Thursday 14 June 2012

P7_TC1-COD(2010)0377

Position of the European Parliament adopted at first reading on 14 June 2012 with a view to the adoption of Directive 2012/…/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Directive 2012/18/EU).

Annex to the legislative resolution

Statement by the Commission

Declaration on the exclusion of category acute toxic 3 dermal (Seveso Annex I, part 1)

The Commission acknowledges that the compromise reached on its proposal implies an improvement of the level of protection of human health and safety and of the environment as compared with that provided by the current Seveso II Directive 96/82/EC.

The Commission intends to undertake further analysis of the likelihood, risks and potential consequences of major accidents involving dangerous substances classified acute toxic 3 dermal. Depending on the outcome of this analysis, the Commission may present a legislative proposal to also include this category within the scope of the Directive.

Food intended for infants and young children and food for special medical purposes ***I

P7_TA(2012)0255

European Parliament legislative resolution of 14 June 2012 on 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 (COM(2011)0353 – C7-0169/2011 – 2011/0156(COD))

(2013/C 332 E/36)

(Ordinary legislative procedure: first reading)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2011)0353),

— having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C7-0169/2011),

— having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

— having regard to the reasoned opinion submitted, within the framework of the Protocol (No 2) on the application of the principles of subsidiarity and proportionality, by the Italian Senate, asserting that the draft legislative act does not comply with the principle of subsidiarity,

— having regard to the opinion of the European Economic and Social Committee of 26 October 2011 ([1]),

([1]) OJ C 24, 28.1.2012, p. 119.

Thursday 14 June 2012

— having regard to Rule 55 of its Rules of Procedure,

— having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on the Internal Market and Consumer Protection (A7-0059/2012),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P7_TC1-COD(2011)0156

Position of the European Parliament adopted at first reading on 14 June 2012 with a view to the adoption of Regulation (EU) No …/2012 of the European Parliament and of the Council on food intended for infants and young children ~~and~~, on food for special medical purposes*, on food for people intolerant to gluten and on food intended for use in low and very low calorie diets* [Am. 1]

(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 measures having as their object the establishment and functioning of the internal market and which concern *inter alia* health, safety and consumer protection must 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~~ ***safety*** of ~~safe and wholesome~~ food***, especially when it is intended for vulnerable groups, such as infants, young children and persons with special diseases,*** is a ~~aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests~~ ***prerequisite for the free movement of such persons and the proper functioning of the internal market.*** [Am. 2]

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[1] OJ C 24, 28.1.2012, p. 119.
[2] Position of the European Parliament of 14 June 2012.

(2a) In this context, given that the relevant Union law has been drawn up to ensure that no food is placed on the market if it is dangerous, any substances that are liable to be harmful to the health of the groups of the population concerned should be excluded from the composition of the categories of foods covered by this Regulation. **[Am. 3]**

(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses [1] 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~~ ***fail to address the difficulty experienced by consumers in making an informed choice between dietetic foods, fortified foods, foods bearing claims and foods for normal consumption. The interaction between that legislation and Union law adopted more recently, such as 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 [2], 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 [3], 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 food [4] and 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 [5], is a further factor making it necessary to thoroughly overhaul Directive 2009/39/EC.*** **[Am. 4]**

(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.

(5) The general composition 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 [6] lays down harmonised rules with respect to infant formulae and follow-on formulae, whereas Commission Directive 2006/125/EC [7] 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 [8], Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes [9] and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten [10].

(6) In addition, Council Directive 92/52/EEC [11] lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries.

(6a) According to the Council Resolution of 18 June 1992 [12], the Union should contribute to the application of appropriate practices for the marketing of breast-milk substitutes in third countries by Community-based manufacturers. **[Am. 5]**

[1] OJ L 124, 20.5.2009, p. 21.
[2] ***OJ L 183, 12.7.2002, p. 51.***
[3] ***OJ L 404, 30.12.2006, p. 9.***
[4] ***OJ L 404, 30.12.2006, p. 26.***
[5] ***OJ L 304, 22.11.2011, p. 18.***
[6] OJ L 401, 30.12.2006, p. 1.
[7] OJ L 339, 6.12.2006, p. 16.
[8] OJ L 55, 6.3.1996, p. 22.
[9] OJ L 91, 7.4.1999, p. 29.
[10] OJ L 16, 21.1.2009, p. 3.
[11] OJ L 179, 1.7.1992, p. 129.
[12] ***OJ C 172, 8.7.1992, p. 1.***

