COUNCIL OF THE EUROPEAN UNION

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"A" ITEM NOTE

from:	Permanent Representatives Committee (Part I)
to:	Council
No. prev. doc.:	16958/12 DENLEG 113 AGRI 819 SAN 299 CODEC 2849 + COR 1
No. Cion prop.:	12099/11 DENLEG 98 AGRI 480 SAN 137 CODEC 1180
Subject:	Proposal for a Regulation of the European Parliament and of the Council on food intended for **infants and young children** and on food for **special medical purposes (First reading) (Legislative deliberation)** - *Political agreement*

1. The proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes[1] was submitted by the Commission on 24 June 2011 on the basis of Article 114 of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

2. The proposal aims to replace the Directive 2009/39/EC on foodstuffs intended for particular nutritional uses[2]. It abolishes the concept of dietetic foods and provides for a new framework establishing general provisions only for a limited number of categories of food that are considered essential for certain vulnerable groups of the population.

[1] 12099/11 (COM(2011)353 final).
[2] OJ L 124, 20.5.2009, p. 21.

3. The European Economic and Social Committee issued its opinion on 26 October 2011[3].

4. The Council agreed on the general approach[4] on 7 June 2012.

5. The European Parliament adopted its position at first reading on 14 June 2012[5], voting on 83 amendments.

6. Negotiations were conducted between the European Parliament, the Council and the Commission in view of an agreement on the basis of the Council's position at first reading ("early second reading agreement") and concluded at the trilogue meeting on 14 November 2012.

7. On 5 December 2012, the Coreper agreed on the compromise text and on its submission, as an "A" item, to the Council in order to reach political agreement, subject to receiving an approval letter from the Chair of the European Parliament's ENVI Committee confirming the agreement reached between the institutions.

8. The Council is therefore invited to:
   - agree the text of political agreement as set out in the Annex to this note with the abstention of the United Kingdom and Germany;
   - note the statements contained in ADD 1 to this note to be entered in the minutes of the Council meeting;
   - instruct the Committee of Permanent Representatives to proceed with the legal-linguistic revision of the text and submit it, as an "I/A item note and accompanied by the statement of the Council's reasons, to the Council for adoption of the position at first reading at one of its forthcoming sessions.

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3 NAT/518 – CESE 1604/2011.
4 10086/12.
5 EP-PE_TC1-COD(2011)0156.

ANNEX

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(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 ***p***arliaments,

Having regard to the opinion of the European Economic and Social Committee,

Acting in accordance with the ordinary legislative procedure[1],

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 will*** 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.

[1] Position of the European Parliament of … and the position of the Council at first reading of …

(2a) Union law is drawn up to ensure that no food is placed on the market if it is unsafe. Therefore, any substances that are considered to be injurious to health of the groups of the population concerned or unfit for human consumption should be excluded from the composition of categories of foods covered by this Regulation.

(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[2] lays down general rules on the composition and preparation of such foods that are specially designed to meet the particular nutritional requirements of the persons to whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and should therefore be reviewed.

(4) 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 claimed nutritional purposes.

[2] OJ L 124, 20.5.2009, p. 21.

(5) 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, Commission Directive 2006/141/EC of 22 December 2006[3] lays down harmonised rules with respect to infant formulae and follow-on formulae, whereas Commission Directive 2006/125/EC of 5 December 2006[4] lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Similarly, harmonised rules are also laid down by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[5], Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[6] and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable people intolerant to gluten[7].

(6) In addition, Council Directive 92/52/EEC of 18 June 1992[8] lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries ***and Commission Regulation (EC) No 953/2009 of 13 October 2009[9] lays down rules for substances that may be added for specific nutritional purposes in foods for particular nutritional uses.***

3 OJ L 401, 30.12.2006. p. 1.
4 OJ L 339, 6.12.2006, p. 16.
5 OJ L 55, 6.3.1996, p. 22.
6 OJ L 91,7.4.1999, p. 29.
7 OJ L 16, 21.1.2009, p. 3.
8 OJ L 179, 1.7.1992, p. 129.
9 ***OJ L 269, 14.10.2009, p. 9.***

