

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 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.

**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 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\(7\)\(c\)\(ii\)](#)