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W E L S H S T A T U T O R Y  
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**2019 No. 70 (W. 22)**

**FOOD, WALES**

**FOOD SAFETY**

**The Food for Specific Groups  
(Information and Compositional  
Requirements) (Amendment)  
(Wales) Regulations 2019**

**EXPLANATORY NOTE**

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

These Regulations make provision to enforce, in Wales, Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific information and compositional requirements for food for special medical purposes (“the Delegated Regulation”).

They do this by amending the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the 2016 Regulations”), which make provision to enforce, in Wales, the requirements of Regulation (EU) No 609/2013 of the European Parliament and of the Council on the food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (“the EU Regulation”).

The EU Regulation sets out the general information and compositional requirements for certain categories of food. The Delegated Regulation sets out the specific information and compositional requirements for food for special medical purposes.

The 2016 Regulations provide for the enforcement of requirements specified by the EU Regulation by applying, with modifications, certain provisions of the Food Safety Act 1990.

The specific information and compositional requirements of food for special medical purposes are inserted into Schedule 1 to the 2016 Regulations, and

become ‘specified EU requirements’, to which the modified provisions of the Food Safety Act 1990 apply. This enables an improvement notice to be served requiring compliance. A failure to comply with an improvement notice is a criminal offence.

References to the provisions of the Delegated Regulation are to be read as references to those provisions as amended from time to time.

A definition of food for medical purposes is contained in the EU Regulation and this expressly includes such foods for infants. From 22 February 2019 the Delegated Regulation applies only to food for special medical purposes other than that developed to satisfy the nutritional needs of infants. It is therefore necessary to limit the application of these Regulations.

These Regulations also amend the definition of medical food in the Medical Food (Wales) Regulations 2000 (“the 2000 Regulations”) so that those Regulations apply only to medical food developed to satisfy the nutritional needs of infants.

These Regulations include transitional provisions for medical foods that are labelled or placed on the market before 22 February 2019. Such foods may continue to be marketed until stocks are exhausted as long as they are sold in compliance with the specified requirements of the EU Regulation and regulation 3(1) and (2) of the 2000 Regulations.

The Welsh Ministers’ Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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**The Food for Specific Groups  
(Information and Compositional  
Requirements) (Amendment)  
(Wales) Regulations 2019**

*Made* 17 January 2019

*Laid before the National Assembly for Wales*  
21 January 2019

*Coming into force* 22 February 2019

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 17(1) and (2), 26(1) and (3) and 48(1)(b) and (c) of the Food Safety Act 1990(1) as read with paragraph 1A(1) of Schedule 2 to the European Communities Act 1972(2).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972, and it appears to the Welsh Ministers that it is expedient for certain provisions of

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- (1) 1990 c. 16. Section 17 was amended by paragraphs 8 and 12 of Schedule 5 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”) and S.I. 2011/1043. Section 26(3) was partially repealed by paragraph 1 of Schedule 6 to the 1999 Act. Section 48(1) was amended by paragraph 8 of Schedule 5 to the 1999 Act. Functions formerly exercisable by “the Ministers” so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act, and subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
- (2) 1972 c. 68. Paragraph 1A(1) of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c. 51) and was amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c. 7) and S.I. 2007/1388.

Commission Delegated Regulation (EU) 2016/128(1), referred to in these Regulations, to be construed as references to those provisions as amended from time to time.

The Welsh Ministers have had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A)(2) of the Food Safety Act 1990.

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(3), during the preparation and evaluation of these Regulations.

#### **Title, application, commencement and interpretation**

1.—(1) The title of these Regulations is the Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019.

(2) These Regulations apply in relation to Wales.

(3) These Regulations come into force on 22 February 2019.

(4) In these Regulations—

“the 2000 Regulations” (“*Rheoliadau 2000*”) means the Medical Food (Wales) Regulations 2000(4);

“the 2016 Regulations” (“*Rheoliadau 2016*”) means the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016(5).

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- (1) Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ No. L 25, 02.02.2016, p. 30).
- (2) Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the Food Standards Act 1999 (c. 28).
- (3) OJ No. L 31, 1.2.2002, p. 1, last amended by Commission Regulation (EU) No 2017/228 (OJ No L 35, 10.02.2017, p. 10).
- (4) S.I. 2000/1866 (W. 125), amended by S.I. 2016/639 (W. 175) and S.I. 2018/806 (W. 162); there are other amending instruments but none is relevant.
- (5) S.I. 2016/639 (W. 175).

