

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
Article 2	Compositional requirements
Article 3	Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children
Article 4	Name of the food
Article 5	Specific requirements on food information
Article 6	Specific requirements on the nutrition declaration
Article 7	Nutrition and health claims
Article 8	Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants
Article 9	Notification
Article 10	Directive 1999/21/EC
Article 11	Entry into force and application
	Signature

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(3)

PART A

Food for special medical purposes developed to satisfy the nutritional...

1. Products referred to in Article 2(1)(a) developed to satisfy the...
2. Products referred to in Article 2(1)(b) developed to satisfy the...
3. Maximum levels of vitamins and mineral substances present in products...
4. Where this is not contrary to the requirements dictated by...

PART B

Food for special medical purposes other than that developed to...

1. Products referred to in Article 2(1)(a) other than those developed...
2. Products referred to in Article 2(1)(b) other than those developed...
3. Maximum levels of vitamins and mineral substances present in products...

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. (See end of Document for details) [View outstanding changes](#)

ANNEX II

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(3)

Chemical name of the substance Maximum residue level(mg/kg)
Cadusafos 0,006...

ANNEX III

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(4)

Chemical name of the substance (residue definition)

ANNEX IV

NAME REFERRED TO IN ARTICLE 4

The name of food for special medical purposes shall be...
in Bulgarian: 'Храни за специални медицински цели', in
Spanish: 'Alimento...

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- (1) [OJ L 181, 29.6.2013, p. 35.](#)
- (2) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes ([OJ L 91, 7.4.1999, p. 29.](#)).
- (3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses ([OJ L 124, 20.5.2009, p. 21.](#)).
- (4) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children ([OJ L 339, 6.12.2006, p. 16.](#)).
- (5) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC ([OJ L 401, 30.12.2006, p. 1.](#)).
- (6) Opinion of the Scientific Committee for Food on a maximum residue limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (expressed on the 19 September 1997).
- (7) Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998).
- (8) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([OJ L 309, 24.11.2009, p. 1.](#)).
- (9) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 ([OJ L 304, 22.11.2011, p. 18.](#)).
- (10) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([OJ L 404, 30.12.2006, p. 9.](#)).
- (11) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 ([OJ L 31, 1.2.2002, p. 1.](#)).

Changes to legislation:

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