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SCOTTISH STATUTORY INSTRUMENTS

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**2020 No. 6**

**FOOD**

**The Foods for Specific Groups (Infant Formula and  
Follow-on Formula) (Scotland) Regulations 2020**

*Made - - - - 14th January 2020*  
*Laid before the Scottish*  
*Parliament - - - - 15th January 2020*  
*Coming into force in accordance with regulation 1*

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<sup>(1)</sup> and section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972<sup>(2)</sup> 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 (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 and (EC) No. 953/2009<sup>(3)</sup> and of Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and

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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 (a) 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 Section 26(3) was partially repealed by the 1999 Act, schedule 6, paragraph 1.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 181, 29.6.2013, p.53, as amended by Commission Delegated Regulation (EU) 2017/1091 (OJ L 158, 21.6.2017, p.5).

follow-on formula and as regards requirements on information relating to infant and young child feeding<sup>(4)</sup> 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<sup>(5)</sup>, 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<sup>(6)</sup>.

### **Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 and come into force on 22 February 2020, except where paragraph (2) applies.

(2) Regulations 2 to 5 come into force on 22 February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates.

(3) These Regulations extend to Scotland only.

### **Interpretation**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990,

“the Delegated Regulation” means Commission Delegated Regulation (EU) 2016/127 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 infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding,

“the EU Regulation” means 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 and (EC) No 953/2009,

“specified EU law requirement” means any provision of the Delegated Regulation specified in column 1 of the table in schedule 1, as read with the provisions specified in the corresponding entry in column 2 of that table.

(2) Any reference to a provision of the Delegated Regulation is a reference to that provision as amended from time to time.

(3) Expressions defined in Article 2 of the EU Regulation have the same meaning in these Regulations as they have in that Regulation.

(4) OJ L 25, 2.2.2016, p.1, as last amended by Commission Delegated Regulation (EU) 2019/828 (OJ L 137, 23.5.2019, p.12).

(5) Section 48(4A) was inserted by the 1999 Act, schedule 5, paragraph 21.

(6) 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).

## **Enforcement**

3. Each food authority must enforce and execute these Regulations within its area.

## **Offences and penalties**

4.—(1) Subject to regulation 6(3), a person is commits an offence if they fail to comply with any specified EU law requirement.

(2) A person who commits an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

## **Application of provisions of the Act**

5. The provisions of the Act specified in column 1 of the table in schedule 2 apply, with the modifications specified in column 2 of that table, for the purposes of these Regulations.

## **Revocations, savings and transitional provisions**

6.—(1) The instruments specified in column 1 of the table in schedule 3 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 schedule 3 continue to have effect (so far as otherwise revoked to the extent specified in column 3 of that table)—

- (a) until 21 February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates, and
- (b) for the purposes of paragraph 3.

(3) A person does not commit an offence under regulation 4(1) if they continue to market infant formula or follow-on formula which does not comply with a specified EU law requirement, provided that—

- (a) it was placed on the market or labelled—
  - (i) before 22 February 2020, or
  - (ii) before 22 February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates, and
- (b) the conditions specified in the following provision of the Infant Formula and Follow-on Formula (Scotland) Regulations 2007<sup>(7)</sup> are met—
  - (i) regulation 3(1) in the case of infant formula,
  - (ii) regulation 3(2) in the case of follow-on formula.

## **Consequential amendment**

7.—(1) The Welfare Foods (Best Start Foods) (Scotland) Regulations 2019<sup>(8)</sup> are amended as follows.

(2) In paragraph 1 of schedule 1, omit “,which meets the requirements of the Infant and Follow-on Formula (Scotland) Regulations 2007 or the Infant Formula and Follow-on Formula (England) Regulations 2007”.

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<sup>(7)</sup> S.S.I. 2007/549, as modified by S.S.I. 2008/322, S.I. 2011/1043, S.S.I. 2014/12, S.S.I. 2015/100 and S.S.I. 2016/190.

<sup>(8)</sup> S.S.I. 2019/193, as amended by S.S.I. 2019/232.

