

Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (Text with EEA relevance)

CHAPTER II

COMPOSITIONAL AND INFORMATION REQUIREMENTS

SECTION I

General requirements

Article 6

General provisions

- 1 Food referred to in Article 1(1) shall comply with any requirement of Union law applicable to food.
- 2 The requirements laid down in this Regulation shall prevail over any conflicting requirement of Union law applicable to food.

Article 7

Opinions of the Authority

The Authority shall provide scientific opinions in accordance with Articles 22 and 23 of Regulation (EC) No 178/2002 for the purpose of the application of this Regulation. Those opinions shall serve as the scientific basis for any Union measure adopted pursuant to this Regulation which is likely to have an effect on public health.

Article 8

Access to documents

The Commission shall apply Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽¹⁾ to applications for access to any document covered by this Regulation.

Status: Point in time view as at 31/01/2020.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) No 609/2013 of the European Parliament and of the Council. 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)

Article 9

General compositional and information requirements

1 The composition of food referred to in Article 1(1) shall be such that it is appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended, in accordance with generally accepted scientific data.

2 Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons for whom it is intended.

For substances which are engineered nanomaterials, compliance with the requirement referred to in the first subparagraph shall be demonstrated on the basis of adequate test methods, where appropriate.

3 On the basis of generally accepted scientific data, substances added to food referred to in Article 1(1) for the purposes of the requirements under paragraph 1 of this Article shall be bio-available for use by the human body, have a nutritional or physiological effect and be suitable for the persons for whom the food is intended.

4 Without prejudice to Article 4(1) of this Regulation, food referred to in Article 1(1) of this Regulation may contain substances covered by Article 1 of Regulation (EC) No 258/97, provided that those substances fulfil the conditions under that Regulation for being placed on the market.

5 The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties.

6 Paragraph 5 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.

Article 10

Additional requirements for infant formula and follow-on formula

1 The labelling, presentation and advertising of infant formula and follow-on formula shall be designed so as not to discourage breast-feeding.

2 The labelling, presentation and advertising of infant formula, and the labelling of follow-on formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae.

Without prejudice to the first subparagraph, graphic representations for easy identification of infant formula and follow-on formula and for illustrating methods of preparation shall be permitted.

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SECTION 2

Specific requirements

Article 11

Specific compositional and information requirements

1 Subject to the general requirements set out in Articles 6 and 9, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 18, with respect to the following:

- a the specific compositional requirements applicable to food referred to in Article 1(1), with the exception of requirements as set out in the Annex;
- b the specific requirements on the use of pesticides in products intended for the production of food referred to in Article 1(1) and on pesticide residues in such food. The specific requirements for the categories of food referred to in points (a) and (b) of Article 1(1) and food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall be updated regularly and include, inter alia, provisions to restrict the use of pesticides as much as possible;
- c the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims in relation thereto;
- d the notification requirements for the placing on the market of food referred to in Article 1(1), in order to facilitate the efficient official monitoring of such food, and on the basis of which food business operators shall notify the competent authorities of Member States where that food is being marketed;
- e the requirements concerning promotional and commercial practices relating to infant formula;
- f the requirements concerning information to be provided in relation to infant and young child feeding in order to ensure adequate information on appropriate feeding practices;
- g the specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants, including compositional requirements and requirements on the use of pesticides in products intended for the production of such food, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices, as appropriate.

These delegated acts shall be adopted by 20 July 2015.

2 Subject to the general requirements set out in Articles 6 and 9, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress, including data provided by interested parties in relation to innovative products, the Commission shall be empowered to adopt delegated acts in accordance with Article 18 in order to update the acts referred to in paragraph 1 of this Article.

Where in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided for in Article 19 shall apply to delegated acts adopted pursuant to this paragraph.

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Article 12

Milk-based drinks and similar products intended for young children

By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children regarding compositional and labelling requirements and, if appropriate, other types of requirements. The Commission shall consider in the report, inter alia, the nutritional requirements of young children, the role of those products in the diet of young children and whether those products have any nutritional benefits when compared to a normal diet for a child who is being weaned. Such a report may, if necessary, be accompanied by an appropriate legislative proposal.

Article 13

Food intended for sportspeople

By 20 July 2015, the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of provisions for food intended for sportspeople. Such a report may, if necessary, be accompanied by an appropriate legislative proposal.

Article 14

Technical guidelines

The Commission may adopt technical guidelines to facilitate compliance by food business operators, in particular SMEs, with this Chapter and Chapter III.

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(1) [OJ L 145, 31.5.2001, p. 43.](#)

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