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SCOTTISH STATUTORY INSTRUMENTS

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**2018 No. 392**

**FOOD**

**The Foods for Specific Groups (Medical Foods)  
(Miscellaneous Amendments) (Scotland) Regulations 2018**

<i>Made</i>	- - - -	<i>19th December 2018</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>20th December 2018</i>
<i>Coming into force</i>	- -	<i>22nd February 2019</i>

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(1), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup> and all other powers enabling them to do so.

In accordance with section 48(4A) of that Act<sup>(2)</sup>, before making these Regulations the Scottish Ministers have had regard to any relevant advice given by Food Standards Scotland.

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>(3)</sup>.

**Citation, commencement and extent**

**1.—(1)** These Regulations may be cited as the Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018 and come into force on 22 February 2019.

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- (1) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 16(1) and 48(1) were amended by paragraph 8 of schedule 5 of the Food Standards Act 1999 (c.28) (“the 1999 Act”) and section 16(1) was also amended by section 34(1) of the Food (Scotland) Act 2015 (asp 1) (“the 2015 Act”). Section 17(1) was amended by the 1999 Act, schedule 5, paragraphs 8 and 12(a), and S.I. 2011/1043. Section 17(2) was amended by the 1999 Act, schedule 5, paragraphs 8 and 12(b) and S.I. 2011/1043. Section 26(3) was amended by the 1999 Act, schedule 6. Amendments made by schedule 5 of the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, and in so far as relating to food (including drink) including the primary production of food, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish ministers etc.) Order 2005 (S.I. 2005/849).
- (2) Section 48(4A) was inserted by paragraph 21 of schedule 5 of the 1999 Act. The reference in that subsection to the Food Standards Agency is, by virtue of section 48(6) of the 1990 Act, to be read as a reference to Food Standards Scotland. Section 48(6) was inserted by paragraph 3(11) of the schedule of the 2015 Act. Section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990.
- (3) OJ L 31, 1.2.2002, p.1.

- (2) These Regulations extend to Scotland only.

### **Amendment of the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997**

**2.—**(1) The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997<sup>(4)</sup> are amended in accordance with paragraphs (2) to (4).

- (2) In regulation 2 (name of the food and compositional requirements)—

- (a) for paragraph (1) substitute—

“(1) No person shall sell any relevant food under any name other than “total diet replacement for weight control”.”, and

- (b) in paragraph (2) omit “or “meal replacement for weight control””.

- (3) In regulation 3 (labelling requirements)—

- (a) at the end of paragraph (e) insert “and”,

- (b) in paragraph (f), for “regulation 2(1)(a)” substitute “regulation 2(1)”,

- (c) at the end of paragraph (f) omit “and”, and

- (d) omit paragraph (g).

- (4) In schedule 1 (essential composition of relevant food)—

- (a) in each of paragraphs 1.1, 2.1, 3.2, 4 and 5.1, for “regulation 2(1)(a)” substitute “regulation 2(1)”,

- (b) in paragraph 2.1 omit “and (b)”, and

- (c) omit paragraphs 1.2, 3.3 and 5.2.

### **Amendment of the Foods for Special Medical Purposes (Scotland) Regulations 2000**

**3.—**(1) The Foods for Special Medical Purposes (Scotland) Regulations 2000<sup>(5)</sup> are amended as follows.

- (2) In regulation 2 (interpretation) for the definition of “dietary food” substitute—

““dietary food” means—

- (a) food coming within the classification of dietary foods for special medical purposes for which compositional labelling requirements are laid down in the Directive and which has been developed to satisfy the nutritional needs of infants, or

- (b) food coming within the classification of dietary foods for special purposes for which compositional and labelling requirements are laid down in the Directive and which has been labelled or placed on the market before 22nd February 2019, and”.

### **Amendment of the Foods for Specific Groups (Scotland) Regulations 2016**

**4.—**(1) The Foods for Specific Groups (Scotland) Regulations 2016<sup>(6)</sup> are amended in accordance with paragraphs (2) and (3).

