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STATUTORY INSTRUMENTS

# 2020 No. 43

# FOOD, ENGLAND

FOOD SAFETY

# The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020

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|---|---|
| *Made - - - -* | *at 1.00 p.m. on 27th January 2020* |
| *Laid before Parliament* | *at 3.45 p.m. on 27th January 2020* |

*Coming into force in accordance with regulation 1*

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

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the

(**1**) 1990 c. 16. Section 6(4) of the Food Safety Act 1990 ("the 1990 Act") was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40), paragraph 10(3) of Schedule 5, and Schedule 6 to, the Food Standards Act 1999 (c. 28) ("the 1999 Act"), and S.I. 2002/794. Section 16 of the 1990 Act was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act. Section 17 of the 1990 Act was amended by paragraphs 7, 8 and 12 of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 48 was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.

(**2**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (c. 46) as read with section 40(2) of the 1999 Act.

(**3**) 1972 c. 68 ("the 1972 Act"). Section 2(2) of the 1972 Act was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7). Paragraph 1A of Schedule 2 to the 1972 Act was inserted by section 28 of the Legislative and Regulatory Reform Act 2006. It was amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 and by S.I. 2007/1388. Paragraph 1A(1) of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 and amended by section 3(3) of, and the Schedule to, the European Union (Amendment) Act 2008.

primary production of food(**4**), and food and drink intended for sale for human consumption including the presentation, packaging, labelling, marketing and advertising of such food and drink(**5**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for certain references to provisions of 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(**6**) to be construed as references to those provisions as amended from time to time.

It further appears to the Secretary of State that it is expedient for certain provisions of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes(**7**) to be construed as a reference to those provisions as amended from time to time.

The Secretary of State has had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990(**8**).

There has been open and transparent public 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(**9**), during the preparation and evaluation of these Regulations.

# PART 1

## Preliminary

### Citation, commencement, interpretation and application

**1.**—(1) These Regulations may be cited as the Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020 and come into force on 22nd February 2020, except where paragraph (2) applies.

(2) Regulations 2 to 4 come into force on 22nd February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates.

(3) In these Regulations, "the 1990 Act" means the Food Safety Act 1990.

(4) These Regulations apply in relation to England only.

(**4**) S.I. 2003/2901, to which there are amendments not relevant to these Regulations.
(**5**) S.I. 2005/2766, to which there are amendments not relevant to these Regulations.
(**6**) O.J. No. L 25, 2.2.2016, p. 1, as last amended by Commission Delegated Regulation (EU) 2019/828 (O.J. No. L 137, 23.5.2019, p.12).
(**7**) O.J. No. L 25, 2.2.2016, p. 30.
(**8**) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
(**9**) O.J. No. L 31, 1.2.2002, p. 1, as last amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council (O.J. No. L 198, 25.07.2019, p. 241).

# PART 2

## Infant Formula and Follow-on Formula

### Interpretation of Part 2

**2.**—(1) In this Part—

"Delegated Regulation 127" 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;

"food authority" means—

(a) a county council;

(b) a metropolitan district council;

(c) a non-metropolitan district council;

(d) a London borough council;

(e) the Common Council of the City of London (in its capacity as a local authority);

(f) the Council of the Isles of Scilly;

"specified EU law requirement" means any provision of Delegated Regulation 127 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 Delegated Regulation 127 is a reference to that provision as amended from time to time.

(3) Expressions used both in this Part of these Regulations and in Delegated Regulation 127 have the same meaning in this Part as they have in Delegated Regulation 127.

### Enforcement

**3.** Each food authority must execute and enforce this Part of these Regulations within its area.

### Application of provisions of the 1990 Act

**4.**—(1) Section 10(1) and (2) of the 1990 Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in Part 1 of Schedule 2, for the purposes of—

(a) enabling an improvement notice to be served on a person requiring that person to secure compliance with any specified EU law requirement; and

(b) making a failure to comply with a notice referred to in sub-paragraph (a) an offence.

(2) Section 32(1) to (8) of the 1990 Act(**10**) (powers of entry) applies, with the modifications (in the case of section 32(1)) specified in Part 2 of Schedule 2, for the purposes of enabling an authorised officer of an enforcement authority—

(a) to exercise a power of entry to ascertain whether food that does not comply with a specified EU law requirement is, or has been, sold;

(b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of a specified EU law requirement.

(**10**) There are amendments to section 32(5) and (6), but none is relevant.