Thursday 14 June 2012

(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)'. With regard to food intended to meet the expenditure of intense muscular effort, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among 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 requirements and the potential impact on innovation in product development. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report ([1]) concludes that the scientific basis for setting specific compositional requirements is lacking~~. ***Nevertheless, the undertaking made by the Commission in Directive 2009/39/EC to recognise the nutritional requirements of sportspeople should still apply, as supported by scientific opinions of the European Food Safety Authority (the 'Authority') on claims relevant to active individuals, and 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. Therefore, the Commission should assess, not later than 1 July 2015, the need to review general food law in this regard.*** **[Am. 6]**

(7a) The Commission report of 26 June 2008 on food for persons suffering from carbohydrate metabolism disorders (diabetes) ([2]) concludes that the scientific basis for setting specific compositional requirements is lacking. This Regulation is therefore not the appropriate legal framework for that category of food. According to the Commission, it is more important, as regards persons with diabetes, to consider the quantity and model of food absorbed. This conclusion is in no way contrary to the establishment of a Union-wide strategy comprehensively targeting diabetes (Type 1 and Type 2), which affects more than 32 million Union citizens. Those figures, which are expected to increase by 16 % by 2030 as a result of the obesity epidemic and the ageing of the European population, therefore merit careful consideration at Union level, including in the area of research and development. **[Am. 7]**

(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 ([3]) 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 the scope of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of the Union legislation.

(10) A study report ([4]) concerning the revision of the legislation on foodstuffs for particular nutritional uses confirms the findings of the abovementioned 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 Directive 2009/39/EC. The study report also points out that the type of food regulated under that

([1]) ~~COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes), Brussels, 26.6.2008.~~

([2]) ***COM(2008)0392.***

([3]) Report from the Commission to the European Parliament and the Council on the implementation of Article 9 of Council Directive 89/398/EEC on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, COM (2008)0393, dated 27.6.2008.

([4]) An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting, dated 29.4.2009.

legislation 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 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 and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out.

(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, Regulation (EC) No 1924/2006 and Regulation (EC) No 1925/2006. Furthermore, the provisions of these 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.

(11a) There is therefore a need to remove differences in interpretation and to tackle difficulties for Member States and food business operators in combining the different pieces of food legislation, by simplifying the regulatory environment. This would ensure that similar products are treated in the same way across the Union and would create a more level playing field for all operators across the internal market, especially small and medium-sized enterprises (SMEs). **[Am. 8]**

(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 the present act. To simplify its application and to ensure consistency throughout the Member States, the present 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 [1] establishes common principles and definitions for Union food law in order to ensure a high level of ~~health~~ protection ~~and~~ ***of human health and consumer interests, while ensuring*** the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food***, sets out that pursuant to the precautionary principle provisional risk management measures can be adopted,*** 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 must also apply in the context of the present Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health. **[Am. 9]**

(14a) Where a risk to life or health exists, whether immediate or in the long term, but scientific uncertainty persists, the precautionary principle should apply to ensure a high level of health protection, taking into account cumulative toxic effects and the particular health sensitivities of the particularly vulnerable groups of the population specified in this Regulation. **[Am. 10]**

(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 formulae and follow-on formulae, processed cereal-based food and baby food ~~and~~***,*** food for special medical purposes, ***food for people intolerant to gluten and food intended for use in low and very low calorie diets***. Experience has shown that the provisions laid down in Directive

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

Thursday 14 June 2012

2006/141/EC, Directive 2006/125/EC, as well as Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. ***Food intended for use in very low calorie diets is currently not covered by Directive 96/8/EC but solely by Directive 2009/39/EC.*** It is appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children ~~and to~~***,*** food for special medical purposes***, food for people intolerant to gluten and food intended for use in low and very low calorie diets***, ***while*** taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC. **[Am. 11]**

(16) To ensure legal certainty, definitions laid down in Directive 2006/141/EC, Directive 2006/125/EC ~~and~~***,*** Directive 1999/21/EC***, Regulation (EC) No 41/2009 and Directive 96/8/EC*** should be transferred to this Regulation. However, the definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, ~~and~~ food for special medical purposes, ***food for people intolerant to gluten and food intended for use in low and very low calorie diets*** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate. **[Am. 12]**

(16a) According to the recommendations of the World Health Organization, low-birth-weight infants should be fed their mother's own milk. Nonetheless, low-birth-weight and pre-term infants often have special nutritional requirements which cannot be met by the mother's own milk or standard infant formulae. Food for such infants should comply with rules applicable to food for special medical purposes, when this kind of food is chosen as the most appropriate formula, taking into account the specific medical situation of the infant. Formula intended for low-birth-weight or pre-term infants should in any event comply with the requirements of Directive 2006/141/EC. **[Am. 13]**

(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 ***and independent*** review of the available scientific data. **[Am. 14]**

(17a) It is important that pesticides, maximum residue levels for which are authorised by Directive 2006/141/EC and Directive 2006/125/EC and which do not satisfy the safety conditions set out in 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 [1] be banned from the market and that they not be used in the production of food covered by this Regulation. **[Am. 15]**

(17b) 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 [2], should apply without prejudice to specific provisions set out in this Regulation and the delegated acts adopted in accordance with this Regulation. **[Am. 16]**

(17c) However, given the vulnerable nature of infants and young children, severe limitations on pesticide residues are required in infant formula and follow-on formula and processed cereal-based food and baby food for infants and young children. Specific maximum residue levels of pesticides for such

[1] ***OJ L 309, 24.11.2009, p. 1.***
[2] ***OJ L 70, 16.3.2005, p. 1.***

products are set in Directive 2006/141/EC and Directive 2006/125/EC. Particular attention should be paid to pesticides containing substances classified as specifically hazardous to human health. **[Am. 17]**

(17d) At all stages of the food production chain, food businesses and food business operators, as defined in Regulation (EC) No 178/2002, should ensure that the food covered by this Regulation comply with the requirements of food law in general and of this Regulation in particular. **[Am. 18]**

(18) General labelling requirements are laid down in ~~Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the law of the Member States relating to labelling, presentation and advertising of foodstuffs (1)~~ ***Regulation (EU) No 1169/2011***. 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 ~~Directive 2000/13/EC~~ ***Regulation (EU) No 1169/2011***, where necessary, in order to meet the specific objectives of this Regulation. **[Am. 19]**

(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, ~~and~~ food for special medical purposes***, food for people intolerant to gluten and food intended for use in low and very low calorie diets***, taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC. In order to ~~adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes laid down in this Regulation taking into account technical and scientific progress and relevant developments at international level, 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 Directive 2000/13/EC and for the authorisation of nutrition and health claims~~, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. 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. **[Am. 20]**

(19a) The Commission should, after consulting the Authority, clarify the status of milks intended for children between 12 and 36 months, which are currently regulated by different legal acts of the Union, such as Regulation (EC) No 178/2002, Regulation (EC) No 1924/2006, Regulation (EC) No 1925/2006 and Directive 2009/39/EC, and submit a report to the European Parliament and the Council assessing whether further legislative action is required, at the latest 1 year after the date of the entry into force of this Regulation. If appropriate the report should be accompanied by a legislative proposal. **[Am. 21]**

(20) It is appropriate to establish and update a ~~Union~~ list ***annexed to this Regulation*** of vitamins, minerals~~, amino acids~~ and other substances that may be added to infant formula, follow-on formula, processed cereal-based food and baby food, ~~and~~ food for special medical purposes ***and food intended for use in low and very low calorie diets***, subject to certain criteria laid down in this Regulation. ***The annexed list should be adopted taking due account of the specific dietary habits of the groups of the population concerned and should take into account and replace the lists set out in Directives 2006/141/EC and 2006/125/EC, and 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 (2), which does not apply to liquid or solid formula for infants and***

(1) ~~OJ L 184, 17.7.1999, p. 23.~~
(2) ***OJ L 269, 14.10.2009, p. 9.***

Thursday 14 June 2012

young children. Given the fact that the adoption ***and updating*** of ~~the list~~ ***the Annex*** ~~implies the~~ ***is a measure of general*** application ~~of criteria set out in this Regulation, implementing powers should be conferred on the Commission in that respect. 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 (1)~~ ***to supplement or amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in that respect***. The Commission should adopt immediately applicable ~~implementing~~ ***delegated*** acts updating the ~~Union list~~ ***Annex***, where, in duly justified cases relating to public health, imperative grounds of urgency so require. **[Am. 22]**

(21) At present, pursuant to the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the risk assessment of products of nanotechnologies, dated 19 January 2009, there is inadequate information on the risks associated with engineered nanomaterials and existing test methods may not be sufficient to address all of the issues arising in relation to engineered nanomaterials. ~~Therefore~~ ***Taking account of that scientific opinion and in view of the particular sensitivity of the vulnerable groups for whom foods covered by this Regulation are intended***, engineered nanomaterials should not be included in the ~~Union~~ list ***annexed to this Regulation*** for the categories of food covered by this Regulation~~, until an evaluation~~ ***as long as their safety, based on adequate and sufficient test methods, their nutritional value and their suitability for the persons for whom the food is intended have not been demonstrated*** by the Authority ~~is carried out~~. **[Am. 23]**

(22) In the interests of ~~efficiency and~~ legislative simplification ***and a clear desire to support innovation***, there should be a medium-term examination of the question whether to extend the scope of the ~~Union~~ list ***annexed to this Regulation*** to other categories of food governed by other specific Union legislation. ***Such an extension should be decided by the European Parliament and the Council in accordance with the ordinary legislative procedure, on the basis of an evaluation by the Authority.*** **[Am. 24]**

(23) It is necessary to establish procedures for the adoption of emergency measures in situations where food covered by this Regulation constitutes a serious risk to human health. In order to ensure uniform conditions for the implementation of emergency measures, implementing powers should be conferred on the Commission. 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 (2). The Commission should adopt immediately applicable implementing acts relating to emergency measures, where, in duly justified cases relating to public health, imperative grounds of urgency so require.

(24) Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the European 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.

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

(1) ~~OJ L 55, 28.2.2011, p. 13.~~
(2) OJ L 55, 28.2.2011, p. 13.

(26) Currently, the statements 'gluten-free' and 'very low gluten' may be used for food intended for particular nutritional uses and for food for normal consumption under the rules specified in Regulation (EC) No 41/2009. ~~Such~~ ***Those*** statements ~~could be construed as nutrition claims, as defined in Regulation (EC) No 1924/2006. For the sake of simplification, those statements~~ should be regulated solely by ~~Regulation (EC) No 1924/2006~~ ***this Regulation*** and comply with requirements ~~therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the nutrition claims 'gluten free' and 'very low gluten' and their associated conditions of use as regulated under~~ ***herein.*** Regulation (EC) No 41/2009 ~~be completed prior to the entry into application of this Regulation~~ ***should therefore be repealed.*** **[Am. 90]**

(26a) Labelling indicating 'lactose free' and 'very low lactose content' is currently not covered by Union law. Those indications are, however, important for people who are intolerant to lactose. The Commission should therefore clarify their status under general food law. **[Am. 25]**

(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are ***currently*** considered as food for particular nutritional uses and are governed by specific rules adopted under Directive 96/8/EC***, while foods intended for use in very low calorie diets are governed by Directive 2009/39/EC only***. 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. ***Against the background of the growing number of food products containing generic claims and the risk of disorders in dietary habits arising from certain unsupervised diets, the Authority regularly carries out scientific assessments of health claim applications relating to meal replacement. The assessment carried out by the Authority does not cover the safety of compositional criteria put forward by the food business operator applying for the use of a claim or certain labelling methods. Specific provisions are therefore needed in this Regulation on food intended for use in low and very low calorie diets. Such provisions are an important nutrition and health safety tool for people seeking to lose weight.*** In order to eliminate any potential confusion between food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, ***while protecting the most vulnerable,*** such statements ***on food intended for the general population*** should be regulated by Regulation (EC) No 1924/2006 and comply with requirements therein***, with the exception of foods intended for use in low and very low calorie diets, which should comply with this Regulation***. 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 'total diet replacement for weight control' and as 'meal replacement for weight control' and associated conditions of use as regulated under Directive 96/8/EC be completed prior to the entry into application of this Regulation. **[Am. 26]**

(27a) In order to ensure a high level of consumer protection, adequate procedures for oversight, in respect of both hygiene and composition, both before and after foods are placed on the market, should be established at Member State level. **[Am. 27]**

(27b) Pursuant to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [1], Member States should conduct inspections on the compliance of undertakings with this Regulation and the delegated acts adopted pursuant thereto, following a risk-based approach. **[Am. 28]**

[1] ***OJ L 165, 30.4.2004, p. 1.***

Thursday 14 June 2012

(28) Since the objectives of this Regulation 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.

(29) ***The Commission should take*** adequate ~~transitional~~ measures ~~are necessary~~ ***to ensure legal certainty between entry into force and application of this Regulation and provide the assistance and up-to-date information necessary to the food business operators*** to enable ~~food business operators~~ ***them*** to adapt to the requirements of this Regulation. **[Am. 29]**

(29a) To ease access of SMEs to the market which in some sectors, for example baby food and medical food, appear to be dominated by a few large companies, the Commission should, in close cooperation with concerned stakeholders, adopt guidelines, by means of delegated acts, in order to help undertakings, in particular SMEs, to comply with the requirements laid down in this Regulation and thus facilitate competitiveness and innovation. **[Am. 30]**

(29b) In order to facilitate market access for food business operators – especially SMEs – wishing to sell foods resulting from scientific and technological progress, the Commission, in close cooperation with the relevant stakeholders, should adopt guidelines on the procedure for placing such food on the market on a temporary basis. **[Am. 31]**

(29c) The Commission should be empowered to authorise, by means of delegated acts, food resulting from scientific and technological progress to be placed on the market on a temporary basis in order that proper benefit may be derived from the fruits of industry research pending the amendment of the delegated act for the specific food category concerned. However, in the interests of consumer health protection, a marketing authorisation may be granted only after the Authority has been consulted. **[Am. 91]**

HAVE ADOPTED THIS REGULATION:

Chapter I

Subject matter and definitions

Article 1

Subject matter

1. This Regulation***, which complements Union law on food,*** establishes compositional and information requirements for the following categories of food: **[Am. 33]**

(a) infant formula and follow-on formula;

(b) processed cereal-based food and baby food for infants and young children;

(c) food for special medical purposes, ***including formula intended for low-birth-weight and pre-term infants;*** **[Am. 34]**

(ca) food for people intolerant to gluten; and **[Am. 35]**

(cb) foods intended for use in low and very low calorie diets. **[Am. 36]**

2. This Regulation lays down rules for the establishment and updating of a ***clearly defined*** ~~Union~~ list, ***in Annex I,*** of vitamins, minerals and other substances that can be added to the categories of food referred to in paragraph 1 ***for a specific nutritional purpose***. **[Am. 37]**

2a. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food. **[Am. 38]**

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 in Article 2 and Article ***3(7) and*** 3(8) of Regulation (EC) No 178/2002; **[Am. 39]**

(b) the definitions of ***'prepacked food' and*** 'labelling' ~~and 'pre-packaged foodstuff~~ ***set out*** in points ~~(a)~~ ***(e)*** and ~~(b)~~ ***(j)*** of Article ~~1(3)~~ ***2(2)*** of ~~Directive 2000/13/EC~~ ***Regulation (EU) No 1169/2011***; **[Am. 40]**

(c) the definitions of 'nutrition claim' and 'health claim' set out in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006;

(d) the definition of 'other substance' set out in Article 2(2) of Regulation (EC) No 1925/2006; and

(da) the definition of 'engineered nanomaterial' set out in point (t) of Article 2(2) of Regulation (EU) No 1169/2011. **[Am. 41]**

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 for their progressive adaptation to ordinary food; and

Thursday 14 June 2012

(ii) falling within 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 intended for young children;

(h) 'food for special medical purposes' means food ***specially processed or formulated and*** intended for the dietary management of patients 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. ***Food for special medical purposes also includes formula intended for low-birth-weight and pre-term infants. Such formula also has to comply with Directive 2006/141/EC;*** **[Am. 92]**

