

SCOTTISH STATUTORY INSTRUMENTS

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 ^{F1} and section 2(2) and paragraph 1A of schedule 2 of the European Communities Act 1972 ^{F2} 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^{F3} 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 follow-on formula and as regards requirements on information relating to infant and young child feeding^{F4} 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 ^{F5}, 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^{F6}.

F1 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

*Status: Point in time view as at 26/03/2021.***Changes to legislation:** *There are currently no known outstanding effects for the The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020. (See end of Document for details)*

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](#).

- F2** [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).
- F3** 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).
- F4** 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).
- F5** Section 48(4A) was inserted by the 1999 Act, schedule 5, paragraph 21.
- F6** 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).

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.

Commencement Information

- II** Reg. 1 in force at 22.2.2020, see reg. 1(1)

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.

Commencement Information

- I2** Reg. 2 in force at 22.2.2020 for specified purposes, see reg. 1(1)
I3 Reg. 2 in force at 22.2.2021 in so far as not already in force, see reg. 1(2)

Enforcement

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

Commencement Information

- I4** Reg. 3 in force at 22.2.2020 for specified purposes, see reg. 1(1)
I5 Reg. 3 in force at 22.2.2021 in so far as not already in force, see reg. 1(2)

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.

Commencement Information

- I6** Reg. 4 in force at 22.2.2020 for specified purposes, see reg. 1(1)
I7 Reg. 4 in force at 22.2.2021 in so far as not already in force, see reg. 1(2)

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.

Commencement Information

- I8** Reg. 5 in force at 22.2.2020 for specified purposes, see reg. 1(1)
I9 Reg. 5 in force at 22.2.2021 in so far as not already in force, see reg. 1(2)

*Status: Point in time view as at 26/03/2021.**Changes to legislation: There are currently no known outstanding effects for the The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020. (See end of Document for details)***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 ^{F7} are met—
 - (i) regulation 3(1) in the case of infant formula,
 - (ii) regulation 3(2) in the case of follow-on formula.

[^{F8}(4) Regulations 2 to 5 do not apply in respect of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.

(5) Schedule 4 makes provision in relation to infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.]

F7 [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](#).

F8 [Reg. 6\(4\)\(5\) inserted \(26.3.2021\) by The Foods for Specific Groups \(Infant Formula and Follow-on Formula\) \(Scotland\) Amendment Regulations 2021 \(S.S.I. 2021/123\), regs. 1, 2\(2\)](#)

Commencement Information

I10 Reg. 6 in force at 22.2.2020, see reg. 1(1)

Consequential amendment

7.—(1) The Welfare Foods (Best Start Foods) (Scotland) Regulations 2019 ^{F9} 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”.

F9 [S.S.I. 2019/193](#), as amended by [S.S.I. 2019/232](#).

Commencement Information

I11 Reg. 7 in force at 22.2.2020, see reg. 1(1)

St Andrew's House,
Edinburgh

JOE FITZPATRICK
Authorised to sign by the Scottish Ministers

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SCHEDULE 1

Regulation 2(1)

Specified EU law requirements

Commencement Information**I12** Sch. 1 in force at 22.2.2020, see reg. 1(1)

<i>Column 1</i> <i>Provision of the Delegated Regulation</i>	<i>Column 2</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
F10	Articles 1(1), 6(2), (3), and (4) and 7(1), (2), (3), (5), (6), (7) and (8)
Article 6(1) (requirement for infant formula and follow-on formula to comply with Regulation (EU) No. 1169/2011 unless otherwise provided for)	
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)

Article 6(5) (requirement for mandatory Article 1(1)
particulars to be in a language easily understood
by consumers)

Article 6(6) (requirements on labelling, Article 1(1)
presentation and advertising of infant formula
and follow-on formula)

Article 7(1) (specific requirements on the Articles 1(1) and 7(4), Annex I and Annex II
nutrition declaration)

Article 7(3) (repetition of information included Articles 1(1) and 7(1)
in mandatory nutrition declaration)

Article 7(5) (application of articles 31 to 35 of Articles 1(1) and 7(6), (7) and (8)
Regulation (EU) No 1169/2011)

Article 7(6) (expression of energy value and Articles 1(1) and 7(5)
amounts of nutrients)

The first subparagraph of Article 7(7) Articles 1(1) and 7(5)
(prohibition on expressing energy value and
amount of nutrients as a percentage of reference
intake)

Article 7(8) (presentation of particulars included Article 1(1)
in the nutrition declaration)