(7) Directive 2009/39/EC foresees that specific provisions could be adopted regarding the two following 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*** concludes 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 regard the development of specific provisions due to widely diverging views among the Member States and stakeholders concerning the scope of the specific legislation, the number of sub-categories of the food to be included, the criteria for establishing composition***al*** requirements and the potential impact on innovation in product development. ***Therefore, specific rules should not be developed at this stage. Meanwhile, based on the submission of requests by food business operators, relevant claims have been assessed to be included under the rules set out in 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***[10]***.***

[10] ***OJ L 404, 30.12.2006, p. 9.***

(7a) However, different views exist on whether additional rules would be needed to ensure an adequate protection of the 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 for food intended for sportsmen. The consultation of the European Food Safety Authority ('the Authority') should take into account the report of the Scientific Committee on Food of 28 February 2001 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.

(8) Directive 2009/39/EC also requires a general notification procedure at national level for food presented by food business operators as falling under the definition of 'foodstuffs for particular nutritional uses' and for which no specific provisions are laid down in Union law, prior to their placing on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.

(9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure showed that difficulties may arise from different interpretations of the definition of foodstuffs for particular nutritional uses which appeared to be open to different 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 the Union legislation.

(10) A study report ***of 29 April 2009 by Agra CEAS Consulting,*** concerning the revision of ***Directive 2009/39/EC*** confirms the findings of the Commission report on the implementation of the notification procedure and indicates that an increasing number of foodstuffs are today marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in ***that*** Directive. The study report also points out that the type of 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 sub-groups 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 enterprises (SME's)*** and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out. ***There is therefore a need to remove differences in interpretation by simplifying the regulatory environment.***

(11) It appears that other Union acts recently adopted 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 the Council of 10 June 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 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 the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to foods[13]**.** Furthermore, the provisions of ***those*** Union acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less administrative burden and more clarity as to the scope and objectives.

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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.

(12) Moreover, experience shows that certain rules included in or adopted under Directive 2009/39/EC are no longer effective to ensure 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 its application and to ensure consistency 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 in order to ensure a high level of health protection and the effective functioning of the internal market. It 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 Authority. Therefore, certain definitions laid down in that Regulation ***should*** also apply in the context of ***this*** Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.

[14] OJ L 31, 1.2.2002, p. 1.

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. 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 Directive***s*** 2006/141/EC, 2006/125/EC, as well as 1999/21/EC ensure the free movement of such 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 infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children and to food for special medical purposes, taking into account Directive***s*** 2006/141/EC, 2006/125/EC and 1999/21/EC.

(15a) In addition, in view of the growing rates of people with overweight and obesity problems, an increasing number of food is placed on the market as total diet replacement for weight control. Currently, such food present in the market may be distinguished in products intended for low calorie diets, which contain between 3360kJ (800 kcal) and 5040 kJ (1200 kcal), and, products intended for very low calorie diets, which normally contain less than 3360kJ (800 kcal). Given the nature of the food in question it would be appropriate to set certain specific provisions for it. Experience has shown that the relevant provisions laid down in Directive 96/8/EC ensure the free movement of food presented as total daily 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 composition and information requirements for food intended to replace the whole of the daily diet including food the energy content of which is very low taking into account the relevant provisions of Directive 96/8/EC.

(16) ***This Regulation should establish, among others, 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 2006/141/EC, 2006/125/EC, 1999/21/EC and 1996/8/EC.***

(16a) According to the recommendations of the World Health Organisation, 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 low birth weight and/or preterm infants may depend on the medical condition of the infant, in particular on his 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 needs of infants (formula) adapted for the dietary management of his specific condition.

(16aa) While Directive 1999/21/EC requires that certain composition requirements for infant formula and for follow-on formula as set out in Directive 2006/141/EC should apply to food for special medical purposes for infants depending on the age, certain provisions including labelling, presentation, advertising, promotional and commercial practices set out in Directive 2006/141/EC currently do not apply to these products. Developments in the market accompanied by a notable increase of such products makes it necessary to review requirements such as pesticides residues, labelling, presentation, advertising, promotional and commercial practices of formulas intended for infants that should also apply, as appropriate, to food for special medical purposes intended for infants.

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom they are 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.

(17a) Maximum residue levels of pesticides set out in relevant Union law, in particular Regulation (EC) No 396/2005 of the 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 the delegated acts adopted in accordance with this Regulation.

