

Commission Delegated Regulation (EU) 2016/127 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 infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance)

Article 1	Placing on the market
Article 2	Compositional requirements
Article 3	Suitability of ingredients
Article 4	Requirements on pesticides
Article 5	Name of the food
Article 6	Specific requirements on food information
Article 7	Specific requirements on the nutrition declaration
Article 8	Nutrition and health claims for infant formula
Article 9	Statements related to lactose and docosahexaenoic acid (DHA)
Article 10	Requirements for promotional and commercial practices for infant formula
Article 11	Requirements on information relating to infant and young child feeding
Article 12	Notification
Article 13	Directive 2006/141/EC
Article 14	Entry into force and application
	Signature

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(1)

1. ENERGY
2. PROTEINS
 - 2.1. Infant formula manufactured from cows' milk or goats' milk proteins...
 - 2.2. Infant formula manufactured from soya protein isolates, alone or in...
 - 2.3. Infant formula manufactured from protein hydrolysates
 - 2.3.1. Protein source
 - 2.3.2. Protein processing
 - 2.3.3. Indispensable and conditionally indispensable amino acids and L-carnitine
 - 2.4. In all cases, amino acids may be added to infant...
3. TAURINE
4. CHOLINE
5. LIPIDS
 - 5.1. The use of the following substances shall be prohibited:
 - 5.2. The trans fatty acid content shall not exceed 3 % of...

- 5.3. The erucic acid content shall not exceed 0,4 % of the...
- 5.4. Linoleic acid
- 5.5. Alpha-linolenic acid
- 5.6. Docosahexaenoic acid
- 5.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids...
6. PHOSPHOLIPIDS
7. INOSITOL
8. CARBOHYDRATES
 - 8.1. Only the following carbohydrates may be used:
 - 8.2. Lactose
 - 8.3. Sucrose
 - 8.4. Glucose
 - 8.5. Glucose syrup or dried glucose syrup
 - 8.6. Pre-cooked starch and/or gelatinised starch
9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES
10. MINERAL SUBSTANCES
 - 10.1. Infant formula manufactured from cows' milk or goats' milk proteins...
 - 10.2. Infant formula manufactured from soya protein isolates, alone or in...
11. VITAMINS
12. NUCLEOTIDES

ANNEX II

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(2)

1. ENERGY
2. PROTEINS
 - 2.1. Follow-on formula manufactured from cows' milk or goats' milk proteins...
 - 2.2. Follow-on formula manufactured from soya protein isolates, alone or in...
 - 2.3. Follow-on formula manufactured from protein hydrolysates
 - 2.3.1. Protein source
 - 2.3.2. Protein processing
 - 2.3.3. Indispensable and conditionally indispensable amino acids
 - 2.4. In all cases, amino acids may be added to follow-on...
3. TAURINE
4. LIPIDS
 - 4.1. The use of the following substances shall be prohibited:
 - 4.2. The trans fatty acid content shall not exceed 3 % of...
 - 4.3. The erucic acid content shall not exceed 0,4 % of the...
 - 4.4. Linoleic acid
 - 4.5. Alpha-linolenic acid
 - 4.6. Docosahexaenoic acid

- 4.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids...
- 5. PHOSPHOLIPIDS
- 6. CARBOHYDRATES
 - 6.1. The use of ingredients containing gluten shall be prohibited.
 - 6.2. Lactose
 - 6.3. Sucrose, fructose, honey
 - 6.4. Glucose
 - 6.5. Glucose syrup or dried glucose syrup
- 7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES
- 8. MINERAL SUBSTANCES
 - 8.1. Follow-on formula manufactured from cows' milk or goats' milk proteins...
 - 8.2. Follow-on formula manufactured from soya protein isolates, alone or in...
- 9. VITAMINS
- 10. NUCLEOTIDES

ANNEX III

INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purposes of point 2 of Annexes I and...

- A. Infant formula and follow-on formula manufactured from cows' milk or...
- B. Infant formula and follow-on formula manufactured from protein hydrolysates

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(3)

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

ANNEX V

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(4)

Chemical name of the substance (residue definition)

Changes to legislation: There are currently no known outstanding effects for the
Commission Delegated Regulation (EU) 2016/127. (See end of Document for details)

ANNEX VI

NAMES REFERRED TO IN ARTICLE 5

PART A

Name referred to in Article 5(1)

PART B

Name referred to in Article 5(2)

ANNEX VII

REFERENCE INTAKES REFERRED TO IN ARTICLE 7(7)

Nutrient Reference intake Vitamin A (μg) 400 Vitamin D (μg)...

Changes to legislation: There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2016/127. (See end of Document for details)

- (1) [OJ L 181, 29.6.2013, p. 35.](#)
- (2) 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.](#))
- (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) EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760.
- (5) 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.](#))
- (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 (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.](#))
- (9) 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.](#))
- (10) [OJ C 213, 8.7.2014, p. 1.](#)
- (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:

There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2016/127.