STATUTORY RULES OF NORTHERN IRELAND

2020 No. 16

FOOD

The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2020

Made - - - -	*27th January 2020*
Coming into operation	*22nd February 2020*

The Department of Health(**1**) makes the following Regulations in exercise of the powers conferred by Articles 15(1)(a) and (e) and (2)(b), 16(1) and (2), 25(1) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**2**), and section 2(2) of, and paragraph 1A(1) of Schedule 2 to, the European Communities Act 1972(**3**).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972, and it appears to the Department of Health that it is expedient for certain provisions of Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 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 or of Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 as regards the specific compositional and information requirements for food for special medical purposes(**4**) both supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council to be construed as a reference to those provisions as amended from time to time.

In accordance with section 47(3A) of the Food Safety (Northern Ireland) Order 1991, the Department of Health has had regard to relevant advice given by the Food Standards Agency.

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(**5**) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

(**1**) Formerly the Department of Health, Social Services and Public Safety; see 2016 c.5 (N.I.) section 1(5)

(**2**) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1663 (N.I. 12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R. 2004 No. 482 and 505

(**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

(**4**) OJ No. L 25, 2.2.2016, p. 30

(**5**) 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 1

Preliminary

Citation and commencement

1. These Regulations may be cited as the Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2020 and come into operation on 22nd February 2020.

Interpretation

2. In these Regulations—

"the 2016 Regulations" means the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016(**6**);

PART 2

Amendment of the 2016 Regulations

Amendment of the 2016 Regulations

3. The 2016 Regulations are amended as follows.

Amendment of regulation 2 of the 2016 Regulations

4.—(1) In regulation 2 (Interpretation), for the definition of "the Delegated Regulation", substitute—

""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(**7**);

Delegated Regulation 128" means 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(**8**);"

(2) For the definition of "specified EU requirement" substitute—

""specified EU requirement" means any provision of the EU Regulation or Delegated Regulation 127 or Delegated Regulation 128 specified in column 1 of Schedule 1, as read with the provisions specified in the corresponding entry in column 2.".

(3) In regulation 2 (interpretation)—

(a) For paragraph (4) substitute—

(**6**) S.R. 2016 No. 251, amended by S.R. 2019 No. 9 and 651 **[DN omit 651 if no exit day**
(**7**) 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)
(**8**) OJ No. L 25, 2.2.2016, p. 30–43

"(4) Any reference to a provision of Delegated Regulation 127 or Delegated Regulation 128 contained in the table in Schedule 1 is a reference to that provision as amended from time to time.".

(b) For paragraph (5) substitute—

"(5) Any expression used in both these Regulations and in Delegated Regulation 127 or Delegated Regulation 128 has the same meaning it bears in Delegated Regulation 127 or Delegated Regulation 128, as the case may be.".

Amendment of regulation 8 of the 2016 Regulations

5. For regulation 8 (Transitional Arrangements) substitute—

"**8.**—(1) Infant Formula and Follow on Formula that does not comply with any specified provision of Delegated Regulation 127 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 2020; or

(ii) before 22nd February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates, and

(c) the requirements specified in the following provisions of the Infant Formula and Follow on Formula Regulations (Northern Ireland) 2007(**9**) are met —

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

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

(2) Food for special medical purposes that does not comply with any specified provision of Delegated Regulation 128 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 the following provisions of the Medical Food Regulations (Northern Ireland) 2000(**10**) are met-

(i) regulation 3(1) (restrictions on sale of a medical food);

(ii) regulation 3(2) (restrictions on sale of a medical food of a particular type).".

Amendment of Schedule 1 to the 2016 Regulations

6. In Schedule 1(**11**) to the 2016 Regulations (specified EU Requirements), substitute Schedule 1 of these Regulations.

(**9**) S.R. 2007 No. 506, as amended by S.R. 2008 No. 405 and S.R. 2014 No. 11
(**10**) S.R. 2000 No. 187
(**11**) The table in Schedule 1 was substituted by regulation 4 of the Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019. S.R. 2019 No. 9

PART 3

Revocations and savings

Revocations, savings and transitional provisions.

7.—(1) The Regulations specified in column 1 of the table in Schedule 2 are revoked to the extent specified in column 3, subject to paragraph (2).

(2) The Regulations specified in column 1 of the table in Schedule 2 continue to have effect (so far as otherwise revoked to the extent specified in column 3 of that table)—

(a) until 21st February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates;

(b) for the purposes of regulation 8(1)(c) and regulation 8(2)(c) of the 2016 Regulations as substituted by regulation 5 of these Regulations.

