

2020 No. (W.)

FOOD, WALES

FOOD SAFETY

**The Food for Specific Groups
(Information and Compositional
Requirements) (Wales)
(Amendment) Regulations 2020**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which apply to Wales, amend the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639 (W. 175)) (“the 2016 Regulations”) in order to provide for the enforcement in domestic law of the provisions of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 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 developed to satisfy the nutritional requirements of infants (OJ No. L 25, 2.2.2016, p. 30) (“the Delegated Regulation”).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (c. 68) and references in them to provisions of the Delegated Regulation are to be construed as references to such provisions as they are amended from time to time.

Regulation 4 of these Regulations amends regulation 2 of the 2016 Regulations so that references in the 2016 Regulations to the Delegated Regulation are to the Delegated Regulation as it applies to food for special medical purposes including that developed to satisfy the nutritional requirements of infants.

Regulation 6 of these Regulations substitutes a new regulation 7 of the 2016 Regulations to provide new transitional arrangements which ensure that stocks of food for special medical purposes which were labelled

or placed on the market before the date of application of provisions of the Delegated Regulation may continue to be marketed until those stocks are exhausted.

Regulation 7 of these Regulations amends the table in Schedule 1 to the 2016 Regulations to include further provisions into the definition of “specified EU requirement”.

These Regulations also make amendments to the 2016 Regulations to correct drafting errors and to provide further clarity. Regulation 8 inserts new paragraphs 6A and 7A in Part 3 of Schedule 3 to the 2016 Regulations to provide clarity regarding the application of section 35 of the Food Safety Act 1990 to the 2016 Regulations and regulation 5 corrects a drafting error in regulation 4(5) of the 2016 Regulations.

Regulation 9 of these Regulations contains revocations and savings provisions. Regulation 9 of, and the Schedule to, these Regulations revoke the Medical Food (Wales) Regulations 2000 (S.I. 2000/1866 (W. 125)) and provisions which amend them. The Medical Food (Wales) Regulations 2000 implement Commission Directive 1999/21/EC on dietary foods for special medical purposes developed to satisfy the nutritional requirements of infants (OJ No. L 91, 7.4.1999, p. 29, as corrected by a corrigendum published on 5 January 2000 (OJ No. L 2, 5.1.2000, p. 79)).

Regulation 9 of these Regulations further provides for the revocations to be saved for the purposes of the transitional provisions in regulation 7 of the 2016 Regulations as substituted by these Regulations, and for the purposes of the transitional provisions in regulation 5(3) of the Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/**** W. **).

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.

2020 No. (W.)

FOOD, WALES

FOOD SAFETY

**The Food for Specific Groups
(Information and Compositional
Requirements) (Wales)
(Amendment) Regulations 2020**

Made 30 January 2020

Laid before the National Assembly for Wales
31 January 2020

Coming into force 22 February 2020

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4) 16(1)(a) and (e) and (2)(b), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990⁽¹⁾ and now vested in them⁽²⁾ and section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972⁽³⁾.

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- (1) 1990 c. 16. Section 6(4) of the Food Safety Act 1990 (“the 1990 Act”) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40), paragraph 10(1) and (3)(a) of Schedule 5, and Schedule 6 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”) and S.I. 2002/794. Section 16(1) of the 1990 Act was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act. Section 17 of the 1990 Act was amended by paragraphs 7, 8 and 12 of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 48(1) was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.
- (2) Those functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, 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 thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
- (3) 1972 c. 68 (“the 1972 Act”). Section 2(2) of the 1972 Act was amended by section 27(1)(a) of the Legislative and

The Welsh Ministers have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food⁽¹⁾.

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 references to provisions of Commission Delegated Regulation (EU) 2016/128⁽²⁾, 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)⁽³⁾ 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⁽⁴⁾, during the preparation and evaluation of these Regulations.

Title, commencement and application

1.—(1) The title of these Regulations is the Food for Specific Groups (Information and Compositional Requirements) (Wales) (Amendment) Regulations 2020.

(2) These Regulations come into force on 22 February 2020.

(3) These Regulations apply in relation to Wales.

Regulatory Reform Act 2006 (c. 51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7). Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006. It was amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 and S.I. 2007/1388.

- (1) S.I. 2005/1971 to which there are amendments not relevant to these Regulations.
- (2) 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).
- (3) Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.
- (4) OJ No. L 31, 1.2.2002, p. 1, last amended by Regulation (EU) No 2019/1243 of the European Parliament and of the Council (OJ No. L 198, 25.07.2019, p. 241).

Interpretation

2. In these Regulations, “the 2016 Regulations” means the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016(1).

Amendment of the 2016 Regulations

3. The 2016 Regulations are amended in accordance with regulations 4 to 8.

4. In regulation 2 (interpretation), omit paragraph (6).

5. In regulation 4 (application of provisions of the Act), in paragraph (5) for “applies to an improvement notice” substitute “applies to an appeal against an improvement notice”.

6. For regulation 7 (transitional arrangements) substitute—

“7. Food for special medical purposes that does not comply with any specified provision of the Delegated Regulation specified in Schedule 1 may continue to be marketed until stocks of such food are exhausted provided that—

- (a) it complies with the provisions of the EU Regulation specified in Schedule 1,
- (b) it was placed on the market or labelled—
 - (i) before 22 February 2019, or
 - (ii) before 22 February 2020 in the case of food for special medical purposes developed to satisfy the nutritional requirements of infants, and
- (c) the requirements specified in regulation 3(1) and (2) of the Medical Food (Wales) Regulations 2000(2) are met.”