(3) Section 35 of the 1990 Act (punishment of offences) applies, with the modifications specified in Part 3 of Schedule 2, for the purposes of specifying the punishment of an offence committed under section 10(2) as applied by paragraph (1)(b).

(4) Section 37 of the 1990 Act (appeals) applies, with the modifications specified in Part 4 of Schedule 2, for the purpose of enabling a person to appeal a decision to serve a notice referred to in paragraph (1)(a).

(5) Section 39 of the 1990 Act (appeals against improvement notices) applies, with the modifications (in the case of section 39(1) and (3)) specified in Part 5 of Schedule 2, for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph (1)(a).

(6) The provisions of the 1990 Act specified in paragraph (7) ("the paragraph (7) provisions") apply, with the modifications specified in Part 6 of Schedule 2, for the purposes of this Part of these Regulations, insofar as they relate to the provisions of the 1990 Act specified in and modified by paragraphs (1) to (5), and any reference in the paragraph (7) provisions to a section of the 1990 Act, including a reference to "any of the preceding provisions of this Part", is to be read as a reference to such sections of the 1990 Act as applied by this Part of, and modified by Schedule 2 to, these Regulations.

(7) The provisions of the 1990 Act are—

(a) section 3 (presumptions that food intended for human consumption);

(b) section 20 (offences due to fault of another person);

(c) section 21(**11**) (defence of due diligence);

(d) section 22 (defence of publication in the course of business);

(e) section 29 (procurement of samples);

(f) section 30(**12**) (analysis etc. of samples);

(g) section 33(**13**) (obstruction etc. of officers);

(h) section 36 (offences by bodies corporate);

(i) section 36A(**14**) (offences by Scottish partnerships);

(j) section 44 (protection of officers acting in good faith);

(k) section 53 (general interpretation).

**Revocations, savings and transitional provisions relating to infant formula and follow-on formula**

**5.**—(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 21st February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates;

(b) for the purposes of paragraph (3)(b).

(3) Infant formula and follow-on formula which does not comply with a specified EU law requirement may continue to be marketed until stocks of such food are exhausted, provided that—

(a) it was placed on the market or labelled—

(**11**) Section 21 was amended by S.I. 2004/3279.
(**12**) Section 30 was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.
(**13**) Section 33 was amended by paragraph 3(1) and (4) of the Schedule to the Food (Scotland) Act 2015 (asp 1).
(**14**) Section 36A was inserted by paragraph 16 of Schedule 5 to the 1999 Act.

(i) before 22nd February 2020; or

(ii) before 22nd 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 (England) Regulations 2007(**15**) are met—

(i) regulation 3(1) (prohibition on the marketing of infant formula unless certain conditions are met) in the case of infant formula;

(ii) regulation 3(2) (prohibition on the marketing of follow-on formula unless certain conditions are met) in the case of follow-on formula.

# PART 3

## Amendments, revocations, saving and review

### Amendment of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016

**6.** Schedule 4 has effect.

### Miscellaneous amendments

**7.** Schedule 5 has effect.

### Revocations and saving relating to food for special medical purposes

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

(a) regulation 8(c) of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016(**16**) (transitional arrangements) as substituted by paragraph 3 of Schedule 4 to these Regulations; and

(b) regulation 5(3)(b) of these Regulations.

### Revocation of regulation 4 of the Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017

**9.** Regulation 4 of the Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017(**17**) (amendment of Schedule 3 to the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016) is revoked.

### Review

**10.**—(1) The Secretary of State must from time to time—

(a) carry out a review of the regulatory provision made by these Regulations; and

(b) publish a report setting out the conclusions of the review.

(**15**) S.I. 2007/3521, the relevant amending instrument is S.I. 2008/2445.
(**16**) S.I. 2016/688, regulation 8 was inserted by S.I. 2019/44.
(**17**) S.I. 2017/62.

(2) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory provision made by these Regulations;

(b) assess the extent to which those objectives are achieved;

(c) assess whether those objectives remain appropriate; and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(3) The first report under this regulation must be published before 22nd February 2025.

(4) Subsequent reports under this regulation must be published at intervals not exceeding five years.

(5) In this regulation "regulatory provision" has the meaning given by section 32(4) of the Small Business, Enterprise and Employment Act 2015(**18**).

Signed by authority of the Secretary of State for Health and Social Care.

