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)

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that, for measures having as their object the establishment and functioning of the internal market, and which concern, inter alia, health, safety and consumer protection, the Commission is to take as a base a high level of protection taking account in particular of any new development based on scientific facts.

(2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) 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.

(4) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[3] lays down general rules on the composition and preparation of foods that are specially designed to meet the particular nutritional requirements of the persons for whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and need to be reviewed.

(5) Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses', and general labelling requirements, including that such foods should bear an indication of their suitability for the nutritional purposes being claimed.

(6) The general compositional and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, harmonised rules are laid down in Commission Directives 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[4] and 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[5]. Similarly, Commission Directive 2006/125/EC[6] lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC[7] lays down harmonised rules with respect to infant formulae and follow-on formulae and Commission Regulation (EC) No 41/2009[8] lays down harmonised rules concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

(7) In addition, harmonised rules are laid down in Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries[9] and in Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses[10].

(8) Directive 2009/39/EC requires a general notification procedure at national level for food presented by food business operators as coming within the definition of 'foodstuffs for particular nutritional uses' for which no specific provisions have been laid down in Union law, prior to its being placed on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.

(9) A report from the Commission of 27 June 2008 to the European Parliament and to the Council on the implementation of that notification procedure showed that difficulties can arise from the definition of 'foodstuffs for particular nutritional uses' which appeared to be open to differing interpretations by the national authorities. It therefore concluded that a revision of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of Union legal acts.

(10) A study report of 29 April 2009 by Agra CEAS Consulting, concerning the revision of Directive 2009/39/EC, confirmed the findings of the Commission report of 27 June 2008 on the implementation of the notification procedure and indicated that an increasing number of foodstuffs are currently marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in that Directive. The study report also pointed out that food regulated under that Directive

differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators, in particular small and medium-sized enterprises (SMEs), and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out. There is therefore a need to eliminate differences in interpretation by simplifying the regulatory environment.

(11) It appears that other, recently adopted, Union legal acts are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[(11)], 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[(12)] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[(13)]. Furthermore, the provisions of those Union legal acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less of an administrative burden and more clarity as to scope and objectives.

(12) Moreover, experience shows that certain rules included in, or adopted under, Directive 2009/39/EC are no longer effective in ensuring the functioning of the internal market.

(13) Therefore, the concept of 'foodstuffs for particular nutritional uses' should be abolished and Directive 2009/39/EC should be replaced by this act. To simplify the application of this act and to ensure consistency of application throughout the Member States, this act should take the form of a Regulation.

(14) 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[(14)] establishes common principles and definitions for Union food law. Certain definitions laid down in that Regulation should also apply in the context of this Regulation.

(15) 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. Experience has shown that the provisions laid down in Directives 1999/21/EC, 2006/125/EC and 2006/141/EC ensure the free movement of those categories of food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that

this Regulation focuses on the general compositional and information requirements for those categories of food, taking into account Directives 1999/21/EC, 2006/125/EC and 2006/141/EC.

(16) In addition, in view of the growing rates of people with problems related to being overweight or obese, an increasing number of foods are placed on the market as total diet replacement for weight control. Currently, for such foods present in the market a distinction can be made between products intended for low calorie diets, which contain between 3 360 kJ (800 kcal) and 5 040 kJ (1 200 kcal), and products intended for very low calorie diets, which normally contain fewer than 3 360 kJ (800 kcal). Given the nature of the foods in question it is appropriate to lay down certain specific provisions for them. Experience has shown that the relevant provisions laid down in Directive 96/8/EC ensure the free movement of foods presented as total diet replacement for weight control in a satisfactory manner while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for foods intended to replace the whole of the daily diet including foods of which the energy content is very low, taking into account the relevant provisions of Directive 96/8/EC.

(17) This Regulation should establish, inter alia, definitions of infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account relevant provisions in Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(18) Regulation (EC) No 178/2002 establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority ('the Authority'). For the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.

(19) It is important that ingredients used in the manufacture of food covered by this Regulation are appropriate for satisfying the nutritional requirements of, and are suitable for, the persons for whom such food is intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

(20) Maximum residue levels of pesticides set out in relevant Union law, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin[(15)], should apply without prejudice to specific provisions set out in this Regulation and delegated acts adopted pursuant to this Regulation.

(21) The use of pesticides can lead to pesticide residues in food that is covered by this Regulation. Such use should, therefore, be restricted as much as possible, taking into account the requirements of 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[(16)]. However, a restriction on, or a prohibition of, use would not necessarily guarantee that food covered by this Regulation, including food for infants and young children, is free from pesticides, since some pesticides contaminate the

environment and their residues can be found in such food. Therefore, the maximum residue levels in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

(22) Restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directives 2006/125/EC and 2006/141/EC should be taken into account in delegated acts adopted pursuant to this Regulation. Those restrictions and prohibitions should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures[(17)] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, or considered to have endocrine-disrupting properties that can cause adverse effects in humans.

(23) Substances falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[(18)] should not be added to food covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) No 258/97 in addition to the conditions set out in this Regulation and delegated acts adopted pursuant to this Regulation. When there is a significant change in the production method of a substance that has been used in accordance with this Regulation or a change in particle size of such a substance, for example through nanotechnology, that substance should be considered different from the one that has been used in accordance with this Regulation and should be re-evaluated under Regulation (EC) No 258/97 and subsequently under this Regulation.

(24) 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[(19)] lays down general labelling requirements. Those labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, Regulation (EU) No 1169/2011, where necessary, in order to meet the specific objectives of this Regulation.

(25) The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties. Food for special medical purposes, however, is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the food is intended should not be considered as attribution of the property of preventing, treating or curing a human disease.

(26) 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.

(27) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(28) Regulation (EC) No 1924/2006 establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or delegated acts adopted pursuant to this Regulation.

(29) According to the recommendations of the World Health Organisation (WHO), low birth weight infants should be fed mother's milk. Nonetheless, low birth weight infants and pre-term infants may have special nutritional requirements which cannot be met by mother's milk or standard infant formula. In fact, the nutritional requirements of a low birth weight infant and a pre-term infant can depend on the medical condition of that infant, in particular on that infant's weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case-by-case basis whether the infant's condition requires the consumption, under medical supervision, of a food for special medical purposes developed to satisfy the nutritional requirements of infants (formula) and adapted for the dietary management of that infant's specific condition.

(30) Directive 1999/21/EC requires that certain compositional requirements for infant formula and for follow-on formula as set out in Directive 2006/141/EC apply to food for special medical purposes intended for infants, depending on their age. However, certain provisions, including those relating to labelling, presentation, advertising, and promotional and commercial practices, set out in Directive 2006/141/EC currently do not apply to such food. Developments in the market accompanied by a significant increase of such food make it necessary to review requirements for formulae intended for infants such as requirements on the use of pesticides in products intended for production of such formulae, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices that should also apply, as appropriate, to food for special medical purposes developed to satisfy the nutritional requirements of infants.

(31) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suitable for young children. Such products, which can be derived from protein of animal or vegetable origin such as cows' milk, goats' milk, soy or rice, are often marketed as 'growing up milks' or 'toddlers' milks' or with similar terminology. While these products are currently

regulated by different legal acts of the Union, such as Regulations (EC) No 178/2002, (EC) No 1924/2006 and (EC) No 1925/2006, and Directive 2009/39/EC, they are not covered by the existing specific measures applying to food intended for infants and young children. Different views exist as to whether such products satisfy the specific nutritional requirements of the population group they target. The Commission should therefore, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of those products. This report should consider, inter alia, the nutritional requirements of young children and the role of those products in their diet, taking into account the pattern of consumption, the nutritional intake and the levels of exposure of young children to contaminants and pesticides. The report should also consider the composition of such products and whether they have any nutritional benefits when compared to a normal diet for a child who is being weaned. The Commission could accompany this report with a legislative proposal.

(32) Directive 2009/39/EC provides that specific provisions can be adopted regarding the following two specific categories of food falling within the definition of foodstuffs for particular nutritional uses: ‘food intended to meet the expenditure of intense muscular effort, especially for sportsmen’ and ‘food for persons suffering from carbohydrate metabolism disorders (diabetes)’. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report to the European Parliament and to the Council of 26 June 2008 on foods for persons suffering from carbohydrate metabolism disorders (diabetes) concluded that the scientific basis for setting specific compositional requirements is lacking. With regard to food intended to meet the expenditure of intense muscular effort, especially for sportsmen, no successful conclusion could be reached as regards the development of specific provisions due to widely diverging views among the Member States and stakeholders concerning the scope of specific legislation, the number of subcategories of food to be included, the criteria for establishing compositional requirements and the potential impact on innovation in product development. Therefore, specific provisions should not be developed at this stage. Meanwhile, on the basis of requests submitted by food business operators, relevant claims have been considered for authorisation in accordance with Regulation (EC) No 1924/2006.

(33) However, different views exist as to whether additional rules are needed to ensure an adequate protection of consumers of food intended for sportsmen, also called food intended to meet the expenditure of intense muscular effort. The Commission should, therefore, be invited, after consulting the Authority, to submit to the European Parliament and to the Council a report on the necessity, if any, of provisions concerning food intended for sportsmen. The consultation of the Authority should take into account the report of 28 February 2001 of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether provisions are necessary to ensure the protection of consumers.

(34) The Commission should be able to adopt technical guidelines aimed at facilitating compliance by food business operators, in particular SMEs, with this Regulation.

(35) Taking into account the existing situation on the market and Directives 2006/125/EC and 2006/141/EC, and Regulation (EC) No 953/2009, 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.

(36) The inclusion of substances in the Union list should not mean that their addition to one or more categories of food covered by this Regulation is necessary or desirable. The Union list is intended only to reflect which substances belonging to certain categories of substances are authorised to be added to one or more categories of food covered by this Regulation, whereas the specific compositional requirements are intended to establish the composition of each category of food covered by this Regulation.

(37) A number of the substances that may be added to food covered by this Regulation 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 this context specifications are adopted for those substances at Union level. It is appropriate that those specifications should be applicable to the substances whatever the purpose of their use in food unless otherwise provided for by this Regulation.

(38) For the substances included in the Union list for which purity criteria have not yet been adopted at Union level, and in order to ensure a high level of protection of public health, generally acceptable purity criteria recommended by international organisations or agencies including but not limited to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and European Pharmacopoeia should apply. Member States should be permitted to maintain national rules setting stricter purity criteria, without prejudice to the rules set out in the TFEU.

(39) In order to specify requirements for the categories of food covered by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the laying down of specific compositional and information requirements with regard to the categories of food covered by this Regulation, including additional labelling requirements to, or derogations from, Regulation (EU) No 1169/2011 and with regard to the authorisation of nutrition and health claims. Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and thus to stimulate innovation the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of the regular updating of those specific requirements, taking into account all relevant data, including data provided by interested parties. In addition, in order to take into account technical progress,

scientific developments or consumers' health, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the addition of categories of substances that have a nutritional or physiological effect to be covered by the Union list, or in respect of the removal of such categories from the categories of substances covered by the Union list. For the same purposes and subject to additional requirements laid down in this Regulation, the power to adopt delegated acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of amending the Union list by adding a new substance, removing a substance or adding, removing or amending the elements in the Union list related to a substance. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(40) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether a given food falls within the scope of this Regulation and to which category of food it belongs. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[(20)].

(41) 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.

(42) Labelling and compositional rules indicating the absence or reduced presence of lactose in food are currently not harmonised at Union level. Those indications are, however, important for people who are intolerant to lactose. Regulation (EU) No 1169/2011 sets out rules on information to be provided concerning substances with a scientifically proven allergenic or intolerant effect, to enable consumers, such as lactose-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the establishment of rules on the use of statements indicating the absence or reduced presence of lactose in food should be regulated under Regulation (EU) No 1169/2011, taking into account the Scientific Opinion of the Authority of 10 September 2010 on lactose thresholds in lactose intolerance and galactosaemia.

