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SCOTTISH STATUTORY INSTRUMENTS

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**2020 No. 7**

**FOOD**

**The Foods for Specific Groups (Medical Foods for Infants) and Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2020**

*Made* - - - - 14th January 2020  
*Laid before the Scottish Parliament* - - - - 15th January 2020  
*Coming into force* - - 22nd February 2020

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990(1) and section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972(2) and all other powers enabling them to do so.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for certain references in these Regulations to provisions of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods(3), of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39 of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009

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- (1) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c.40), schedule 9, paragraph 6, the Food Standards Act 1999 (c.28) (“the 1999 Act”), schedule 5, paragraph 10(1) and (3) and S.I. 2002/794. Sections 16(1) and 48(1) were amended by the 1999 Act, schedule 5, paragraph 8 and section 16(1) was also amended by the Food (Scotland) Act 2015 (asp 1) (“the 2015 Act”), section 34(1). Section 17(1) and (2) was amended by the 1999 Act, schedule 5, paragraphs 8 and 12 and S.I. 2011/1043. Section 26(3) was partially repealed by the 1999 Act, schedule 6, paragraph 1. Amendments made by schedule 5 of the 1999 Act are to be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) 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 S.I. 2005/849.
- (2) 1972 c.68 (“the 1972 Act”). Section 2(2) was amended by the Scotland Act 1998 (c.46) (“the 1998 Act”), schedule 8, paragraph 15(3) (which was amended by section 27(4) of the Legislative and Regulatory Reform Act 2006 (c.51) (“the 2006 Act”). Section 2(2) was also amended by the 2006 Act, section 27(1)(a) and by the European Union (Amendment) Act 2008 (c.7) (“the 2008 Act”), section 3(3) and schedule 1, Part 1. The functions conferred upon the Minister of the Crown under section 2(2), insofar as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. Paragraph 1A of schedule 2 was inserted by section 28 of the 2006 Act and was amended by the 2008 Act, schedule 1, Part 1. The 1972 Act is prospectively repealed by section 1 of the European Union (Withdrawal) Act 2018 (c.16) from exit day (see section 20 of that Act).
- (3) OJ L 404, 30.12.2006, p.26, as last amended by Commission Regulation (EU) 2019/650 (OJ L 110, 25.4.2019, p.21).

and (EC) No 953/2009(4) and of 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(5) to be construed as references to those provisions as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990(6), the Scottish Ministers have had regard to 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(7).

### **Citation and commencement**

1. These Regulations may be cited as the Foods for Specific Groups (Medical Foods for Infants) and Addition of Vitamins, Minerals and Other Substances (Scotland) Amendment Regulations 2020 and come into force on 22February 2020.

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

2. Schedule 1 has effect.

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

3.—(1) The Addition of Vitamins, Minerals and Other Substances (Scotland) Regulations 2007(8) are amended as follows.

(2) In regulation 2(1) (interpretation), in the definition of “the EC Regulation”, for “I or II”, substitute “I, II or III”.

(3) In regulation 4(2) (offences and penalties)—

(a) at the end of sub-paragraph (d), omit “and”,

(b) after sub-paragraph (e), insert—

“(f) Article 8(2)(a)(i) (prohibition of the addition of a substance listed in Annex III, Part A to foods or its use in the manufacture of foods), and

(g) Article (8)(2)(a)(ii) (prohibition of the addition of a substance listed in Annex III, Part B to foods or its use in the manufacture of foods, unless that substance is added or used in accordance with the conditions specified in that Part).”.

### **Revocations and saving**

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

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(4) OJ L 181, 29.6.2013, p.53, as amended by Commission Delegated Regulation (EU) 2017/1091 (OJ L 158, 21.6.2017, p.5).

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

(6) Section 48(4A) was inserted by the Food Standards Act 1999, schedule 5, paragraph 21. Section 48(6) was added by the Food (Scotland) Act 2015, schedule 1, paragraph 3(11). By virtue of section 48(6), in the application of section 48 to Scotland, references to the “Food Standards Agency” are to be read as references to “Food Standards Scotland”.