*Jo Churchill*
Parliamentary Under-Secretary of State,
Department of Health and Social Care

At 1.00 p.m. on 27th January 2020

(**18**) 2015 c. 26.

SCHEDULE 1 Regulation 2(1)

Specified EU law requirements

| **Column 1** | **Column 2** |
|---|---|
| *Specified provision of Delegated Regulation 127* | *Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127* |
| 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 1 and Annex 3 |
| Article 2(2) (compositional requirements for follow-on formula) | Articles 1(1) and 2(3), Annex 2 and Annex 3 |
| Article 2(3) (preparation of infant and follow-on formula) | Articles 1(1), 2(1) and (2) |
| Article 3(1) (suitability of ingredients for infant formula) | Articles 1(1) and 3(3) and paragraph 2 of Annex 1 |
| Article 3(2) (suitability of ingredients for follow-on formula) | Articles 1(1) and 3(3) and paragraph 2 of Annex 2 |
| 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 protein) | Article 1(1) and Part A of Annex 6 |
| Article 5(2) (name of food manufactured entirely from cows' or goats' milk protein) | Article 1(1) and Part B of Annex 6 |
| Article 6 (specific requirements on food information) | Articles 1(1) and 7(1), (2), (3), (5), (6), (7) and (8) |
| Article 7(1) (specific requirements on the nutrition declaration) | Articles 1(1) and 7(4), Annex 1 and Annex 2 |
| Article 7(3) (repetition of information included in mandatory nutrition declaration) | Article 1(1) |
| Article 7(4) (nutrition declaration mandatory regardless of size of packaging or container) | Articles 1(1) and 7(1), Annex 1 and Annex 2 |
| Article 7(5) (application of Articles 31 to 35 of Regulation (EU) No. 1169/2011(**19**)) | 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 sub-paragraph of Article 7(7) (prohibition on expressing energy value and | Articles 1(1) and 7(5) |

(**19**) Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, etc. (O.J. No. L 304, 22.11.2011, p. 18).

| **Column 1** | **Column 2** |
|---|---|
| *Specified provision of Delegated Regulation 127* | *Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127* |
| amount of nutrients as a percentage of reference intake) | |
| Article 7(8) (presentation of particulars included in the nutrition declaration) | Article 1(1) |
| Article 8 (prohibition on making nutrition and health claims on infant formula) | Article 1(1) |
| Article 9(1) ("lactose only" statement) | Article 1(1) |
| The first sub-paragraph of Article 9(2) ("lactose free" statement) | Article 1(1) |
| The second sub-paragraph 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 docosahexaenoic acid where infant formula placed on the market on or after 22nd February 2025) | Article 1(1) |
| 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 relating to infant formula to the general public, pregnant women, mothers or members of their families) | Article 1(1) |
| 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 1(1) |
| Article 11(3) (requirements on donations of informational or educational equipment or materials) | |
| Article 12 (notification requirements) | Article 1(1) |

SCHEDULE 2 Regulation 4

Modification of provisions of the 1990 Act

# PART 1

## Modification of section 10 of the 1990 Act

**1.** Section 10 of the 1990 Act (improvement notices) applies as if, for subsection (1), there were substituted—

"(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with a specified EU law requirement, the authorised officer may, by a notice served on that person (in this Act referred to as an "improvement notice")—

(a) state the officer's grounds for believing that the person is failing to comply or, as the case may be, that the food does not comply with the specified EU law requirement;

(b) specify the matters which constitute the failure to comply;

(c) specify the measures which, in the officer's opinion, the person must take in order to secure compliance; and

(d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the improvement notice.".

# PART 2

## Modification of section 32 of the 1990 Act

**2.** Section 32 of the 1990 Act(**20**) (powers of entry) applies as if—

(a) in subsection (1) for paragraphs (a) to (c) there were substituted—

"(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;

(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 a specified EU law requirement; and

(c) when exercising a power of entry under this section, to exercise the associated powers in subsections (5) and (6) relating to records;";

(b) subsection (9) were omitted.

(**20**) Section 32(5) and (6) was amended by section 70 of, and paragraph 18 of Schedule 2 to, the Criminal Justice and Police Act 2001 (c. 16).

# PART 3

## Modification of section 35 of the 1990 Act

**3.** Section 35 of the 1990 Act (punishment of offences) applies as if, before subsection (2), there were inserted—

"(1B) A person guilty of an offence under section 10(2), as applied by regulation 4(1) of the 2020 Regulations, is liable on summary conviction, to a fine.".