(17b) The use of pesticides may lead to pesticide residues in food covered by this Regulation. Therefore such use should be restricted as far 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 use restriction or a prohibition 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 may be found in the products concerned. Therefore, the maximum residues levels in the products concerned should be set at the lowest achievable level to protect vulnerable groups of the population, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

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15 ***OJ L 70, 16.3, 2005, p.1.***

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

(17c) Limitations or bans of certain pesticides equivalent to those currently establised by the annexes to the Directives 2006/141/EC and 2006/125/EC should be taken into account in delegated acts. Those limitations or bans 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 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 may cause adverse effects in humans.

(18) General labelling requirements are laid down in ***Regulation (EU) No 1169/2011*** of the European Parliament and of the Council of ***25 October 2011***[17]. Those general 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, the provisions of ***Regulation (EU) No 1169/2011***, where necessary, in order to meet the specific objectives of this Regulation.

(18a) The labelling, presentation or advertising of food falling under the scope of this Regulation should not attribute properties to such food for the prevention, treatment or cure of human disease or 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 an 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 a property for the prevention, treatment or cure of human disease.

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17 OJ L 304, 22.11.2011, p.18.

(18b) In the interest of protecting vulnerable consumers, labelling requirements should ensure accurate product identification for the consumer. 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. This risk should be avoided by appropriate restrictions on labelling.
Furthermore, taking into account that infant formula constitutes food satisfying by itself the nutritional needs of infants from birth and until introduction of appropriate complementary feeding, a proper product identification is crucial for protection of consumers. Hence, appropriate restrictions should be introduced on presentation and advertising of infant formula.

(18c) This Regulation does not have the effect of modifying the obligation to respect fundamental rights and fundamental legal principles, including the freedom of expression, as enshrined in Article 11 read in conjunction with Article 52 of the Charter of Fundamental Rights of the European Union, and in other relevant provisions.

(19) 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 Directive***s*** 2006/141/EC, 2006/125/EC***,*** 1999/21/EC ***and 96/8/EC***. In order to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, including for additional labelling requirements to, or derogations from, the provisions of ***Regulation (EU) No 1169/2011*** and for the authorisation of nutrition and health claims, the power to adopt acts in accordance with Article 290 of the ***TFEU*** should be delegated to the Commission. ***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 for the purpose of a regular update of the requirements applying to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes and total diet replacement for weight control, taking into account all relevant data, including data provided by interested parties.*** It is of particular importance that the Commission carries 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 Council.

(19a) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suited for young children. These products, which can be derived from protein of animal or vegetable origin such as, for example, 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 Union law, such as for example Regulation (EC) No 178/2002, Regulation (EC) No 1924/2006, Regulation (EC) No 1925/2006 and Directive 2009/39/EC, they are not covered by the specific existing measures applying to food intended for infants and young children. Different views exist on whether these products respond to specific nutritional requirements of the population 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 these milk-based drinks and similar products intended for young children. This report should consider, among others, the nutritional needs of young children and the role of these products in their diet, taking into account the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of these young children. The report should also consider the composition of these products and whether they have any nutritional benefits when compared to a normal diet for a child who is being weaned. The Commission may accompany this report with a legislative proposal.

(19b) Taking into account the existing situation on the market and the provisions of Directive 2006/141/EC, Directive 2006/125/EC and Regulation 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, only those included in the Union list may be added to 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.

(19c) 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 also be delegated to the Commission in respect of extending the Union list to additional categories of substances that have a nutritional or physiological effect or removing a category from the list of 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 acts in accordance with Article 290 TFEU should also be delegated to the Commission to amend the Union list in respect of adding a new substance, removing a substance, as well as adding, removing or amending the elements in the Union list related to a substance. It is of particular importance that the Commission carries 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.

(19d) The inclusion of substances in the Union list does not mean that their addition to one or more categories of food covered by this Regulation is necessary or desirable. The Union list only reflects 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 establish the composition of each category of food covered by this Regulation.

(19e) A number of the substances that can be added to food covered by this Regulation may be added for technological purposes as additives, colourings, flavourings or other such uses including authorised oenological practices and processes provided for by relevant Union legislation applicable to food. In this context specifications are adopted for them at Union level. It is appropriate that those specifications should be applicable for the substances whatever the purpose of their use in food unless otherwise provided by this Regulation.

