

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 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)'.

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