# PART 4

## Modification of section 37 of the 1990 Act

**4.** Section 37 of the 1990 Act (appeals) applies as if—

(a) for the heading there were substituted "Appeals";

(b) for subsection (1) there were substituted—

"(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 4(1) of, and Part 1 of Schedule 2 to, the 2020 Regulations, may appeal to the First-tier Tribunal.";

(c) subsection (2) were omitted;

(d) for subsection (3) there were substituted—

"(3) The appeals procedure under the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009(**21**) applies to appeals made under subsection (1).";

(e) subsection (4) were omitted;

(f) for subsection (5) there were substituted—

"(5) The notice of appeal period under rule 22 of the Tribunal Procedure (First-tier Tribunal) (General Regulatory Chamber) Rules 2009 applies to appeals made under subsection (1).";

(g) in subsection (6)—

(i) for "subsection (3) or (4)" there were substituted "subsection (1)"; and

(ii) in paragraph (a), for "a magistrates' court or to the sheriff" there were substituted "the First-tier Tribunal".

# PART 5

## Modification of section 39 of the 1990 Act

**5.** Section 39 of the 1990 Act (appeals against improvement notices) applies as if—

(a) for subsection (1) there were substituted—

"(1) On an appeal against an improvement notice served under section 10(1), as applied and modified by regulation 4(1) of, and Part 1 of Schedule 2 to, the 2020 Regulations, the First-tier Tribunal may either cancel or affirm the notice and, if it

(**21**) S.I. 2009/1976, amended by S.I. 2010/43, 2653, 2011/651, 2012/500, 2013/477, 2014/2128, 2015/2059, 2017/1168, 2018/1053 and 2019/925.

affirms it, it may do so either in its original form or with such modifications as the First-tier Tribunal may in the circumstances think fit.";

(b) in subsection (3), "for want of prosecution" were omitted.

# PART 6

## Further modifications of provisions of the 1990 Act

**6.** Section 3 of the 1990 Act (presumptions that food intended for human consumption) applies as if, in subsection (1), for "this Act" there were substituted "the 2020 Regulations".

**7.** Section 20 of the 1990 Act (offences due to fault of another person) applies as if, for "any of the preceding provisions of this Part", there were substituted "the 2020 Regulations".

**8.** Section 21 of the 1990 Act (defence of due diligence) applies as if, in subsection (1), for "any of the preceding provisions of this Part", there were substituted "the 2020 Regulations".

**9.** Section 22 of the 1990 Act (defence of publication in the course of business) applies as if, for "any of the preceding provisions of this Part", there were substituted "the 2020 Regulations".

**10.** Section 29 of the 1990 Act (procurement of samples) applies as if, in paragraph (b)(ii), after "under section 32 below", there were inserted ", including under section 32 as applied and modified by regulation 4(2) of, and Part 2 of Schedule 2 to, the 2020 Regulations".

**11.** Section 30 of the 1990 Act (analysis etc. of samples) applies as if—

(a) in subsection (1), after "under section 29 above", there were inserted ", including under section 29 as applied and modified by regulation 4(6) of, and Part 6 of Schedule 2 to, the 2020 Regulations"; and

(b) in subsection (8), for "this Act" there were substituted "the 2020 Regulations".

**12.** Section 33 of the 1990 Act (obstruction etc. of officers) applies as if, in subsection (1), for "this Act" (in each place where it occurs) there were substituted "the 2020 Regulations".

**13.** Section 36 of the 1990 Act (offences by bodies corporate) applies as if, in subsection (1), for "this Act" there were substituted "the 2020 Regulations".

**14.** Section 36A of the 1990 Act(**22**) (offences by Scottish partnerships) applies as if, for "this Act", there were substituted "the 2020 Regulations".

**15.** Section 44 of the 1990 Act (protection of officers acting in good faith) applies as if, for "this Act", in each place where those words appear, there were substituted "the 2020 Regulations".

**16.** Section 53 of the 1990 Act (general interpretation) applies as if—

(a) after the definition of "the 1956 Act" there were inserted—

> ""the 2020 Regulations" means the Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020;";

(b) after the definition of "slaughterhouse" there were inserted—

> ""specified EU law requirement" has the meaning given in regulation 2(1) of the 2020 Regulations;".

(**22**) Section 36A was inserted by section 40(1) of, and paragraph 16 of Schedule 5 to, the 1999 Act.