(19f) Pending the adoption of purity criteria for the rest of the substances 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 EUP (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 Treaty.

(20) ***In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether or not a given food falls within the scope of this Regulation and to which category of food under the scope 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[18].

(21) ***The 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[19] should not be added to the foods covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) 258/97 in addition to the conditions set out in accordance with this Regulation. When, for a substance that has been used in accordance with this Regulation, there is a significant change in the production method or a change in particle size, for example through nanotechnology, this 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.***

(22) (deleted)

(23) (deleted)

(24) Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the Union have to comply with Union law unless otherwise required by the importing country. This 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.

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18 OJ L 55, 28.2.2011, p. 13.

19 ***OJ L 43, 14.2.1997, p. 1.***

(25) 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[20] 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 non-legislative acts adopted pursuant to this Regulation.

(26) Currently, ***the rules on the use of*** the statements 'gluten-free' and 'very low gluten' ***are*** specified in Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten[21]***. 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 processed, prepared or manufactured 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 naturally free of gluten. Regulation (EU) No 1169/2011 sets out rules on information to provide on the presence in all food, including non-prepacked food, of ingredients, such as gluten containing ingredients, with a scientifically proven allergenic or intolerant effect 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 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. The transfer of the rules should be completed prior to the application of this Regulation. Furthermore, the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between food that is especially processed, prepared or manufactured to reduce the gluten content of one or more gluten containing ingredients and other food that is naturally free of gluten.***

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[20] OJ L 404, 30.12.2006, p. 9.
[21] OJ L 14, 20.1.2009, p. 5.

(26a) 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. As mentioned above, Regulation (EU) No 1169/2011 sets out rules on information to provide on 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 the 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.

(27) '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 adopted under Directive 96/8/EC. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. In order to eliminate any potential confusion ***within this group*** of food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statement should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'meal replacement for weight control' and associated conditions of use as regulated by Directive 96/8/EC be completed prior to the entry into application of this Regulation.

(28) Since the objectives of the actions to be taken cannot be sufficiently achieved by the Member States and can therefore 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.

(28a) Directives 2009/39/EC, 92/52/EC, 96/8/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC and Regulations (EC) No 41/2009 and (EC) No 953/2009 should be repealed.

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

(30) The Commission should be able to adopt guidelines providing technical guidance aimed at facilitating compliance of food business operators, in particular the SME's, with Chapters III and IV of this Regulation.

HAVE ADOPTED THIS REGULATION

CHAPTER I
SUBJECT MATTER AND DEFINITIONS

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*** categories of food referred to in paragraph 1 ***and provides the rules for the update of this list***.

Article 2

Definitions

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

   a) the definitions of 'food'***, 'retail'*** and 'placing on the market' set out ***respectively*** in Articles 2 and ***Article*** 3***(7) and*** (8) 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***; ***and***
   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.
   d) (deleted).

2. The following definitions shall also apply:

a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;

b) 'infant' means ***a*** child under the age of 12 months;

c) 'young child' means ***a*** child between one and three years;

d) 'infant formula' means food used 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;

e) follow-on formula' means food used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

f) '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

(ii) for their progressive adaptation to ordinary food and pertaining to ***one of*** the following four 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;

g) ‘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;

h) ‘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 only by modification of the normal diet.

i) '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, replace the whole total daily diet.***

3. (deleted)

Article 2a

Interpretation decisions

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

– ***whether or not a given food falls within the scope of this Regulation;***

– ***to which specific category 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 14(2).

CHAPTER II
PLACING ON THE MARKET

Article 3

Placing on the market

1. Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of 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, manufacturing, presentation or labelling.

Article 4

Moved to Article 3(2)

Article 5

Moved to Article 3(3)

Article 6

1. Deleted
2. Deleted
3. Deleted

Article 6a

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

CHAPTER III
REQUIREMENTS

Section 1
Introductory provisions

Article 7

Introductory 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 other conflicting requirement of Union law applicable to food.***

Article 8

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 application of ***this*** Regulation. ***These 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 8a

Access to documents

The Commission shall apply Regulation (EC) No 1049/2001 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 to satisfy the nutritional needs of, and it is suitable for the persons to 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 to whom ***it is*** intended.

For substances which are engineered nanomaterials, the requirement referred to in the previous sub-paragraph shall be demonstrated on the basis of adequate test methods, where appropriate.