St Andrew's House,  
Edinburgh  
14th January 2020

*JOE FITZPATRICK*  
Authorised to sign by the Scottish Ministers

## SCHEDULE 1

Regulation 2(1)

## Specified EU law requirements

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Delegated Regulation</i>	<i>Provision of the Delegated Regulation to be read with the provision of the Delegated Regulation specified in column 1</i>
Article 1(2) (placing on the market)	Article 1(1)
Article 2(1) (compositional requirements for infant formula)	Articles 1(1) and 2(3), Annex I and Annex III
Article 2(2) (compositional requirements for follow-on formula)	Articles 1(1) and 2(3), Annex II and Annex III
Article 2(3) (preparation of infant and follow-on formula)	Articles 1(1) and 2(1) and (2)
Article 3(1) (suitability of ingredients for infant formula)	Articles 1(1) and 3(3) and point 2 of Annex I
Article 3(2) (suitability of ingredients for follow-on formula)	Articles 1(1) and 3(3) and point 2 of Annex II
Article 4(2) (active substance residue threshold)	Articles 1(1) and 4(1), (3) and (5)
Article 4(3) (derogation from active substance residue threshold)	Articles 1(1) and 4(1), (2) and (5)
Article 4(4) (requirements on pesticides)	Articles 1(1) and 4(1) and (5)
Article 5(1) (name of food not manufactured entirely from cows' or goats' milk proteins)	Article 1(1) and Part A of Annex VI
Article 5(2) (name of food manufactured entirely from cows' or goats' milk proteins)	Article 1(1) and Part B of Annex VI
Article 6(1) (requirement for infant formula and follow-on formula to comply with Regulation (EU) No. 1169/2011 <sup>(9)</sup> unless otherwise provided for)	Articles 1(1), 6(2), (3), and (4) and 7(1), (2), (3), (5), (6), (7) and (8)
Article 6(2) (additional mandatory particulars for infant formula)	Articles 1(1) and 6(1) and (4)
Article 6(3) (additional mandatory particulars for follow-on formula)	Articles 1(1) and 6(1) and (4)
Article 6(4) (application of articles 13(2) and (3) of Regulation (EU) No. 1169/2011 to additional mandatory particulars)	Articles 1(1) and 6(2) and (3)

(9) 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 (OJ L 304, 22.11.2011, p.18).

*Status: This is the original version (as it was originally made).*

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Delegated Regulation</i>	<i>Provision of the Delegated Regulation to be read with the provision of the Delegated Regulation specified in column 1</i>
Article 6(5) (requirement for mandatory particulars to be in a language easily understood by consumers)	Article 1(1)
Article 6(6) (requirements on labelling, presentation and advertising of infant formula and follow-on formula)	Article 1(1)
Article 7(1) (specific requirements on the nutrition declaration)	Articles 1(1) and 7(4), Annex I and Annex II
Article 7(3) (repetition of information included in mandatory nutrition declaration)	Articles 1(1) and 7(1)
Article 7(5) (application of articles 31 to 35 of Regulation (EU) No 1169/2011)	Articles 1(1) and 7(6), (7) and (8)
Article 7(6) (expression of energy value and amounts of nutrients)	Articles 1(1) and 7(5)
The first subparagraph of Article 7(7) (prohibition on expressing energy value and amount of nutrients as a percentage of reference intake)	Articles 1(1) and 7(5)
Article 7(8) (presentation of particulars included in the nutrition declaration)	Article 1(1)
Article 8 (prohibition on making health claims on infant formula)	Article 1(1)
Article 9(1) (“lactose only” statement)	Article 1(1)
The first subparagraph of Article 9(2) (“lactose free” statement)	Article 1(1)
The second subparagraph of Article 9(2), (statement that lactose free infant formula and follow-on formula is not suitable for infants with galactosaemia)	Article 1(1)
Article 9(3) (prohibition on references to decosahexaenoic acid where infant formula placed on the market on or after 22 February 2025)	Article 1(1)
The first subparagraph of article 10(1) (restriction on advertising for infant formula)	Article 1(1)
Article 10(2) (prohibition of promotional devices to induce sales of infant formula)	Article 1(1)
Article 10(3) (prohibition of provision of free or low-priced products, samples or other promotional gifts to the general public, pregnant women, mothers or members of their families)	Article 1(1)

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Delegated Regulation</i>	<i>Provision of the Delegated Regulation to be read with the provision of the Delegated Regulation specified in column 1</i>
Article 10(4) (requirements for donations or low-priced sales of supplies of infant formula to institutions or organisations)	Article 1(1)
Article 11(2) (requirements on information relating to infant and young child feeding)	
Article 11(3) (requirements on donations of informational or educational equipment or materials)	
Article 12 (notification requirements)	Article 1(1)