## SCHEDULE 3

Regulation 5(1)

Revocations relating to Infant Formula and Follow-on Formula

| **Column 1** | **Column 2** | **Column 3** |
|---|---|---|
| *Instrument* | *Reference* | *Extent of revocation* |
| Infant Formula and Follow-on Formula (England) Regulations 2007 | S.I. 2007/3521 | The whole of the Regulations, except regulation 30 |
| Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 | S.I. 2008/2445 | Regulation 2 |
| Transfer of Functions (Food) Regulations 2011 | S.I. 2011/3012 | Regulation 5 |
| Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2013 | S.I. 2013/3243 | The whole of the Regulations |
| Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 | S.I. 2016/688 | Schedule 3, paragraph 4 |
| The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020 | S.I. 2020/43 | Schedule 5, paragraph 4 |

## SCHEDULE 4

Regulation 6

Amendment of the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016

### Interpretation

**1.** In this Schedule, "the 2016 Regulations" means the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016(**23**).

### Amendment of regulation 2 of the 2016 Regulations

**2.** In regulation 2 of the 2016 Regulations (interpretation), omit paragraph (6).

(**23**) S.I. 2016/688, amended by S.I. 2017/62 and 2019/44.

**Amendment of regulation 8 of the 2016 Regulations**

**3.** For regulation 8 of the 2016 Regulations (transitional arrangements) substitute—

"**Transitional arrangements**

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

(a) it complies with the provisions of the EU Regulation specified in Schedule 1;

(b) it was placed on the market or labelled—

(i) before 22nd February 2019; or

(ii) before 22nd February 2020 in the case of food for special medical purposes developed to satisfy the nutritional requirements of infants; and

(c) the requirements specified in regulation 3(1) and (2) of the Medical Food (England) Regulations 2000(**24**) (restrictions on sale) are met.".

**Amendment of Schedule 1 to the 2016 Regulations**

**4.** In Schedule 1 to the 2016 Regulations(**25**) (specified EU Requirements)—

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

(b) for the part of the table relating to the Delegated Regulation substitute—

| *"Specified provision of the Delegated Regulation* | *Provisions to be read with the specified provision of the Delegated Regulation* |
|---|---|
| Article 2(2) (requirement for the formulation of food to be based on sound medical and nutritional principles) | Article 1 |
| The first 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 compositional requirements in Part A of Annex 1) | Articles 1 and 2(4) and Part A of Annex 1 |
| 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 1) | Articles 1 and 2(4) and Part B of Annex 1 |
| Article 3(2) (requirement relating to residue threshold for certain active substances where food for special medical purposes is developed | Articles 1 and 3(1), (3) and (5) and Annex 2 |

(**24**) S.I. 2000/845, the relevant amending instrument is S.I. 2011/3012.
(**25**) The table in Schedule 1 was substituted by S.I. 2019/44.

| *"Specified provision of the Delegated Regulation* | *Provisions to be read with the specified provision of the Delegated Regulation* |
|---|---|
| to satisfy the nutritional requirements of infants and young children) | |
| Article 3(3) (maximum residue levels for substances listed in Annex 2) | Articles 1 and 3(1), (2) and (5) and Annex 2 |
| Article 3(4) (prohibition on the use of plant protection products) | Articles 1 and 3(1) and (5) and Annex 3 |
| Article 4 (name of the food) | Article 1 and Annex 4 |
| Article 5(1) (requirement for food for special medical purposes to comply with Regulation (EU) No. 1169/2011 unless otherwise specified) | Articles 1 and 5(2) |
| Article 5(2) (additional mandatory particulars relating to food information) | Articles 1 and 5(1) and (3) |
| Article 5(3) (application of articles 13(2) and (3) of Regulation (EU) No. 1169/2011 to additional mandatory particulars) | Articles 1 and 5(1) and (2) |
| Article 6 (specific requirements on the nutrition declaration) | Article 1 and Annex 1 |
| Article 7 (nutrition and health claims) | Article 1 |
| Article 8(1) (requirement for mandatory particulars to appear in a language easily understood by consumers) | Article 1 |
| The first 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 5

Regulation 7

### Miscellaneous Amendments

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

**1.**—(1) The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997(**26**) are amended as follows.

(2) In Schedule 3 (modification of the improvement notice provisions of the Act)—

(a) In Part 1, in paragraph 1, in the modification of section 10(1) of the 1990 Act (improvement notices) in paragraph (a) for "state the officer's grounds for suspecting" substitute "state the officer's grounds for believing";

(b) in Part 5, in paragraph 10, in the modification of section 39(1) of the 1990 Act (appeals against improvement notices) for "either cancel of affirm the notice" substitute "either cancel or affirm the notice".

**Amendment of the Medical Food (England) Regulations 2000**

**2.**—(1) The Medical Food (England) Regulations 2000(**27**) (insofar as they continue to have effect in accordance with regulation 8(2) of these Regulations) are amended as follows.

(2) In the Schedule (modification of the improvement notice provisions of the Act)—

(a) in Part 1, in paragraph 1, in the modification of section 10(1) of the 1990 Act (improvement notices) in paragraph (a) for "state the officer's grounds for suspecting" substitute "state the officer's grounds for believing";

(b) in Part 5, in paragraph 10, in the modification of section 39(1) of the 1990 Act (appeals against improvement notices) for "either cancel of affirm the notice" substitute "either cancel or affirm the notice".

**Amendment of the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003**

**3.**—(1) The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003(**28**) are amended as follows.

(2) In Schedule 9 (modification of the improvement notice provisions of the Act)—

(a) in Part 1, in paragraph 1, in the modification of section 10(1) of the 1990 Act (improvement notices)—

(i) omit "in England";

(ii) in paragraph (a) for "state the officer's grounds for suspecting" substitute "state the officer's grounds for believing";

(b) in Part 5, in paragraph 10, in the modification of section 39(1) of the 1990 Act (appeals against improvement notices) for "either cancel of affirm the notice" substitute "either cancel or affirm the notice".

(**26**) S.I. 1997/2182, the relevant amending instrument is S.I. 2016/688.
(**27**) S.I. 2000/845, the relevant amending instrument is S.I. 2016/688.
(**28**) S.I. 2003/3207, the relevant amending instrument is S.I. 2016/688.

**Amendment of the Infant Formula and Follow-on Formula (England) Regulations 2007**

**4.**—(1) The Infant Formula and Follow-on Formula (England) Regulations 2007(**29**) (insofar as they continue to have effect in accordance with regulation 5(2) of these Regulations) are amended as follows.

(2) In the Schedule (modification of the improvement notice provisions of the Act)—

(a) in Part 1, in paragraph 1, in the modification of section 10(1) of the 1990 Act (improvement notices)—

(i) omit "in England";

(ii) in paragraph (a) for "state the officer's grounds for suspecting" substitute "state the officer's grounds for believing";

(b) in Part 5, in paragraph 10, in the modification of section 39(1) of the 1990 Act (appeals against improvement notices) for "either cancel of affirm the notice" substitute "either cancel or affirm the notice".

**Amendment of the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009**

**5.**—(1) The Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009(**30**) are amended as follows.

(2) In regulation 3A(1) (application of the improvement notice provisions of the Act) for "Part 1 of the Schedule" substitute "Part 1 of Schedule 2".

(3) In Schedule 2 (modification of the improvement notice provisions of the Act)—

(a) in Part 1, in paragraph 1, in the modification of section 10(1) of the 1990 Act (improvement notices)—

(i) omit "in England";

(ii) in paragraph (a) for "state the officer's grounds for suspecting" substitute "state the officer's grounds for believing";

(b) in Part 5, in paragraph 10, in the modification of section 39(1) of the 1990 Act (appeals against improvement notices) for "either cancel of affirm the notice" substitute "either cancel or affirm the notice".

SCHEDULE 6 Regulation 8

Revocations relating to food for special medical purposes

| **Column 1** | **Column 2** | **Column 3** |
|---|---|---|
| *Instrument* | *Reference* | *Extent of revocation* |
| Medical Food (England) Regulations 2000 | S.I. 2000/845 | The whole of the Regulations |
| Infant Formula and Follow-on Formula (England) Regulations 2007 | S.I. 2007/3521 | Regulation 30 |

(**29**) S.I. 2007/3521, the relevant amending instrument is S.I. 2016/688.
(**30**) S.I. 2009/3051, the relevant amending instrument is S.I. 2016/688.

| **Column 1** | **Column 2** | **Column 3** |
|---|---|---|
| *Instrument* | *Reference* | *Extent of revocation* |
| Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008 | S.I. 2008/2445 | Regulation 3 |
| Transfer of Functions (Food) Regulations 2011 | S.I. 2011/3012 | Regulation 2 |
| Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 | S.I. 2016/688 | In Part 2 of Schedule 3, paragraph 2 |
| Food for Specific Groups (Information and Compositional Requirements) (Amendment) (England) Regulations 2019 | S.I. 2019/44 | Regulation 5 |
| The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020 | S.I. 2020/ 43 | Schedule 5, paragraph 2 |

## EXPLANATORY NOTE

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

These Regulations, which apply to England only, make provision to enforce 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 (O.J. No. L 25, 2.2.2016, p. 1, "Delegated Regulation 127").