Sealed with the official seal of the Department of Health on 27th January 2020.

L.S.

Dr Naresh Chada
A senior officer of the Department of Health

SCHEDULE 1 Regulation 6

"SCHEDULE 1 Regulation 2(1)

Specified EU Requirements

Column 1 Specified provision of the EU Regulation	*Column 2 Provisions to be read with the specified provision of the EU Regulation*
Article 4(2) (requirement for relevant food to be pre-packed)	Articles 1(1) and 4(1)
Article 9(1) (requirement for the composition of food to be nutritionally appropriate and suitable)	Articles 1(1), 4(1) and 9(3)
Article 9(2) (prohibition on substances in dangerous quantities)	Articles 1(1) and 4(1)
Article 9(5) (requirements as to labelling, presentation and advertising of relevant food)	Articles 1(1), 4(1) and 9(6)
Article 10 (additional requirements for infant formula and follow-on formula)	Article 4(1)
Article 15(1) (Union list)	Articles 1(1) (a) and (c) and 4(1) and the Annex insofar as it applies to infant formula and follow-on formula and food for special medical purposes

Specified provision of Delegated Regulation (EU) 2016/127	*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 point 2 of Annex 1
Article 3(2) (suitability of ingredients for follow-on formula)	Articles 1(1) and 3(3) and point 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

Specified provision of Delegated Regulation (EU) 2016/127	*Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127*
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(**12**))	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 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 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 22 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)

(**12**) 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)

Specified provision of Delegated Regulation (EU) 2016/127	*Provision of Delegated Regulation 127 to be read with the specified provision of Delegated Regulation 127*
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)
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)
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)
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)

Specified provision of Delegated Regulation 128	*Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128*
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 I)	Articles 1 and 2(4) and Part A of Annex 1

Specified provision of Delegated Regulation 128	*Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128*
The second-sub paragraph of article 2(3) (requirement for food other than that developed to satisfy the nutritional requirements of infants to comply with the compositional requirements in Part B of Annex I)	Articles 1 and 2(4) and Part B of Annex 1
Article 3(2) (requirement relating residue threshold for certain active substances where food for special medical purposes is developed to satisfy the nutritional requirements of infants and young children)	Articles 1 and 3(1), (3) and (5) and Annex 2
Article 3(3) (maximum residue levels for substances listed in Annex II)	Articles 1 and 3(1) 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

Specified provision of Delegated Regulation 128	*Provision of Delegated Regulation 128 to be read with the specified provision of the Delegated Regulation 128*
Article 9 (notification)	Article 1
Article 7(5) (application of articles 31 to 35 of Regulation (EU) No. 1169/2011)	Article 1(1), 7(6), (7) and (8)
Article 7(6) (expression of energy value and amounts of nutrients)	Article 1(1) and 7(5)
The first sub-paragraph of Article 7(7) (prohibition on expressing energy value and amount of nutrients as a percentage of reference intake)	Article 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 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 decosahexaenoic acid where infant formula placed on the market on or after 22 February 2025)	Article 1(1)
The first paragraph 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)
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 7

Revocations

Column 1	*Column 2*	*Column 3*
Instrument	*Reference*	*Extent of revocation*
The Medical Food Regulations (Northern Ireland) 2000	S.R. 200 No. 187	The whole Regulations
The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007	S.R. 2007 No.506	The whole Regulations
The Infant Formula and Follow-on Formula Amendment Regulations (Northern Ireland) 2008	S.R 2008 No. 405	Regulation 3
The Infant Formula and Follow-on Formula Amendment Regulations (Northern Ireland) 2014	S.R. 2014 No. 11	The whole Regulations
The Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016	S.R. 2016 No. 251	Schedule 3, paragraph 2
The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019	S.R. 2019 No. 9	Regulation 5

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016 (S.R. 2016 No. 251) ("the 2016 Regulations").

These Regulations make provision to enforce the 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 (O.J. No. L 25, 2.2.2016, p.1, "Delegated Regulation 127") and make provision to enforce 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 (OJ No. L25, 2.2.2016, p. 30) ("Delegated Regulation 128") (regulation 5 and Schedule 2).

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 the Delegated Regulation 127 and the Delegated Regulation 128 are to be construed as references to such provisions as they are amended from time to time.