Article 8 (prohibition on making health claims Article 1(1)
on infant formula)

Article 9(1) (“lactose only” statement) Article 1(1)

The first subparagraph of Article 9(2) (“lactose Article 1(1)
free” statement)

The second subparagraph of Article 9(2), Article 1(1)
(statement that lactose free infant formula and
follow-on formula is not suitable for infants with
galactosaemia)

Article 9(3) (prohibition on references to Article 1(1)
decosahexaenoic acid where infant formula
placed on the market on or after 22 February
2025)

The first subparagraph of article 10(1) Article 1(1)
(restriction on advertising for infant formula)

Article 10(2) (prohibition of promotional Article 1(1)
devices to induce sales of infant formula)

Article 10(3) (prohibition of provision of Article 1(1)
free or low-priced products, samples or other
promotional gifts to the general public, pregnant
women, mothers or members of their families)

Article 10(4) (requirements for donations or low- Article 1(1)
priced sales of supplies of infant formula to
institutions or organisations)

Status: Point in time view as at 26/03/2021.**Changes to legislation:** There are currently no known outstanding effects for the The Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020. (See end of Document for details)

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)

F10 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).

SCHEDULE 2

Regulation 5

Modification of provisions of the Act

Commencement Information

I13 Sch. 2 in force at 22.2.2020, see reg. 1(1)

<i>Column 1</i> <i>Provision of the Act</i>	<i>Column 2</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)	<p>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 (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 ”.</p> <p>In sub-section (8), for “this Act” substitute “ the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 ”.</p>
Section 32 (powers of entry)	<p>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 ”.</p>
Section 33 (obstruction etc. of officers)	<p>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 ”.</p>
Section 35 (punishment of offences)	<p>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 ”.</p> <p>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 ”.</p>
Section 36 (offences by bodies corporate)	<p>In sub-section (1), for “this Act” substitute “ the Foods for Specific Groups (Infant Formula and Follow-on Formula) (Scotland) Regulations 2020 ”.</p>

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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 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

Commencement Information**I14** Sch. 3 in force at 22.2.2020, see reg. 1(1)

Column 1 Instrument	Column 2 Reference	Column 3 Extent of revocation
The Infant Formula and Follow-on Formula (Scotland) Regulations 2007	S.S.I. 2007/549	The whole Regulations, except regulation 30
The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2008	S.S.I. 2008/322	Regulation 2
The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014	S.S.I. 2014/12	The whole Regulations
The Food (Scotland) Act 2015 (Consequential and Transitional Provisions) Order 2015	S.S.I. 2015/100	Paragraph 19 of the schedule

[^{F11}SCHEDULE 4

Regulation 6(5)

Regulation of infant formula and follow-on formula
manufactured from protein hydrolysates until 22 February 2022

F11 Sch. 4 inserted (26.3.2021) by [The Foods for Specific Groups \(Infant Formula and Follow-on Formula\) \(Scotland\) Amendment Regulations 2021 \(S.S.I. 2021/123\)](#), reg. 1, [sch.](#)

Interpretation

1.—(1) In this schedule—

“the Act” means the Food Safety Act 1990,

“the Directive” means Commission [Directive 2006/141/EC](#) on infant formulae and follow-on formulae and amending [Directive 1999/21/EC](#),

“follow-on formula” means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants,

“health care system” means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child care institutions and health workers in private practice,

“infants” means children under the age of 12 months,

“infant formula” means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding,

“young children” means children aged between one and three years.

(2) Subject to sub-paragraph (3), any expression other than one defined in sub-paragraph (1) that is used both in this schedule and in the Act has the meaning it bears in the Act.

(3) Any expression used both in this schedule and in the Directive has the meaning that it bears in the Directive.

(4) In this schedule any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met

2.—(1) It is an offence for a person to market infant formula which contravenes or fails to comply with paragraphs 4, 5, 7, 9, 10, 11, 13(1), (2) or (3), 14, 16, 18 or 19(1).

(2) It is an offence for a person to market follow-on formula which contravenes or fails to comply with paragraphs 4, 6, 8, 9, 10, 11, 13(1), (2) or (3), 15, 17, 18 or 19(2).

Prohibition on the marketing of products other than infant formula for normal healthy infants

3. It is an offence to market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.

Substances in such quantity as to endanger the health of infants and young children

4. Infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children.

Protein hydrolysates and other food ingredients suitable for infants from birth (infant formula)

5.—(1) Infant formula must be manufactured from —

(a) protein hydrolysates, and

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- (b) other food ingredients the suitability of which for particular nutritional use by infants from birth has been established by generally accepted scientific data and demonstrated in accordance with sub-paragraph (2).