- (2) In regulation 2 (interpretation)—

- (a) in paragraph (1)—

<sup>(4)</sup> [S.I. 1997/2182](#), last relevantly amended by [S.S.I. 2016/190](#).

<sup>(5)</sup> [S.S.I. 2000/130](#), amended by [S.S.I. 2004/395](#), [2005/616](#), [2007/549](#), [2008/322](#) and [2015/100](#).

<sup>(6)</sup> [S.S.I. 2016/190](#).

- (i) after the definition of “the Act” insert ““the Delegated Regulation” means Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes”(7), and
- (ii) in the definition of “specified EU requirement” after “the EU Regulation” insert “or the Delegated Regulation”,
- (b) in paragraph (2) after “EU Regulation” insert “or the Delegated Regulation, as the case may be”,
- (c) for paragraph (3) substitute—
  - “(3) Expressions defined in Article 2 of the EU Regulation have the same meaning in these Regulations as they have in that Regulation.”, and
- (d) in paragraph (4)—
  - (i) after “Article 2” insert “of the EU Regulation”, and
  - (ii) after “EU Regulation” in the second place it appears insert “or the Delegated Regulation, as the case may be”.
- (3) In schedule 1 (specified EU requirements) replace the table with the following.

<b><i>“Column 1</i></b>	<b><i>Column 2</i></b>
<b><i>Specified provision of the EU Regulation</i></b>	<b><i>Provisions of the EU Regulation to be read with the specified provision of the EU Regulation</i></b>
Article 4(1) (requirement for placing food on the market)	Article 1 (1)
Article 4(2) (requirement for 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), 9(3) and (4)
Article 9(2) (prohibition on substances in dangerous quantities)	Articles 1(1) and 4(1)
Article 9(3) (requirement for substances added to food)	Article 1 (1)
Article 9(5) (requirements as to labelling, presentation and advertising of food)	Articles 1(1), 4(1) and 9(6)
Article 10 (additional requirements for infant formula and follow-on formula)	Article 4(1)
<b><i>Specified provision of the Delegated Regulation</i></b>	<b><i>Provisions of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i></b>
Article 2(2) (requirement for the formulation of food to be based on sound medical and nutritional principles)	Article 1

(7) OJ L 25, 2.2.2016, p.30.

<b><i>Specified provision of the Delegated Regulation</i></b>	<b><i>Provisions of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i></b>
The second sub-paragraph of Article 2(3) (requirement for food to comply with Part B of Annex I)	Articles 1 and 2(4), and Part B of Annex I
Article 3(2) (requirement on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children)	Article 3(5)
Article 3(4) (maximum residue levels)	Article 3(5)
Article 4 (name of the food)	Annex IV
Article 5(2) (specific requirements on food information)	Articles 1, and 5(1) (3)
Article 6 (specific requirements on the nutrition declaration)	Article 1
Article 7 (nutrition and health claims)	Article 1
Article 9 (notification)	Article 1”

St Andrew's House,  
Edinburgh  
19th December 2018

*JOE FITZPATRICK*  
Authorised to sign by the Scottish Ministers

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## EXPLANATORY NOTE

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

These Regulations make provision to enforce, in Scotland, Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes.

Regulation 3 restricts the application of the Foods for Special Medical Purposes (Scotland) Regulations 2000 to food for medical purposes developed to satisfy the needs of infants and, in relation to food that is labelled or placed on the market before 22 February 2019.

Regulation 4 amends the Foods for Specific Groups (Scotland) Regulations 2016 which enforce the provisions of Regulation (EU) 609/2013 of the European Parliament and of the Council on the provisions of food intended for infants and young children, food for special medical purposes and total diet replacement for weight control.

In addition, regulation 2 amends the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997, to remove redundant text in respect of labelling requirements.

A full business and regulatory impact assessment of the effect these Regulations will have on the costs for the business sector has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL.