

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 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.

**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 :**

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