(2) Suitability is to be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Protein hydrolysates and other food ingredients suitable for infants aged over six months (follow-on formula)

6. Follow-on formula must be manufactured from—
 - (a) protein hydrolysates, and
 - (b) other food ingredients the suitability of which for particular nutritional use by infants aged over 6 months has been established by generally accepted scientific data and demonstrated in accordance with paragraph 5(2).

Compositional criteria for infant formula

7.—(1) Subject to sub-paragraph (2), infant formula must comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

(2) In the case of infant formula manufactured from protein hydrolysates specified in point 2.2 of Annex I with a protein content between the minimum and 0.56g/100kJ (2.25g/100 kcal)—

- (a) the suitability of the infant formula for the particular nutritional use by infants must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies, and
- (b) the infant formula must be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

8.—(1) Subject to sub-paragraph (2), follow-on formula must comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.

(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kJ (2.25g/100kcal) —

- (a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies, and
- (b) the follow-on formula must be in accordance with the appropriate specifications set out in Annex VI.

Addition of water (infant formula and follow-on formula)

9. In order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water.

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula)

10. The prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula, set out respectively in Annexes I and II, must be observed.

Listed substances and their purity criteria (infant formula and follow-on formula)

11.—(1) Only the substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula in order to satisfy the requirements of Annexes I and II respectively on—

- (a) mineral substances,
- (b) vitamins,
- (c) amino acids and other nitrogen compounds, and
- (d) other substances having a particular nutritional purpose.

(2) Substances used in the manufacture of infant formula and follow-on formula pursuant to sub-paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of sub-paragraph (2) are—

- (a) the purity criteria for substances, as provided for in Retained EU law concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive, and
- (b) in the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Notification of infant formula

12. No food business operator may place an infant formula on the market in Scotland that has not yet been placed on the market in the United Kingdom unless the food business operator has notified Food Standards Scotland by forwarding to it a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

13.—(1) Subject to sub-paragraphs (2) and (3), infant formula and follow-on formula must not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

(3) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Annex IX at a level exceeding the maximum residue level specified in that Annex.

(4) The levels referred to in sub-paragraphs (1) to (3) apply to the infant formula or follow-on formula—

- (a) manufactured in a form that is ready for consumption, or
- (b) if it is not so manufactured, as reconstituted according to the manufacturers' instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this paragraph is to be generally acceptable standardised methods.

Naming of infant formula

14. Infant formula must not be sold unless it is sold under the name “infant formula”.

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Naming of follow-on formula

15. Follow-on formula must not be sold unless it is sold under the name “follow-on formula”.

Labelling of infant formula

16.—(1) Infant formula must not be sold unless the labelling bears—

- (a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed,
- (b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,
- (c) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use,
- (d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage, and
- (e) the words “Important Notice” or their equivalent immediately followed by—
 - (i) a statement concerning the superiority of breast feeding, and
 - (ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(2) The labelling of infant formula must—

- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding, and
- (b) not contain the terms “humanised”, “maternalised”, “adapted” or any similar term.

(3) The labelling of an infant formula must not include—

- (a) any picture of an infant, or
- (b) any other picture or text which may idealise the use of the product,

but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

(4) The labelling of an infant formula may bear nutrition and health claims only when—

- (a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there, and
- (b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.

(5) The labelling of an infant formula may bear the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula

17.—(1) Follow-on formula must not be sold unless the labelling bears—

- (a) a statement to the effect that—
 - (i) the product is suitable only for particular nutritional use by infants over the age of 6 months,
 - (ii) it should form only part of a diversified diet,

- (iii) it is not to be used as a substitute for breast milk during the first 6 months of life, and
 - (iv) the decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before 6 months of age should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant's specific growth and development needs,
 - (b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,
 - (c) the average quantity of each mineral substance and of each vitamin mentioned in Annex II and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use,
 - (d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.
- (2) The labelling of follow-on formula must—
- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding, and
 - (b) not contain the terms “humanised”, “maternalised”, “adapted” or any similar term.
- (3) The labelling of a follow-on formula may bear—
- (a) the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use, and
 - (b) in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given in that Annex, per 100ml of the product ready for use.

Avoidance of the risk of confusion between infant formula and follow-on formula

18. Infant formula and follow-on formula must be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula.

Presentation (infant formula and follow-on formula)

19.—(1) The presentation of infant formula must comply with the provisions of paragraphs 16(1) (e), (2), (3) and (4) and 18.

(2) The presentation of follow-on formula must comply with the provisions of paragraphs 17(2) and 18.

(3) For the purposes of this paragraph presentation includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Restrictions on advertising infant formula

20.—(1) It is an offence to advertise infant formula—

- (a) except—
 - (i) in a scientific publication, or

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- (ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public, and
- (b) unless the advertisement complies with the provisions of paragraphs 16(1)(e), (2), (3) and (4), paragraph 18 and sub-paragraphs (2) and (3).
- (2) Advertisements for infant formula must only contain information of a scientific and factual nature.
- (3) Information in advertisements for infant formula must not imply or create a belief that bottle feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

21. It is an offence to advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions set out in paragraphs 17(2) and 18, in so far as they are relevant to follow-on formula.

Restrictions on promotion of infant formula

- 22.—**(1) It is an offence at any place where any infant formula is sold by retail to—
- (a) advertise any infant formula,
 - (b) make any special display of an infant formula designed to promote sales,
 - (c) give away—
 - (i) any infant formula as a free sample, or
 - (ii) any coupon which may be used to purchase an infant formula at a discount,
 - (d) promote the sale of an infant formula by means of premiums, special sales, loss-leaders or tie-in sales, or
 - (e) undertake any other promotional activity to induce the sale of an infant formula.
- (2) It is an offence for a manufacturer or distributor of any infant formula to provide for promotional purposes any infant formula free or at a reduced or discounted price, samples or any gift designed to promote the sale of an infant formula, to—
- (a) the general public,
 - (b) pregnant women,
 - (c) mothers, or
 - (d) members of the families of persons mentioned in subparagraphs (b) and (c),
- either directly, or indirectly through the health care system or health workers.

Provision of informational and educational material dealing with the feeding of infants

23.—(1) It is an offence to produce or publish any informational or educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless that material includes clear information on all the following points—

- (a) the benefits and superiority of breast feeding,
- (b) maternal nutrition,
- (c) the preparation for and the maintenance of breast feeding,
- (d) the possible negative effect on breast feeding of introducing partial bottle feeding,
- (e) the difficulty of reversing the decision not to breast feed, and

- (f) where needed, the proper use of an infant formula.
- (2) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must include information about—
 - (a) the social and financial implications of its use,
 - (b) the health hazards of inappropriate foods or feeding methods, and
 - (c) the health hazards of improper use of infant formula.
- (3) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must not use any pictures which may idealise the use of infant formula.
- (4) It is an offence for a manufacturer or distributor of an infant formula to make a donation of any informational or educational equipment or materials except in accordance with the following conditions—
 - (a) the donation must be made following a request by the intended recipient,
 - (b) the donation must be made with the written authority of the Scottish Ministers or in accordance with guidelines drawn up by the Scottish Ministers,
 - (c) the equipment and materials must not be marked or labelled with the name of a proprietary brand of infant formula, and
 - (d) the equipment or materials must be distributed only through the health care system.

Free or reduced rate infant formula

24. An institution or organisation which receives any infant formula free or at a reduced rate must—

- (a) if that infant formula is for use in the institution or organisation, only use it for infants who have to be fed on infant formula and only for as long as required by those infants, or
- (b) if that infant formula is for distribution outside the institution or organisation, only distribute it for infants who have to be fed on infant formula and only for as long as required by those infants.

Offences and enforcement

25.—(1) Any person who contravenes or fails to comply with any of the provisions contained in paragraphs 2, 3, 12, 20(1), 21, 22, 23 and 24, is guilty of an offence and is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

- (2) Each food authority must enforce and execute this schedule in its area.

Application of various sections of the Food Safety Act 1990

26. The following provisions of the Act apply for the purposes of this schedule with the modification that any reference in those provisions to the Act or Part thereof are to be construed as a reference to this schedule—

- (a) section 3 (presumptions that food intended for human consumption),
- (b) section 20 (offences due to fault of another person),
- (c) section 21 (defence of due diligence), as it applies for the purpose of section 14 or 15,
- (d) section 30(8) (which relates to documentary evidence),
- (e) section 33 (obstruction etc. of officers),
- (f) section 35(1) to (3) (punishment of offences), in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (e),

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- (g) section 36 (offences by bodies corporate),
- (h) section 36A (offences by Scottish partnerships),
- (i) section 44 (protection of officers acting in good faith).]

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.

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Changes to legislation:

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