These Regulations also amend the Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (S.I. 2016/688) ("the 2016 Regulations") in order to provide for the enforcement in domestic law of the provisions of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants (O.J. No. L 25, 2.2.2016, p. 30) ("the Delegated Regulation") (regulation 6 and Schedule 4).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (c. 68) and references in them to provisions of Delegated Regulation 127 or to provisions of the Delegated Regulation are to be construed as references to such provisions as they are amended from time to time.

These Regulations also make amendments to correct drafting errors which occurred in the Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017 (S.I. 2017/62) ("the 2017 Regulations") and reported on by the Joint Committee on Statutory Instruments in their 25th report for 2016-2017. Accordingly these Regulations are to be issued free of charge to all known recipients of the 2017 Regulations.

Part 2 provides for the enforcement of Delegated Regulation 127. In particular, regulation 3 provides that each food authority must execute and enforce Part 2 within its area. Regulation 2(1) contains a definition of "food authority".

Regulation 4 and Schedule 2 apply and modify provisions of the Food Safety Act 1990 (c. 16) for the purposes of Part 2 of these Regulations.

Regulation 5 and Schedule 3 make provision for revocations and savings as a consequence of Part 2 of these Regulations. The Infant Formula and Follow-on Formula (England) Regulations 2007 (S.I. 2007/3521) ("the 2007 Regulations") and the provisions which amend those Regulations are revoked. The 2007 Regulations implement Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (O.J. No. L 401, 30.12.2006, p. 1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (O.J. No. L 179, 1.7.1992, p. 129). Article 13 of Delegated Regulation 127 repeals Directive 2006/141/EC with effect from 22nd February 2020, and from 22nd February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates.

Regulation 5 further provides for certain revocations to be saved for the purposes of the transitional arrangements in that regulation. Those transitional arrangements provide that where infant formula or follow-on formula which has been placed on the market or labelled prior to the date of application of Delegated Regulation 127 (22nd February 2020 or, in the case of infant formula or follow-on formula manufactured from protein hydrolysates, 22nd February 2021), it can continue to be marketed until stocks are exhausted, provided that certain requirements are met.

Regulation 6 and Schedule 4 make provision for the enforcement of the Delegated Regulation by amending the 2016 Regulations so that references in the 2016 Regulations to the Delegated Regulation are to the Delegated Regulation as it applies to food for special medical purposes including that developed to satisfy the nutritional requirements of infants (paragraph 2 of Schedule 4).

Paragraph 3 of Schedule 4 substitutes a new regulation 8 of the 2016 Regulations to provide new transitional arrangements which ensure that stocks of food for special medical purposes which were labelled or placed on the market before the date of application of provisions of the Delegated Regulation can continue to be marketed until those stocks are exhausted.

Paragraph 4 of Schedule 4 amends the table in Schedule 1 to the 2016 Regulations to include further provisions in the definition of "specified EU requirement".

Regulation 7 and Schedule 5 correct the drafting errors in the 2017 Regulations. Schedule 5 amends the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 (S.I. 1997/2182), the Medical Food (England) Regulations 2000 (S.I. 2000/845) ("the 2000 Regulations"), the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003 (S.I. 2003/3207), the 2007 Regulations and the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) (England) Regulations 2009 (S.I. 2009/3051).

Regulation 8 and Schedule 6 revoke the 2000 Regulations and provisions which amend them. The 2000 Regulations implement Commission Directive 1999/21/EC on dietary foods for special medical purposes (O.J. No. L 91, 7.4.1999, p. 29).

Regulation 8 further provides for the revocations to be saved for the purposes of the transitional provisions in regulation 8 of the 2016 Regulations as substituted by paragraph 3 of Schedule 4, and for the purposes of the transitional provisions in regulation 5.

Regulation 9 revokes regulation 4 of the 2017 Regulations which was defectively drafted.

Regulation 10 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked, or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.