(43) 'Meal replacement for weight control' intended to replace part of the daily diet is considered as food for particular nutritional uses and is currently governed by specific rules under Directive 96/8/EC. However, more and more foods intended for the general population have appeared on the market carrying similar statements which are presented as health claims for weight control. In order to eliminate any potential confusion within this group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, such statements should be regulated solely under Regulation (EC) No 1924/2006 and comply with requirements set out in that Regulation. It is necessary that technical adaptations made pursuant to Regulation (EC) No 1924/2006, relating to health claims referring to control of body weight and made in respect of food presented as 'meal replacement for weight control', and to the conditions of use of such claims, as regulated by Directive 96/8/EC, be completed prior to the application of this Regulation.

(44) This Regulation does not affect the obligation to respect fundamental rights and fundamental legal principles, including the freedom of expression, as enshrined in Article 11, in conjunction with Article 52, of the Charter of Fundamental Rights of the European Union, and in other relevant provisions.

(45) Since the objectives of this Regulation, namely, the establishment of compositional and information requirements for certain categories of food, the establishment of a Union list of substances that may be added to certain categories of food and the establishment of the rules for the update of the Union list, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(46) Directive 92/52/EEC provides that infant formulae and follow-on formulae exported or re-exported from the Union are to comply with Union law unless otherwise requested or stipulated by provisions established by the importing country. That principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.

(47) Directives 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC, 2009/39/EC and Regulations (EC) No 41/2009 and (EC) No 953/2009 should also be repealed.

(48) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation,

HAVE ADOPTED THIS REGULATION:

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[21] 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

ANNEX

UNION LIST AS REFERRED TO IN ARTICLE 15(1)

Substance			**Category 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**
Vitamins						
	Vitamin A					
		retinol	X	X	X	X
		retinyl acetate	X	X	X	X
		retinyl palmitate	X	X	X	X
		beta-carotene		X	X	X
	Vitamin D					
		ergocalciferol	X	X	X	X
		cholecalciferol	X	X	X	X
	Vitamin E					
		D-alpha tocopherol	X	X	X	X
		DL-alpha tocopherol	X	X	X	X
		D-alpha tocopheryl acetate	X	X	X	X
		DL-alpha tocopheryl acetate	X	X	X	X
		D-alpha-tocopheryl acid succinate			X	X
		D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)			X	

Vitamin K					
	phylloquinone (phytomenadione)	X	X	X	X
	Menaquinone[a]			X	X
Vitamin C					
	L-ascorbic acid	X	X	X	X
	sodium-L-ascorbate	X	X	X	X
	calcium-L-ascorbate	X	X	X	X
	potassium-L-ascorbate	X	X	X	X
	L-ascorbyl 6-palmitate	X	X	X	X
Thiamin					
	thiamin hydrochloride	X	X	X	X
	thiamin mononitrate	X	X	X	X
Riboflavin					
	riboflavin	X	X	X	X
	riboflavin 5'-phosphate, sodium	X	X	X	X
Niacin					
	nicotinic acid	X	X	X	X
	nicotinamide	X	X	X	X
Vitamin B_6					
	pyridoxine hydrochloride	X	X	X	X
	pyridoxine 5'-phosphate	X	X	X	X
	pyridoxine dipalmitate		X	X	X
Folate					

		folic acid (pteroylmonoglutamic acid)	X	X	X	X
		calcium-L-methylfolate			X	X
	Vitamin B_{12}					
		cyanocobalamin	X	X	X	X
		hydroxocobalamin	X	X	X	X
	Biotin					
		D-biotin	X	X	X	X
	Pantothenic Acid					
		D-pantothenate, calcium	X	X	X	X
		D-pantothenate, sodium	X	X	X	X
		dexpanthenol	X	X	X	X
Minerals						
	Potassium					
		potassium bicarbonate	X		X	X
		potassium carbonate	X		X	X
		potassium chloride	X	X	X	X
		potassium citrate	X	X	X	X
		potassium gluconate	X	X	X	X
		potassium glycerophosphate		X	X	X
		potassium lactate	X	X	X	X
		potassium hydroxide	X		X	X
		potassium salts of orthophosphoric acid	X		X	X