(7) OJ L 31, 1.2.2002, p.1, as last amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council (OJ L 198, 25.7.2019, p.241).

(8) S.S.I. 2007/325, as amended by S.S.I. 2010/308 and S.S.I. 2014/312.

(2) The instruments specified in column 1 of the table in schedule 2 continue to have effect (so far as otherwise revoked to the extent specified in column 3 of that table) for the purposes of regulation 4A of the Foods for Specific Groups (Scotland) Regulations 2016<sup>(9)</sup>.

St Andrew's House,  
Edinburgh  
14th January 2020

*JOE FITZPATRICK*  
Authorised to sign by the Scottish Ministers

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<sup>(9)</sup> [S.S.I. 2016/190](#), as amended by [S.S.I. 2018/392](#). Regulation 4A is inserted by paragraph 1(3) of schedule 1 of these Regulations.

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SCHEDULE 1

Regulation 2

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

- 1.—(1) The Foods for Specific Groups (Scotland) Regulations 2016 are amended as follows.
- (2) In regulation 4(1) (offences and penalties), for “A person” substitute “Subject to regulation 4A, a person”.
- (3) After regulation 4, insert—

**“Transitional Provision**

**4A.** A person is not guilty of an offence under regulation 4(1) if they continue to market food for special medical purposes which does not comply with a provision of the Delegated Regulation specified in schedule 1, provided that—

- (a) it complies with the requirements 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 of the Foods for Special Medical Purposes (Scotland) Regulations 2000 are met.”.
- (4) In schedule 1 (specified EU requirements)**(10)**—
- (a) in the part of the table relating to the EU Regulation—
    - (i) omit the entry relating to Article 4(1) (requirement for placing food on the market),
    - (ii) omit the entry relating to Article 9(3) (requirement for substances added to food), and
    - (iii) insert, at the end—

“Article 15(1) (Union list)	Article 1(1)(a) and (c) and Articles 4(1) and 15(3) and the Annex, insofar as they apply to infant formula and follow-on formula and food for special medical purposes”.
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- (b) for the part of the table relating to the Delegated Regulation substitute—

<i>“Specified provision of the Delegated Regulation</i>	<i>Provisions of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i>
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Article 2(2) (requirement for the formulation of food for special medical purposes to be based on sound medical and nutritional principles)

Article 1

The first sub-paragraph of Article 2(3) (requirement for food for special medical purposes developed to satisfy the nutritional requirements of infants to comply with the

Articles 1 and 2(4) and Part A of Annex I

**(10)** The table in schedule 1 was substituted by [S.S.I. 2018/392](#).

<i>“Specified provision of the Delegated Regulation</i>	<i>Provisions of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i>
compositional requirements in Part A of Annex I)	
The second sub-paragraph 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 I)	Articles 1 and 2(4) and Part B of Annex I
Article 3(2) (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)
Article 3(3) (maximum residue levels for substances listed in Annex II)	Articles 1 and 3(1) and (5) and Annex II
Article 3(4) (requirements on plant protection products)	Articles 1 and 3(1), (5) and Annex III
Article 4 (name of the food)	Article 1 and Annex IV
Article 5(1) (requirement for food for special medical purposes to comply with Regulation (EU) No 1169/2011 <sup>(11)</sup> unless otherwise specified)	Articles 1 and 5(2)
Article 5(2) (additional mandatory particulars)	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(1) (mandatory nutrition declaration)	Articles 1 and 6(3)
Article 6(2) (prohibition of repetition of information)	Article 1
Article 6(4) (application of articles 31 to 35 of Regulation (EU) No 1169/2011)	Articles 1 and 6(3) and (5)
Article 6(5) (energy value and amount of nutrients of food for special medical purposes)	Articles 1 and 6(4)
Article 6(6) (prohibition of expressing energy value and amount of nutrients as a percentage of reference intakes)	Articles 1 and 6(4)

<sup>(11)</sup> 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 (O.J. No. L 304, 22.11.2011, p.18).

