

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 I

GENERAL PROVISIONS

Article 1

Subject matter

1 This Regulation establishes compositional and information requirements for the following categories of food:

- a infant formula and follow-on formula;
- b processed cereal-based food and baby food;
- c food for special medical purposes;
- d total diet replacement for weight control.

2 This Regulation establishes a Union list of substances that may be added to one or more of the categories of food referred to in paragraph 1 and lays down the rules applicable to the updating of that list.

Article 2

Definitions

1 For the purposes of this Regulation, the following definitions shall apply:

- a the definitions of ‘food’, ‘food business operator’, ‘retail’ and ‘placing on the market’ set out respectively in Article 2 and points (3), (7) and (8) of Article 3 of Regulation (EC) No 178/2002;
- b the definitions of ‘prepacked food’, ‘labelling’ and ‘engineered nanomaterial’ set out respectively in points (e), (j) and (t) of Article 2(2) of Regulation (EU) No 1169/2011;
- c the definitions of ‘nutrition claim’ and ‘health claim’ set out respectively in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006.

2 The following definitions shall also apply:

- a ‘infant’ means a child under the age of 12 months;
- b ‘young child’ means a child aged between one and three years;
- c ‘infant formula’ means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

- d ‘follow-on formula’ means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants;
- e ‘processed cereal-based food’ means food:
 - (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food; and
 - (ii) pertaining to one of the following categories:
 - simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids,
 - cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,
 - pastas which are to be used after cooking in boiling water or other appropriate liquids,
 - rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;
- f ‘baby food’ means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:
 - (i) processed cereal-based food; and
 - (ii) milk-based drinks and similar products intended for young children;
- g ‘food for special medical purposes’ means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone;
- h ‘total diet replacement for weight control’ means food specially formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet.

Article 3

Interpretation decisions

In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts:

- (a) whether a given food falls within the scope of this Regulation;
- (b) to which specific category of food referred to in Article 1(1) a given food belongs.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17(2).

Article 4

Placing on the market

1 Food referred to in Article 1(1) may only be placed on the market if it complies with this Regulation.

2 Food referred to in Article 1(1) shall only be allowed on the retail market in the form of prepacked food.

3 Member States may not restrict or forbid the placing on the market of food which complies with this Regulation, for reasons related to its composition, manufacture, presentation or labelling.

Article 5

Precautionary principle

In order to ensure a high level of health protection in relation to the persons for whom the food referred to in Article 1(1) of this Regulation is intended, the precautionary principle as set out in Article 7 of Regulation (EC) No 178/2002 shall apply.