STATUTORY RULES OF NORTHERN IRELAND

2019 No. 9

FOOD

The Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019

Made - - - -	*29th January 2019*
Coming into operation	*22nd February 2019*

The Department of Health(**1**) makes the following Regulations in exercise of the powers conferred by Articles 16(1) and (2), 25(1) and (3) and 47(2)(b) of the Food Safety (Northern Ireland) Order 1991(**2**) and paragraph 1A 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 references to provisions of Commission Delegated Regulation (EU) 2016/128(**4**) to be construed as a reference to those provisions as amended from time to time.

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

Citation and commencement

1. These Regulations may be cited as the Food Safety (Information and Compositional Requirements) (Amendment) Regulations (Northern Ireland) 2019 and come into operation on 22nd February 2019.

(**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 Nos.482 and 505
(**3**) 1972 c.68. as amended by the Legislative and Regulatory Reform Act 2006 (c.51) and the European Union (Amendment) Act 2008(c.7). Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006 c.51) and amended by Part 1 of the Schedule to the European Union (Amendment) Act 2008 (2008 c.7)
(**4**) Commission Delegated Regulation (EU) 2016/128 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 (OJ No. L 25, 02.02.2016, p 30)
(**5**) OJ No. L 31 1.2.2002, p 1, last amended by Commission Regulation (EU) No. 2017/228 (OJ No. L 35, 10.02.17, p 10)

Interpretation

2. In these Regulations "the 2016 Regulations" means the Food Safety (Information and Compositional Requirements) Regulations (Northern Ireland) 2016(**6**).

Amendment of the 2016 Regulations

3.—(1) The 2016 Regulations are amended as follows.

(2) In regulation 2 (Interpretation)—

(a) in paragraph (1)—

(i) before the definition of "the EU regulation" insert—

""the Delegated Regulation" means Commission Delegated Regulation (EU) 2016/128 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."

(ii) after the definition of "the EU regulation" insert —

""food for special medical purposes" has the same meaning in these Regulations as in the EU Regulation(**7**);

"infant" means a child under the age of 12 months;";

(iii) in the definition of "specified EU requirement", after "the EU Regulation" insert "or the Delegated Regulation".

(b) after paragraph (3) insert —

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

(5) Any reference to the Delegated Regulation is a reference to the Delegated Regulation only insofar as it applies to food for special medical purposes other than that developed to satisfy the nutritional requirements of infants.".

(3) After regulation 7 (Revocation) insert —

"**Transitional Arrangements**

8. Food for special medical purposes, other than that developed to satisfy the nutritional requirements of infants, that does not comply with the specified provisions of the Delegated Regulation may continue to be marketed until stocks of such food are exhausted provided:

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

(b) it was placed on the market or labelled before 22 February 2019; and

(c) the requirements of regulation 3(1) and (2) of the Medical Food Regulations (Northern Ireland) 2000 are met.".

Amendment of Schedule 1 to the 2016 Regulations

4. For the table in Schedule 1 to the 2016 Regulation substitute the following:

(**6**) S.R. 2016 No. 251

(**7**) Article 2(2)(g) of the EU Regulation states "'food for special medical purposes' means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone."

"Column 1	*Column 2*
Specified provision of the EU Regulation	***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)(c),4(1) and the Annex insofar as it applies to food for special medical purposes
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 second paragraph of Article 2(3) (food to comply with 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 levels) insofar as it applies to young children rather than infants	Articles 1 and 3(1), (3) and (5) and Annex 2
Article 3(4) (prohibition on the use of plant protection products) insofar as it applies to young children rather than infants	Articles 1 and 3(1) and (5) and Annex 3
Article 4 (name of the food)	Article 1 and Annex 4
Article 5(2) (specific requirements on food information)	Articles 1, and 5(1), and (3)
Article 6 (specific requirements on the nutrition declaration)	Article 1 and Part B of Annex 1
Article 7 (nutrition and health claims)	Article 1
Article 9 (notification requirement)	Article 1"

Amendment of the Medical Food Regulations (Northern Ireland) 2000

5. In regulation 2 of the Medical Food Regulations (Northern Ireland) 2000 (Interpretation)(**8**) for the definition of "medical food" substitute:

(**8**) S.R. 2000 No. 187, the relevant amending regulation is S.R. 2007 No. 506

""“medical food” means food coming within the classification of dietary foods for special medical purposes for which compositional and labelling requirements are laid down in the Directive and which has been developed to satisfy the nutritional requirements of infants; and”.

Sealed with the official seal of the Department of Health on 29th January 2019

Elizabeth Redmond
A senior officer of the Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision to enforce in Northern Ireland Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific information and compositional requirements for food for special medical purposes ("the Delegated Regulation"). They do this by amending the Food Safety (Information and Compositional Requirements Regulations (Northern Ireland) 2016 (S.R. 2016 No. 251) ("the 2016 Regulations"), which make provision to enforce the requirements of Regulation (EU) No. 609/2013 of the European Parliament and of the Council on the provisions of food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ("the EU Regulation"). The EU Regulation sets out the general information and compositional requirements for certain categories of food and the 2016 Regulations provide for the enforcement of those requirements by applying, with modifications, certain provisions of the Food Safety (Northern Ireland) Order 1991. The Delegated Regulation sets out the specific information and compositional requirements for food for special medical purposes.

Regulation 4 amends the 2016 Regulations so that specified provisions of the Delegated Regulation become 'specified EU requirements', to which the modified provisions of the Food Safety (Northern Ireland) Order 1991 apply. This enables an improvement notice to be served requiring compliance. Failure to comply with an improvement notice is a criminal offence.

References to the provisions of the Delegated Regulation are to be read as references to those provisions as amended from time to time.

A definition of food for medical purposes is contained in the EU Regulation and this expressly includes such foods for infants. From 22 February 2019 the Delegated Regulation applies only to food for special medical purposes other than that developed to satisfy the nutritional needs of infants. Regulation 3(2)(b) therefore ensures that enforcement of the Delegated Regulation is similarly limited. Regulation 5 amends the definition of medical food in the Medical Food Regulations (Northern Ireland) 2000 (S.R. 2000 No. 187) ("the 2000 Regulations") which will continue to apply only to medical food developed to satisfy the nutritional needs of infants, so that they only apply to such food.

Regulation 3(3) includes transitional provisions for medical foods that are labelled or placed on the market before 22 February 2019. Such food may continue to be marketed until stocks are exhausted as long as they are sold in compliance with the specified requirements of the EU Regulation and regulation 3(1) and (2) of the 2000 Regulations.

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