

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The new **Regulation No 609/2013** on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ("**Regulation**"), is due to come into force on **20 July 2016**,

Categories of Food

The **Regulation** (Article 1) establishes **compositional and information requirements** for the following categories of food:

- **Infant formula** and **follow-on formula**;
- **Processed cereal-based food** and **baby food**;
- **Food for special medical purposes**;
- **Total diet replacement for weight control**.

According to the Regulation:

A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes.

Placing on the market

In accordance with **Article 4**, food under Article 1(1) may only be **placed on the market** if it complies with this Regulation and be allowed on the retail market in the form of **prepacked food**.

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 4(3)).

The **Regulation** lays down a **Union list of substances** that may be **added to food intended for infants and young children and, food for special medical purposes**, laying down rules for updating this list.

The Regulation **repeals the PARNUTs Framework Directive** as well as the each of the **specialist PARNUTs Directives** and associated legislation.

Overview

The definitions are set out in Under Article 2:

- **'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;
- **'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;
- **'nutrition claim' and 'health claim'** set out respectively in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006.
- **'infant'** means a child under the age of **12 months**;
- **'young child'** means a child aged between **one and three years**;
- **'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;
- **'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;
- **'processed cereal-based 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; and
 - ❏ 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;
- **'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**:

❏ **processed cereal-based food**; and

❏ **milk-based drinks** and similar products intended for young children;

■ **'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;

■ **'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.

Aim

Food has to be safe:

Union law applicable to food is intended, inter alia, to ensure that no food is placed on the market if it is unsafe. Therefore, any substances that are considered to be injurious to the health of the population groups concerned or unfit for human consumption should be excluded from the composition of the categories of food covered by this Regulation...

Protecting Vulnerable Consumers

Infant formula must satisfy certain nutritional requirements:

In the interest of protecting vulnerable consumers, labelling requirements should ensure accurate product identification for consumers. In the case of infant formula and follow-on formula, all written and pictorial information should enable a clear distinction to be made between different formulae. Difficulty in identifying the precise age of an infant pictured on labelling could confuse consumers and impede product identification. That risk should be avoided by appropriate restrictions on labelling. Furthermore, taking into account that infant formula constitutes food that satisfies by itself the nutritional requirements of infants from birth until introduction of appropriate complementary feeding, proper product identification is crucial for the protection of consumers. Appropriate restrictions should, therefore, be introduced concerning the presentation and advertising of infant formula.

Union List

This **Regulation** lays down a **union list of substances** relating to: **vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol in the Annex to the Regulation.**

...It is appropriate to establish and include in the Annex to this Regulation a Union list of substances belonging to the following categories of substances: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol. Among the substances belonging to those categories, it should only be permissible for those included in the Union list to be added to the categories of food covered by this Regulation. When substances are included in the Union list, it should be specified to which category of food covered by this Regulation such substances may be added.

The **aim** of the **Union list** is to reflect which **substances are authorised to be added to the categories of food covered by this Regulation**, please note that the specific **compositional requirements** are intended to establish the composition of each category of food covered by this Regulation.

A number of these substances could be added for **technological purposes as food additives, colourings or flavourings**, or for other such purposes, including authorised oenological practices and processes, provided for by relevant Union legal acts applicable to food.

In accordance with **Article 15**, the **Union list** details the categories of **substances** below that may be added to 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 Article 15 (3)**:

- (a) **vitamins;**
- (b) **minerals;**
- (c) **amino acids;**
- (d) **carnitine and taurine;**
- (e) **nucleotides;**
- (f) **choline and inositol.**

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

The **Union list** contains the following **elements**:

- 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;
- the **name, the description of the substance and, where appropriate, the specification of its form;**
- where appropriate, the **conditions of use of the substance;**
- where appropriate, the **purity criteria applicable to the substance.**

With regard to **updating the Union list**, the Commission shall **amend the Annex**, with respect to the following:

- the addition of a substance to the Union list;
- the removal of a substance from the Union list;
- the addition, removal or amendment of the elements referred to in Article 15(3).

Use of the statements 'gluten-free' and 'very low gluten'

Currently, the rules on the use of the statements 'gluten-free' and 'very low gluten' are specified in Regulation (EC) No 41/2009. That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in food and sets specific rules for food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients or to substitute such gluten-containing ingredients and other food that is made exclusively from ingredients that are naturally free of gluten. Regulation (EU) No 1169/2011 sets out rules on information to be provided for all food, including non-prepacked food, on the presence of ingredients, such as gluten-containing ingredients, with a scientifically proven allergenic or intolerance effect in order to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should also be regulated under Regulation (EU) No 1169/2011. The legal acts to be adopted pursuant to Regulation (EU) No 1169/2011, which are to transfer the rules on the use of the statements 'gluten-free' and 'very low gluten', as contained in Regulation (EC) No 41/2009, should ensure at least the same level of protection for people who are intolerant to gluten as currently provided for under Regulation (EC) No 41/2009. That transfer of rules should be completed before this Regulation applies. Furthermore, the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between a food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients and other food that is made exclusively from ingredients naturally free of gluten.

General compositional and information requirements

In accordance with **Article 9**, 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.

Food referred to in Article 1(1) **must 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.**

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.

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.

With regard to the **labelling, presentation and advertising of food** referred to in Article 1(1), the **information must be provided 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.**

The above does 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.

Additional requirements for infant formula and follow-on formula

According to **Article 10**, **additional requirements for infant formula and follow-on formula** include:

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

Transitional measures

The **transition measures** under Article 21 state that:

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.

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.

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