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<i>“Specified provision of the Delegated Regulation</i>	<i>Provisions of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i>
The first sub-paragraph of Article 6(7) (presentation of nutrition declaration particulars)	Articles 1 and 6(4)
The second sub-paragraph of Article 6(7) (placement of nutrition declaration particulars)	Articles 1 and 6(4)
The third sub-paragraph of Article 6(7) (indication of amount of sodium)	Articles 1 and 6(4)
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 sub-paragraph 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-paragraph of Article 8(4) (restriction on publication)	Article 1 and the third 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”.

## SCHEDULE 2

Regulation 4

## Revocations

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
<i>Instrument</i>	<i>Reference</i>	<i>Extent of revocation</i>
The Foods for Special Medical Purposes (Scotland) Regulations 2000	<a href="#">S.S.I. 2000/130</a>	The whole Regulations
The Infant Formula and Follow-on Formula (Scotland) Regulations 2007	<a href="#">S.S.I. 2007/549</a>	Regulation 30
The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008	<a href="#">S.S.I. 2008/322</a>	Regulation 3
The Food (Scotland) Act 2015 (Consequential and Transitional Provisions) Order 2015	<a href="#">S.S.I. 2015/100</a>	Paragraph 7 of the schedule

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<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
<i>Instrument</i>	<i>Reference</i>	<i>Extent of revocation</i>
The Foods for Specific Groups (Medical Foods) (Miscellaneous Amendments) (Scotland) Regulations 2018	<a href="#">S.S.I. 2018/392</a>	Regulation 3(2)

## EXPLANATORY NOTE

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

These Regulations are made in consequence of the entry into force of new requirements in Commission Delegated Regulation (EU) 2016/128 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (“the Delegated Regulation”) on 22 February 2020.

Regulation 2 introduces schedule 1 of these Regulations, which amends the Foods for Specific Groups (Scotland) Regulations 2016 (“the 2016 Regulations”) to include reference to provisions of the Delegated Regulation which relate to food for special medical purposes developed to satisfy the nutritional requirements of infants. The amendments made by these Regulations to schedule 1 of the 2016 Regulations have the effect that it becomes a criminal offence not to comply with the requirements of the Delegated Regulation when such food is placed on the market, except where transitional arrangements apply.

The relevant transitional arrangements are inserted into the 2016 Regulations by paragraph 1(3) of schedule 1. These ensure that stocks of food for special medical purposes which were labelled or placed on the market prior to the date of application of provisions of the Delegated Regulation can continue to be marketed until those stocks are exhausted.

Schedule 1 of these Regulations also amends references in schedule 1 of the 2016 Regulations to provisions of Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. It will become a criminal offence to contravene article 15(1) of the EU Regulation (Union list), but will no longer be a criminal offence to breach article 4(1) (placing on the market) of that Regulation alone.

Regulation 3 amends the Vitamins, Minerals and Other Substances (Scotland) Regulations 2007 (“the 2007 Regulations”). Regulation 3(2) ensures that the definition of “the EC Regulation” includes a reference to, as it may be amended from time to time, Annex 3 of Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. Regulation 3(3) amends the 2007 Regulations with the effect that it becomes an offence to add a substance listed in Part A of Annex III of the EC Regulation to foods, or to use such a substance in the manufacture of foods. It also becomes an offence to add a substance listed in Part B of Annex III of the EC Regulation to foods, or to use such a substance in the manufacture of foods, unless that substance is added or used in accordance with the conditions specified in that Part.

Regulation 4 introduces the revocations in schedule 2, which relate to the Foods for Special Medical Purposes (Scotland) Regulations 2000 (“the 2000 Regulations”) and provisions which amend them. The 2000 Regulations implement Commission [Directive 1999/21/EC](#) on dietary foods for special

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medical purposes in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants. [Directive 1999/21/EC](#) applies until 21 February 2020 in respect of such foods and thereafter is repealed by article 10 of the Delegated Regulation.