### Amendment of regulation 2 of the 2000 Regulations

2. For the definition of “medical food” in regulation 2 (interpretation) of the 2000 Regulations substitute—

““medical food” (*“bwyd meddygol”*) means food coming within the classification of dietary foods for special medical purposes for which compositional and labelling requirements are laid down in the Directive and which has been developed to satisfy the nutritional requirements of infants; and”.

### Amendment of the 2016 Regulations

3.—(1) The 2016 Regulations are amended as follows.

(2) In regulation 2 (interpretation)—

(a) in paragraph (1)—

(i) at the appropriate place insert—

““the Delegated Regulation” (*“y Rheoliad Dirprwyedig”*) means Commission Delegated Regulation (EU) 2016/128 as amended from time to time supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes(1);”;

““food for special medical purposes” (*“bwyd at ddibenion meddygol arbennig”*) has the same meaning in these Regulations as in the EU Regulation(2);”;

““infant” (*“baban”*) means a child under the age of 12 months;”;

(ii) in the definition of “specified EU requirement”, after “the EU Regulation” insert “or the Delegated Regulation”; and

(b) after paragraph (4) insert—

“(5) Any reference to a provision of the Delegated Regulation contained in the table in Schedule 1 is a reference to that provision as amended from time to time.

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(1) OJ No. L 25, 2.2.2016, p. 30.

(2) Article 2(2)(g) of the EU Regulation states ““food for special medical purposes’ means food specifically processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.”

(6) Any reference to the Delegated Regulation is a reference to the Delegated Regulation only insofar as it applies to food for special medical purposes other than that developed to satisfy the nutritional requirements of infants.”

(3) After regulation 6 (amendments to statutory instruments) insert—

**“Transitional arrangements**

7. Food for special medical purposes, other than that developed to satisfy the nutritional requirements of infants, that does not comply with the specified provisions of the Delegated Regulation may continue to be marketed until stocks of such food are exhausted provided—

- (a) it complies with the specified provisions of the EU Regulation;
- (b) it was placed on the market or labelled before 22 February 2019; and
- (c) the requirements of regulation 3(1) and (2) of the Medical Food (Wales) Regulations 2000 are met.”

**Amendment of Schedule 1 to the 2016 Regulations**

4. For the Table in Schedule 1 to the 2016 Regulations substitute—

<b>“Column 1</b>	<b>Column 2</b>
<b>Specified provision of the EU Regulation</b>	<b>Provisions to be read with the specified provision of the EU Regulation</b>
Article 4(2) (requirement for relevant food to be pre-packed)	Articles 1(1) and 4(1)
Article 9(1) (requirement for the composition of food to be nutritionally appropriate and suitable)	Articles 1(1), 4(1) and 9(3)
Article 9(2) (prohibition on substances in dangerous quantities)	Articles 1(1) and 4(1)
Article 9(5) (requirements as to labelling, presentation and advertising of relevant food)	Articles 1(1), 4(1) and 9(6)
Article 10 (additional requirements for infant formula and follow-on formula)	Article 4(1)
Article 15(1) (Union list)	Articles 1(1)(c), 4(1) and the Annex insofar as it applies to food for special medical purposes

<b>Specified provision of the Delegated Regulation</b>	<b>Provisions to be read with the specified provision of the Delegated Regulation</b>
Article 2(2) (requirement for the formulation of food to be based on sound medical and nutritional principles)	Article 1
The second sub-paragraph of Article 2(3) (food to comply with compositional requirements in Part B of Annex 1)	Articles 1, 2(4) and Part B of Annex 1
Article 3(2) (requirement relating to residue levels) insofar as it applies to young children rather than infants	Articles 1 and 3(1), (3) and (5) and Annex 2
Article 3(4) (prohibition on the use of plant protection products) insofar as it applies to young children rather than infants	Articles 1 and 3(1) and (5) and Annex 3
Article 5(2) (specific requirements on food information)	Articles 1 and 5(1) and (3)
Article 6 (specific requirements on the nutrition declaration)	Article 1 and Part B of Annex 1
Article 7 (nutrition and health claims)	Article 1
Article 9 (notification requirement)	Article 1”

*Vaughan Gething*  
 Minister for Health and Social Services, one of the  
 Welsh Ministers  
 17 January 2019