7. In Schedule 1(3) (specified EU requirements)—

- (a) in the part of the table relating to the EU Regulation, in the entry relating to “Article 15(1) (Union list)”, in column 2, for “Articles 1(1)(c), 4(1) and the Annex insofar as it applies to food for special medical purposes” substitute “Articles 1(1)(a) and (c) and 4(1) and the Annex insofar as it applies to infant

(1) S.I. 2016/639 (W. 175), amended by S.I. 2019/70 (W. 22) and prospectively amended by S.I. 2019/179 (W. 45).

(2) S.I. 2000/1866 (W. 125); amended by S.I. 2014/1102 (W. 110); there are other amending instruments but none are relevant to these Regulations.

(3) The table in Schedule 1 was substituted by S.I. 2019/70 (W. 22).

- formula, follow-on formula, and food for special medical purposes”;
- (b) for the part of the table relating to the Delegated Regulation substitute—

| “Specified provision of the Delegated Regulation | Provisions to be read with the specified provision of the Delegated Regulation |
|--|---|
| Article 2(2) (requirement for the formulation of food to be based on sound medical and nutritional principles) | Article 1 |
| The first subparagraph of Article 2(3) (requirement for food for special medical purposes developed to satisfy the nutritional requirements of infants to comply with the compositional requirements in Part A of Annex 1) | Articles 1 and 2(4) and Part A of Annex 1 |
| The second subparagraph of Article 2(3) (requirement for food other than that developed to satisfy the nutritional requirements of infants to comply with the compositional requirements in Part B of Annex 1) | Articles 1 and 2(4) and Part B of Annex 1 |
| Article 3(2) (requirement relating to residue threshold for certain active substances where food for special medical purposes is developed to satisfy the nutritional requirements of infants and young children) | Articles 1 and 3(1), (3) and (5) and Annex 2 |
| Article 3(3) (maximum residue levels for substances listed in Annex 2) | Articles 1 and 3(1), (2) and (5) and Annex 2 |
| Article 3(4) (prohibition on the use | Articles 1 and 3(1) and (5) and Annex 3 |

| | |
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| of plant protection products) | |
| Article 4 (name of the food) | Article 1 and Annex 4 |
| Article 5(1) (requirement for food for special medical purposes to comply with Regulation (EU) No. 1169/2011(1) unless otherwise specified) | Articles 1 and 5(2) |
| Article 5(2) (additional mandatory particulars relating to food information) | Articles 1 and 5(1) and (3) |
| Article 5(3) (application of Articles 13(2) and (3) of Regulation (EU) No. 1169/2011 to additional mandatory particulars) | Articles 1 and 5(1) and (2) |
| Article 6 (specific requirements on the nutrition declaration) | Article 1 and Annex 1 |
| Article 7 (nutrition and health claims) | Article 1 |
| Article 8(1) (requirement for mandatory particulars to appear in a language easily understood by consumers) | Article 1 |
| The first subparagraph of Article 8(2) (prohibition of pictures of infants or certain other pictures or text) | Article 1 |
| Article 8(3) (requirements relating to labelling, presentation and advertising) | Article 1 |
| The first sub- | Article 1 and the third |

(1) Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 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 (OJ No. L 304, 22.11.2011, p. 18).

| | |
|---|-------------------------------|
| paragraph of Article 8(4) (restriction on publication) | sub-paragraph of Article 8(4) |
| Article 8(5) (prohibition on use of promotional devices to induce sales) | Article 1 |
| Article 8(6) (prohibition on providing free or low-priced products, samples or other promotional gifts) | Article 1 |
| Article 9 (notification) | Article 1” |

8. In Schedule 2 (modification of provisions of the Act), in Part 3 (modification of section 35)—

(a) before paragraph 7 insert—

“**6A.** In section 35(1), after “section 33(1) above” insert “, as applied by regulation 4(6) and (7) of the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016,”;

(b) after paragraph 7 insert—

“**7A.** In section 35(2), after “any other offence under this Act” insert “including an offence under section 33(2), as applied by regulation 4(6) and (7) of the Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016,”.

Revocations and savings

9.—(1) The instruments specified in column 1 of the table in the Schedule are revoked to the extent specified in column 3 of that table, subject to paragraph (2).

(2) The instruments specified in column 1 of the table in the Schedule continue to have effect (so far as otherwise revoked to the extent specified in column 3 of that table) for the purposes of—

(a) regulation 7(c) of the 2016 Regulations as substituted by regulation 6 of these Regulations, and

(b) regulation 5(3)(b) of the Infant Formula and Follow-on Formula (Wales) Regulations 2020(1).

Vaughan Gething

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

30 January 2020

SCHEDULE Regulation 9
Revocations

| Column 1 | Column 2 | Column 3 |
|--|-------------------------|------------------------------|
| <i>Instrument</i> | <i>Reference</i> | <i>Extent of revocation</i> |
| Medical Food (Wales) Regulations 2000 | S.I. 2000/1866 (W. 125) | The whole of the Regulations |
| Infant Formula and Follow-on Formula (Wales) Regulations 2007 | S.I. 2007/3573 (W. 316) | Regulation 30 |
| Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2008 | S.I. 2008/2602 (W. 228) | Regulation 3 |
| Transfer of Functions (Food) (Wales) Regulations 2014 | S.I. 2014/1102 (W. 110) | Regulation 2 |
| Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 | S.I. 2016/639 (W. 175) | Paragraph 2 of Schedule 3 |
| Food for Specific Groups (Information and Compositional Requirements) (Amendment) (Wales) Regulations 2019 | S.I. 2019/70 (W. 22) | Regulation 2 |