2a. 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 shall be bio-available for use by human body, shall have a nutritional or physiological effect and shall be suitable for the persons to whom the food is intended.

2b. Without prejudice to Article 3(1), food referred to in Article 1(1) may contain substances covered by Article 1 of Regulation (EC) No 258/97, provided that those substances fulfil the conditions for placing on the market under Regulation (EC) No 258/97.

3. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information ***for the appropriate use of the food,*** and ***shall*** not be misleading, ***nor attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.***

4. ***Paragraph 3 shall not prevent*** the dissemination of any useful information or recommendations ***exclusively intended for*** persons having qualifications in medicine, nutrition, pharmacy or other ***health care*** professionals responsible for maternal and child care.

Article 9a

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 not to discourage breast-feeding.

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

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

Section 2

Specific requirements

Article 10

Specific compositional and information requirements

1. *(deleted)*

2. Subject to the general requirements of Articles 7 and 9, ***to the additional requirements of Article 9a*****,** and taking into account ***relevant*** technical and scientific progress, the Commission shall be empowered to adopt delegated ***acts*** in accordance with Article 15, with respect to the following:

   a) the specific compositional requirements of food referred to in Article 1(1), ***with the exception of requirements as set out in accordance with Article 11;***

   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 pesticides residues in such food. ***These specific requirements for the categories of food referred to in Article 1(1) (a) and (b) and for food for special medical purposes developed to satisfy the nutritional needs of infants and young children shall include, among others, provisions to restrict the use of pesticides as far as possible and shall be updated regularly;***

   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 thereof;

d) the notification 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 on the basis of which food ***business*** operators shall notify the competent authority of the Member State(s) where the product is being marketed;

e) the requirements on promotional and commercial practices relating to infant formula; and

f) the requirements on information to be provided on infant and young child feeding in order to ensure adequate information on appropriate feeding practices.

g) the specific requirements for the food for special medical purposes developed to satisfy the nutritional needs of infants, including compositional requirements and requirements on the use of pesticides in products intended for the production of such food, pesticides residues, labelling, presentation, advertising, promotional and commercial practices as appropriate.
Those delegated acts shall be adopted no later than[22] […].

3. Subject to the ***general*** requirements of Articles 7 and 9, ***to the additional requirements of Article 9a*****,** 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 15 in order to update the acts referred to*** in paragraph 2 ***of this Article***.

Where in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided ***for*** in Article 16 shall apply to delegated acts adopted pursuant to this paragraph.

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[22] ***2 years after the date of the entry into force of this Regulation.***

Article 10a

Milk-based drinks and similar products intended for young children

By[23] […], 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 with regard to composition, labelling and , if appropriate, other types of requirements. The Commission shall consider in the report, among others, the nutritional needs of young children, the role of these 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. The Commission may accompany this report with a legislative proposal.

Article 10b

Food intended for sportsmen

By[24] […], 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 sportsmen. The Commission may accompany this report with a legislative proposal.

Article 10c

Technical guidance

The Commission may adopt guidelines providing technical guidance to facilitate compliance of food business operators, in particular SMEs, with Chapters III and IV of this Regulation.

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[23] ***2 years after the date of the entry into force of this Regulation.***

[24] ***2 years after the entry into force of this Regulation.***

CHAPTER IV
UNION LIST

Article 11

Union list

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

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

1a. Substances belonging to the categories listed in paragraph 1 included in the Union list, shall meet the requirements set out in Articles 7 and 9 and, where applicable, the requirements established in accordance with Article 10.

1aa. 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 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;

d) where appropriate, the purity criteria.

1ab. Purity criteria established by Union law applicable to food, which applies to the substances included in the Annex to this Regulation 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.

1ac. For substances listed in the Annex to this Regulation for which purity criteria are not established by Union law applicable to food, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

Member States may maintain national rules setting stricter purity criteria.

1b. For the purposes of taking 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 15 with respect to the following:

(a) the removal of a category of substances;

(b) the addition of a category of substances that has a nutritional or physiological effect.

1c. Substances belonging to categories not listed in paragraph 1 may be added to food referred to in Article 1(1), provided that they satisfy the requirements set out in Articles 7 and 9 and, where applicable, the requirements established in accordance with Article 10.

