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 (Text with EEA relevance)

Article 1

Placing on the market

Food for special medical purposes may only be placed on the market if it complies with this Regulation.

Article 2

Compositional requirements

1 Food for special medical purposes is classified in the following three categories:

- a nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
- b nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;
- c nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

The food referred to in points (a) and (b) of the first subparagraph may also be used as a partial replacement or as a supplement to the patient's diet.

2 The formulation of food for special medical purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.

3 Food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part A of Annex I.

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part B of Annex I.

4 The compositional requirements set out in Annex I shall apply to the food for special medical purposes ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 3

Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children

1 For the purposes of this Article, 'residue' means the residue of an active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009 used in a plant protection product as referred to in Article 2(1) of that Regulation, including metabolites and products resulting from the degradation or reaction of that active substance.

2 Food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall not contain residues at levels exceeding 0,01 mg/kg per active substance.

Those levels shall be determined by generally accepted standardised analytical methods.

3 By way of derogation from paragraph 2, for the active substances listed in Annex II, the maximum residue levels specified in that Annex shall apply.

4 Food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex III have not been used.

However, for the purpose of checks, plant protection products containing the active substances listed in Annex III are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg.

5 The levels referred to in paragraphs 2, 3 and 4 shall apply to the food for special medical purposes ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 4

Name of the food

The name of food for special medical purposes shall be as set out in Annex IV.

Article 5

Specific requirements on food information

1 Unless otherwise provided in this Regulation, food for special medical purposes shall comply with Regulation (EU) No 1169/2011.

2 In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for food for special medical purposes:

a a statement that the product must be used under medical supervision;

b a statement whether the product is suitable for use as the sole source of nourishment;

c a statement that the product is intended for a specific age group, as appropriate;

d where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended;

e the statement 'For the dietary management of …' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended;

f where appropriate, a statement concerning adequate precautions and contra-indications;

g a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;

h where appropriate, a warning that the product is not for parenteral use;

i instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate.

The particulars referred to in points (a) to (d) shall be preceded by the words 'important notice' or their equivalent.

3 Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall also apply to the additional mandatory particulars referred to in paragraph 2 of this Article.

Article 6

Specific requirements on the nutrition declaration

1 In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for food for special medical purposes shall include the following:

a the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation and present in the product;

b the amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product;

c information on the osmolality or the osmolarity of the product where appropriate;

d information on the source and the nature of the protein and/or protein hydrolysates contained in the product.

2 By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling.

3 The nutrition declaration shall be mandatory for all food for special medical purposes, irrespective of the size of the largest surface of the packaging or container.

4 Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for food for special medical purposes.

5 By way of derogation from Article 31(3) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.

6 By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

7 The particulars included in the nutrition declaration for food for special medical purposes that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: ‘Salt: X g (of which sodium: Y mg)’.

Article 7

Nutrition and health claims

Nutrition and health claims shall not be made on food for special medical purposes.

Article 8

Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants

1 All mandatory particulars for food for special medical purposes developed to satisfy the nutritional requirements of infants shall appear in a language easily understood by the consumers.

2 The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not include pictures of infants, or other pictures or text which may idealise the use of the product.

However, graphic representations for easy identification of the product and for illustrating methods of preparation shall be permitted.

3 The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be designed in such a way that it enables consumers to make a clear distinction between such products and infant formula and follow-on formula, in particular as to the text, images and colours used, so as to avoid any risk of confusion.

4 Advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be restricted to publications specialising in baby care and scientific publications.

Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature.

The first and second subparagraphs shall not prevent the dissemination of information exclusively intended for health care professionals.

5 There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of food for special medical purposes developed to satisfy the nutritional requirements of infants directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

6 Manufacturers and distributors of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not directly provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts.

Article 9

Notification

When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.

Article 10

Directive 1999/21/EC

In accordance with Article 20(4) of Regulation (EU) No 609/2013, Directive 1999/21/EC is repealed with effect from 22 February 2019. However, Directive 1999/21/EC shall continue to apply until 21 February 2020 to food for special medical purposes developed to satisfy the nutritional requirements of infants.

References to Directive 1999/21/EC in other acts shall be construed as references to this Regulation in accordance with the scheme set out in the first paragraph.

Article 11

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 22 February 2019, except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

For the purposes of the second subparagraph of Article 21(1) of Regulation (EU) No 609/2013, in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants the later date referred to in the second paragraph of this Article shall be considered as the date of application.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Changes to legislation:
There are outstanding changes not yet made to Commission Delegated Regulation (EU) 2016/128. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Annex 4 words substituted by S.I. 2019/651, reg. 72(8) (as inserted) by S.I. 2020/1476 reg. 6(7)(d)
- Art. 3(1) substituted by S.I. 2023/28 reg. 5(2)
- Art. 8(1) word substituted by S.I. 2019/651, reg. 72(5)(a) (as substituted) by S.I. 2020/1476 reg. 6(7)(b)
- Art. 8(4) words substituted by S.I. 2019/651, reg. 72(5)(b) (as substituted) by S.I. 2020/1476 reg. 6(7)(b)

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Art. 8(7) inserted by S.I. 2019/651, reg. 72(5)(c) (as substituted) by S.I. 2020/1476 reg. 6(7)(b)
- Art. 9(1) words substituted in earlier amending provision S.I. 2019/651, reg. 72(6) by S.I. 2020/1476 reg. 6(7)(c)(i)
- Art. 9(2)(d) and word omitted in earlier amending provision S.I. 2019/651, reg. 72(6) by S.I. 2020/1476 reg. 6(7)(c)(ii)