## SCHEDULE 2

Regulation 5

## Modification of provisions of the Act

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
Section 3 (presumptions that food intended for human consumption)	In sub-section (1), for “this Act” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 20 (offences due to fault of another person)	For “any of the preceding provisions of this Part” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 21 (defence of due diligence)	In sub-section (1), for “any of the preceding provisions of this Part” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 22 (defence of publication in the course of business)	In sub-section (1), for “any of the preceding provisions of this Part” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 29 (procurement of samples)	In paragraph (b)(ii), after “under section 32 below”, insert “including under section 32 as applied and modified by regulation 5 and schedule 2 of the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 30 (analysis etc. of samples)	In sub-section (1), after “under section 29 above”, insert “including under section 29 as applied and modified by regulation 5 and schedule 2 of the Foods for Specific Groups

**Status:** This is the original version (as it was originally made).

<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
	(Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
	In sub-section (8), for “this Act” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 32 (powers of entry)	In sub-section (1), for paragraphs (a) to (c) substitute “(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of a specified EU law requirement (as defined in regulation 2 of the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020), (b) to enter any business premises, whether within or outside the authority’s area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of such a requirement, and (c) when exercising a power of entry under this section, to exercise the associated powers in sub-sections (5) and (6) relating to records”.
Section 33 (obstruction etc. of officers)	In sub-section (1), for “this Act” (in each place where it occurs) substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 35 (punishment of offences)	In sub-section (1), after “section 33(1) above” insert “including as applied and modified by regulation 5 and schedule 2 of the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
	In sub-section (2), for “any other offence under this Act” substitute “an offence under section 33(2) above, as applied and modified by regulation 5 and schedule 2 of the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 36 (offences by bodies corporate)	In sub-section (1), for “this Act” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 36A (offences by Scottish partnerships)	For “this Act” substitute “the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020”.
Section 44 (protection of officers acting in good faith)	Where it first appears, for “this Act” substitute “the Foods for Specific Groups (Infant Formula



<i>Column 1</i>	<i>Column 2</i>
<i>Provision of the Act</i>	<i>Modifications</i>
	and Follow-on Formula) (Scotland) Regulations 2020 (“the 2020 Regulations”).
	On each other occasion where it appears, for “this Act” substitute “the 2020 Regulations”.

## SCHEDULE 3

Regulation 6(1)

## 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 Infant Formula and Follow-on Formula (Scotland) Regulations 2007	<a href="#">S.S.I. 2007/549</a>	The whole Regulations, except regulation 30
The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008	<a href="#">S.S.I. 2008/322</a>	Regulation 2
The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014	<a href="#">S.S.I. 2014/12</a>	The whole Regulations
The Food (Scotland) Act 2015 (Consequential and Transitional Provisions) Order 2015	<a href="#">S.S.I. 2015/100</a>	Paragraph 19 of the schedule

## EXPLANATORY NOTE

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

These Regulations, which extend to Scotland only, make provision to enforce Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (“the Delegated Regulation”).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 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.

Definitions of expressions used in the Delegated Regulation are contained in Article 2 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 (“the EU Regulation”). Expressions used in these Regulations which are defined in Article 2 of the EU Regulation are to be construed in accordance with the definitions in that Article, as it is amended from time to time.

Regulation 3 outlines that each food authority must execute and enforce these Regulations within its area. A “food authority” in relation to Scotland is defined in section 5(2) of the Food Safety Act 1990 (c.16) as a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994 (c.39).

Regulation 4 provides that subject to transitional arrangements, it is an offence under these Regulations to fail to comply with any of the requirements of the Delegated Regulation which are specified in column 1 of the table in schedule 1. Regulation 4 also provides the penalty for breaching any of these requirements.

Regulation 5 introduces schedule 2, which applies provisions of the Food Safety Act 1990 for the purposes of these Regulations.

Regulation 6 outlines transitional arrangements, whereby infant formula or follow-on formula which has been placed on the market or labelled prior to the date of application of the Delegated Regulation (22 February 2020 or, in the case of infant formula or follow-on formula manufactured from protein hydrolysates, 22 February 2021) can continue to be marketed until stocks are exhausted, provided that certain requirements are met.

Regulation 6 and schedule 2 provide for revocations in consequence of these Regulations.

Regulation 7 makes an amendment which arises as a consequence of those revocations.