	magnesium potassium citrate			X	X
Calcium					
	calcium carbonate	X	X	X	X
	calcium chloride	X	X	X	X
	calcium salts of citric acid	X	X	X	X
	calcium gluconate	X	X	X	X
	calcium glycerophosphate	X	X	X	X
	calcium lactate	X	X	X	X
	calcium salts of orthophosphoric acid	X	X	X	X
	calcium hydroxide	X	X	X	X
	calcium oxide		X	X	X
	calcium sulphate			X	X
	calcium bisglycinate			X	X
	calcium citrate malate			X	X
	calcium malate			X	X
	calcium L-pidolate			X	X
Magnesium					
	magnesium acetate			X	X
	magnesium carbonate	X	X	X	X

	magnesium chloride	X	X	X	X
	magnesium salts of citric acid	X	X	X	X
	magnesium gluconate	X	X	X	X
	magnesium glycerophosphate		X	X	X
	magnesium salts of orthophosphoric acid	X	X	X	X
	magnesium lactate		X	X	X
	magnesium hydroxide	X	X	X	X
	magnesium oxide	X	X	X	X
	magnesium sulphate	X	X	X	X
	magnesium L-aspartate			X	
	magnesium bisglycinate			X	X
	magnesium L-pidolate			X	X
	magnesium potassium citrate			X	X
Iron					
	ferrous carbonate		X	X	X
	ferrous citrate	X	X	X	X
	ferric ammonium citrate	X	X	X	X
	ferrous gluconate	X	X	X	X
	ferrous fumarate	X	X	X	X

	ferric sodium diphosphate		X	X	X
	ferrous lactate	X	X	X	X
	ferrous sulphate	X	X	X	X
	ferrous ammonium phosphate			X	X
	ferric sodium EDTA			X	X
	ferric diphosphate (ferric pyrophosphate)	X	X	X	X
	ferric saccharate		X	X	X
	elemental iron (carbonyl + electrolytic + hydrogen reduced)		X	X	X
	ferrous bisglycinate	X		X	X
	ferrous L-pidolate			X	X
Zinc					
	zinc acetate	X	X	X	X
	zinc chloride	X	X	X	X
	zinc citrate	X	X	X	X
	zinc gluconate	X	X	X	X
	zinc lactate	X	X	X	X
	zinc oxide	X	X	X	X
	zinc carbonate			X	X
	zinc sulphate	X	X	X	X

	zinc bisglycinate			X	X
Copper					
	cupric carbonate	X	X	X	X
	cupric citrate	X	X	X	X
	cupric gluconate	X	X	X	X
	cupric sulphate	X	X	X	X
	copper lysine complex	X	X	X	X
Manganese					
	manganese carbonate	X	X	X	X
	manganese chloride	X	X	X	X
	manganese citrate	X	X	X	X
	manganese gluconate	X	X	X	X
	manganese glycerophosphate		X	X	X
	manganese sulphate	X	X	X	X
Fluoride					
	potassium fluoride			X	X
	sodium fluoride			X	X
Selenium					
	sodium selenate	X		X	X
	sodium hydrogen selenite			X	X
	sodium selenite	X		X	X

	selenium enriched yeast[b]			X	X
Chromium					
	chromium (III) chloride and its hexahydrate			X	X
	chromium (III) sulphate and its hexahydrate			X	X
	chromium picolinate			X	X
Molybdenum					
	ammonium molybdate			X	X
	sodium molybdate			X	X
Iodine					
	potassium iodide	X	X	X	X
	potassium iodate	X	X	X	X
	sodium iodide	X	X	X	X
	sodium iodate		X	X	X
Sodium					
	sodium bicarbonate	X		X	X
	sodium carbonate	X		X	X
	sodium chloride	X		X	X
	sodium citrate	X		X	X
	sodium gluconate	X		X	X