Article 11a

Updating the Union list

1. Subject to requirements set out in Article 11(1a) and for the purposes of taking 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 15, to amend the Annex to this Regulation, with respect to the following:

(a) to add a substance to the Union list;

(b) to remove a substance from the Union list;

(c) to add, remove or amend the elements referred to in Article 11(1aa).

2. Where, in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided for in Article 16 shall apply to delegated acts adopted pursuant to the first paragraph of this Article.

Article 12

(deleted)

CHAPTER V
CONFIDENTIALITY

Article 13

(deleted)

CHAPTER VI
PROCEDURAL PROVISIONS

Article 14

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 15

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 Articles 10, ***11(1b) and 11a(1)*** shall be conferred ***on the Commission*** for **a** period of time ***of 5 years from […][25]. 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.***

[25] ***Date of the entry into force of this Regulation.***

3. The delegation of powers referred to in Articles 10, ***11(1b) and 11a(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 Articles 10, ***11(1b) and 11a(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 16

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 15. 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 VII
FINAL PROVISIONS

Article 17

Repeal

1. Directive 2009/39/EC ***is*** repealed ***with effect*** from[26]. References to the repealed acts shall be construed as references to this Regulation.

1a. Directive 92/52/EEC and Regulation (EC) No 41/2009 are repealed with effect from[27] […].

1b. Without prejudice to the first subparagraph of paragraph 2, Directive 96/8/EC shall not apply to foods presented as replacement for one or more meals of the daily diet from[28] […].

2. Directives 96/8/EC, ***2006/141/EC, 2006/125/EC, 1999/21/EC*** and Regulation (EC) ***No 953/2009*** are repealed from ***the date of application of the delegated acts referred to in Article 10(2).***

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

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[26] ***3*** *years after the date of the entry into force of this Regulation.*
[27] ***3 years after the date of the entry into force of this Regulation.***
[28] ***3 years after the date of the entry into force of this Regulation.***

Article 18

Transitional measures

1. Food ***covered by Article 1(1) which does*** not comply with this Regulation but ***complies*** with Directives 2009/39/EC**,** 96/8/EC, ***2006/141/EC, 2006/125/EC, 1999/21/EC and*** Regulation (EC) No 953/2009, ***which is placed on the market or*** labelled before[29] […] 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 17(2) is after[30] […], food covered by Article 1(1) which complies with this Regulation, Regulation (EC) No 953/2009, Directives 96/8/EC, 2006/141/EC, 2006/125/EC and 1999/21/EC but does not comply with the delegated acts referred to in Article 17(2), 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 covered by Article 1(1) of this Regulation but which is placed on the market or labelled in accordance with Directives 2009/39/EC, 96/8/EC, Regulations (EC) 41/2009 and (EC) 953/2009 before[31][…] may continue to be marketed after that date until stocks of such food are exhausted.

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29 ***3*** *years after the date of the entry into force of this Regulation.*

30 ***3 years after the date of the entry into force of this Regulation.***

31 ***3 years after the date of the entry into force of this Regulation***.

Article 19

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[32] […], ***with the exception of the following:***

- ***Articles 15 to 16, as well as the power conferred on the Commission in Articles 10(2), 10(3) and 11a(1) shall apply from the date of entry into force of this Regulation;***
- ***Article 11 and the Annex to this Regulation shall apply from the date of application of the delegated acts referred to in Article 10(2).***

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

Done at **…**,

For the European Parliament	*For the Council*
The President	*The President*

[32] ***3*** *years after the date of the entry into force of this Regulation.*

Union list

Substance			Category of food			
			Infant Formula and Follow on Formula	**Processed cereal based food and baby food intended for infants and young children**	**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[(1)]			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[(2)]			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[3]		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[4]	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 and its hydrochloride	X and its hydrochloride	X	X

		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'-phosphoric acid (AMP)	X		X	X
		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

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

(2) 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 shall not exceed 10 % of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1 % of total extracted selenium.

(3) For aminoacids used in Infant Formulae, Follow on Formulae, Processed cereal based foods and baby foods intended for infants and young children only the hydrochloride specifically mentioned can be used. For aminoacids used in Food for Special Medical Purposes and 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.

(4) In case of use in infant formula, follow-on formula, processed cereal based foods and baby foods intended for infants and young children only the form L-cystine can be used.