of State, the Welsh Ministers, Food Standards Scotland or the Food Standards Agency in Northern Ireland”;
- (c) in the entries relating to Article 4(2) and Article 4(3), for “EU legislation” substitute “retained EU law”.

**Amendment of the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016**

8.—(1) The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016<sup>(15)</sup> are amended as follows.

(2) In regulation 2 (interpretation), omit paragraph (5).

(3) In Schedule 1 (specified EU requirements)<sup>(16)</sup> in the entry in column 1, for “Article 15(1) (Union list)” substitute “Article 15(1) (UK list)”.

4 February 2019

*Vaughan Gething*  
Minister for Health and Social Services, one of  
the Welsh Ministers

<sup>(13)</sup> S.I. 2007/3573 (W. 316) as amended by S.I. 2008/2602 (W. 228), S.I. 2011/1043, 2014/123 (W. 13), S.I. 2014/1102 (W. 110) and S.I. 2016/639 (W. 175).

<sup>(14)</sup> S.I. 2009/3254 (W. 283) as amended by S.I. 2011/1043 and S.I. 2016/639 (W. 175).

<sup>(15)</sup> S.I. 2016/639 (W. 175) as amended by S.I. 2019/70 (W. 22)

<sup>(16)</sup> Schedule 1 was amended by S.I. 2019/70 (W. 22).

## **EXPLANATORY NOTE**

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

These Regulations are made in exercise of the powers in paragraph 1(1) of Schedule 2 and paragraph 21(b) of Schedule 7 to the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

The Regulations make amendments to secondary legislation for Wales in the field of nutrition.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.