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.

CHAPTER II

COMPOSITIONAL AND INFORMATION REQUIREMENTS

SECTION 1

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.

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.

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.

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.

CHAPTER III

UNION LIST

Article 15

Union list

1 Substances belonging to the following categories of substances may be added to one or more of the categories of food referred to in Article 1(1), provided that these substances are included in the Union list set out in the Annex and comply with the elements contained in the Union list in accordance with paragraph 3 of this Article:

a vitamins;

b minerals;

c amino acids;

d carnitine and taurine;
e nucleotides;
f choline and inositol.

2 Substances that are included in the Union list shall meet the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11.

3 The Union list shall contain the following elements:
a the category of food referred to in Article 1(1) to which substances belonging to the categories of substances listed in paragraph 1 of this Article may be added;
b the name, the description of the substance and, where appropriate, the specification of its form;
c where appropriate, the conditions of use of the substance;
d where appropriate, the purity criteria applicable to the substance.

4 Purity criteria established by Union law applicable to food, which apply to the substances included in the Union list when they are used in the manufacture of food for purposes other than those covered by this Regulation, shall also apply to those substances when they are used for purposes covered by this Regulation unless otherwise specified in this Regulation.

5 For substances included in the Union list for which purity criteria are not established by Union law applicable to food, generally acceptable purity criteria recommended by international bodies shall apply until the establishment of such criteria.

Member States may maintain national rules setting stricter purity criteria.

6 In order to take into account technical progress, scientific developments or the protection of consumers' health, the Commission shall be empowered to adopt, in relation to the categories of substances listed in paragraph 1 of this Article, delegated acts in accordance with Article 18 with respect to the following:
a the removal of a category of substances;
b the addition of a category of substances that have a nutritional or physiological effect.

7 Substances belonging to categories not listed in paragraph 1 of this Article may be added to food referred to in Article 1(1), provided that they satisfy the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11.

Article 16

Updating the Union list

1 Subject to the general requirements set out in Articles 6 and 9 and, where applicable, the specific requirements established in accordance with Article 11, and in order to take into account technical progress, scientific developments or the protection of consumers' health, the Commission shall be empowered to adopt delegated acts in accordance with Article 18, to amend the Annex, with respect to the following:
a the addition of a substance to the Union list;
b the removal of a substance from the Union list;
c the addition, removal or amendment of the elements referred to in Article 15(3).

2 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 Article.

CHAPTER IV

PROCEDURAL PROVISIONS

Article 17

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Regulation (EC) No 178/2002. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Article 18

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 11, Article 15(6) and Article 16(1) shall be conferred on the Commission for a period of five years from 19 July 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3 The delegation of power referred to in Article 11, Article 15(6) and Article 16(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 11, Article 15(6) and Article 16(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 19

Urgency procedure

1 Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2 Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 18(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

CHAPTER V

FINAL PROVISIONS

Article 20

Repeal

1 Directive 2009/39/EC is repealed with effect from 20 July 2016. References to the repealed act shall be construed as references to this Regulation.

2 Directive 92/52/EEC and Regulation (EC) No 41/2009 are repealed with effect from 20 July 2016.

3 Without prejudice to the first subparagraph of paragraph 4, Directive 96/8/EC shall not apply from 20 July 2016 to foods presented as a replacement for one or more meals of the daily diet.

4 Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC are repealed from the date of application of the delegated acts referred to in Article 11(1).

In the case of conflict between Regulation (EC) No 953/2009, Directives 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC and this Regulation, this Regulation shall prevail.

Article 21

Transitional measures

1 Food referred to in Article 1(1) of this Regulation which does not comply with this Regulation but complies with Directive 2009/39/EC, and, as applicable, with Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, and which is placed on the market or labelled before 20 July 2016 may continue to be marketed after that date until stocks of such food are exhausted.

Where the date of application of the delegated acts referred to in Article 11(1) of this Regulation is after 20 July 2016, food referred to in Article 1(1) which complies with this Regulation and, as applicable, with Regulation (EC) No 953/2009 and Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC but does not comply with those delegated acts, and which is placed on the market or labelled before the date of application of those delegated acts, may continue to be marketed after that date until stocks of such food are exhausted.

2 Food which is not referred to in Article 1(1) of this Regulation but which is placed on the market or labelled in accordance with Directive 2009/39/EC and Regulation (EC) No 953/2009, and, as applicable, with Directive 96/8/EC and Regulation (EC) No 41/2009 before 20 July 2016 may continue to be marketed after that date until stocks of such food are exhausted.

Article 22

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 20 July 2016, with the exception of the following:

— Articles 11, 16, 18 and 19 which shall apply from 19 July 2013.

— Article 15 and the Annex to this Regulation which shall apply from the date of application of the delegated acts referred to in Article 11(1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 12 June 2013.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

L. CREIGHTON

(**1**) OJ L 145, 31.5.2001, p. 43.