		sodium lactate	X		X	X
		sodium hydroxide	X		X	X
		sodium salts of orthophosphoric acid	X		X	X
	Boron					
		sodium borate			X	X
		boric acid			X	X
Amino acids[c]						
		L-alanine		—	X	X
		L-arginine	X and its hydrochloride	X and its hydrochloride	X	X
		L-aspartic acid			X	
		L-citrulline			X	
		L-cysteine	X and its hydrochloride	X and its hydrochloride	X	X
		Cystine[d]	X and its hydrochloride	X and its hydrochloride	X	X
		L-histidine	X and its hydrochloride	X and its hydrochloride	X	X
		L-glutamic acid			X	X
		L-glutamine			X	X
		glycine			X	
		L-isoleucine	X and its hydrochloride	X and its hydrochloride	X	X
		L-leucine	X and its hydrochloride	X and its hydrochloride	X	X
		L-lysine	X	X	X	X

			and its hydrochloride	and its hydrochloride		
		L-lysine acetate			X	X
		L-methionine	X	X	X	X
		L-ornithine			X	X
		L-phenylalanine	X	X	X	X
		L-proline			X	
		L-threonine	X	X	X	X
		L-tryptophan	X	X	X	X
		L-tyrosine	X	X	X	X
		L-valine	X	X	X	X
		L-serine			X	
		L-arginine-L-aspartate			X	
		L-lysine-L-aspartate			X	
		L-lysine-L-glutamate			X	
		N-acetyl-L-cysteine			X	
		N-acetyl-L-methionine			X (in products intended for persons over 1 year of age)	
Carnitine and taurine						
		L-carnitine	X	X	X	X
		L-carnitine hydrochloride	X	X	X	X
		taurine	X		X	X
		L-carnitine-L-tartrate	X		X	X
Nucleotides						
		adenosine 5’-	X		X	X

		phosphoric acid (AMP)				
		sodium salts of AMP	X		X	X
		cytidine 5'-monophosphoric acid (CMP)	X		X	X
		sodium salts of CMP	X		X	X
		guanosine 5'-phosphoric acid (GMP)	X		X	X
		sodium salts of GMP	X		X	X
		inosine 5'-phosphoric acid (IMP)	X		X	X
		sodium salts of IMP	X		X	X
		uridine 5'-phosphoric acid (UMP)	X		X	X
		sodium salts of UMP	X		X	X
Choline and inositol						
		choline	X	X	X	X
		choline chloride	X	X	X	X
		choline bitartrate	X	X	X	X
		choline citrate	X	X	X	X
		inositol	X	X	X	X

a Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

b Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2,5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85 % of total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine must not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally must not exceed 1 % of total extracted selenium.

c	For amino acids used in infant formula, follow-on formula, processed cereal-based food and baby food only the hydrochloride specifically mentioned may be used. For amino acids used in food for special medical purposes and in total diet replacement for weight control, as far as applicable, also the sodium, potassium, calcium and magnesium salts as well as their hydrochlorides may be used.
d	In the case of use in infant formula, follow-on formula, processed cereal-based food and baby food, only the form L-cystine may be used.

(**1**) OJ C 24, 28.1.2012, p. 119.

(**2**) Position of the European Parliament of 14 June 2012 (not yet published in the Official Journal) and position of the Council at first reading of 22 April 2013 (not yet published in the Official Journal). Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal).

(**3**) OJ L 124, 20.5.2009, p. 21.

(**4**) OJ L 55, 6.3.1996, p. 22.

(**5**) OJ L 91, 7.4.1999, p. 29.

(**6**) OJ L 339, 6.12.2006, p. 16.

(**7**) OJ L 401, 30.12.2006, p. 1.

(**8**) OJ L 16, 21.1.2009, p. 3.

(**9**) OJ L 179, 1.7.1992, p. 129.

(**10**) OJ L 269, 14.10.2009, p. 9.

(**11**) OJ L 183, 12.7.2002, p. 51.

(**12**) OJ L 404, 30.12.2006, p. 9.

(**13**) OJ L 404, 30.12.2006, p. 26.

(**14**) OJ L 31, 1.2.2002, p. 1.

(**15**) OJ L 70, 16.3.2005, p. 1.

(**16**) OJ L 309, 24.11.2009, p. 1.

(**17**) OJ L 353, 31.12.2008, p. 1.

(**18**) OJ L 43, 14.2.1997, p. 1.

(**19**) OJ L 304, 22.11.2011, p. 18.

(**20**) OJ L 55, 28.2.2011, p. 13.

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