(ha) 'formula intended for low-birth-weight and pre-term infants' means a food specifically developed to meet the medically-determined nutrient requirements of infants who are born prematurely or at a low birth weight; **[Am. 43]**

(hb) 'food for people intolerant to gluten' means foodstuffs for particular nutritional uses which are specially produced, prepared or processed to meet the special dietary needs of people intolerant to gluten; **[Am. 44]**

(hc) 'gluten' means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof and which is insoluble in water and 0,5 M sodium chloride solution; **[Am. 45]**

(hd) 'food intended for use in low calorie diets' or 'LCD products', and 'food intended for use in very low calorie diets' or 'VLCD products' means specifically formulated food which, when used as instructed by the manufacturer, replaces the total daily diet.

VLCD products contain between 400 and 800 kcal per day.

LCD products contain between 800 and 1 200 kcal per day. **[Am. 46]**

Food for special medical purposes within the meaning of point (h) of the first subparagraph falls within one of the following three categories:

(i) nutritionally complete foods with a standard nutrient formulation which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(ii) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;

(iii) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment. **[Am. 47]**

~~3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 to adapt the definitions of 'infant formula', 'follow-on formula', 'processed cereal-based food' and 'baby food' and 'food for special medical purposes' taking into account technical and scientific progress and relevant developments at international level, as appropriate.~~ **[Am. 48]**

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 ***and Union law applicable to food***.

2. Food referred to in Article 1(1) that is imported into the Union for the purpose of being placed on the market shall comply with the applicable provisions of Union food law. Food referred to in Article 1(1) that is exported or re-exported from the Union for the purpose of being placed on the market in a third country shall comply with the applicable provisions of Union food law, save if specific circumstances in the importing country, linked, for example, to climate or topography, justify a different composition and a different market preparation.

3. Food referred to in Article 1(1) may be placed on the market only in the form of pre-packed food.

4. Member States may not restrict or forbid the placing on the market of food which complies with this Regulation, for reasons related to their composition, manufacturing, presentation or labelling. **[Am. 49]**

4a. In order to enable food referred to in Article 1(1) and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting the Authority, adopt delegated acts in accordance with Article 15, authorising, for a two-year period, the placing on the market of food referred to in Article 1(1) that does not comply with the rules on composition laid down by this Regulation or by the delegated acts adopted pursuant to this Regulation. **[Am. 50]**

Thursday 14 June 2012

~~Article 4~~

~~Pre-packaged food~~

~~Food referred to in Article 1(1) shall only be allowed on the retail market in the form of pre-packaged food.~~ **[Am. 51]**

~~Article 5~~

~~Free movement of goods~~

~~Member States may not, for reasons related to their composition, manufacturing, presentation or labelling, restrict or forbid the placing on the market of food which complies with this Regulation.~~ **[Am. 52]**

Article 6

Emergency measures

1. Where it is evident that a food referred to in Article 1(1) is likely to constitute a serious risk to human health and that that risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission on its own initiative or at the request of a Member State, shall without delay take appropriate interim emergency measures, including measures restricting or prohibiting the placing on the market of the food concerned, depending on the gravity of the situation. Those measures shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 14(2).

2. On duly justified imperative grounds of urgency to contain or address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 14(3).

3. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not taken action pursuant to paragraph 1, the Member State concerned may adopt appropriate interim emergency measures, including measures restricting or prohibiting the placing on the market of the food concerned, depending on the gravity of the situation, within its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. The Commission shall adopt implementing acts aiming at extending, amending or abrogating the national interim emergency measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2). The Member State may maintain its national interim emergency measures until the implementing acts mentioned in this paragraph have been adopted.

Article 6a

Precautionary principle

Where, following an assessment of available scientific information, there are reasonable grounds for concern for the possibility of adverse effects but scientific uncertainty persists, provisional risk management measures may be adopted that are necessary to ensure a high level of protection of the vulnerable groups of the population for whom the food referred to in Article 1(1) is intended. **[Am. 53]**

Article 6b

Oversight

The national competent authorities shall ensure that an adequate system of oversight is put in place to ensure that food business operators comply with this Regulation and with the relevant health requirements. **[Am. 54]**

Chapter III

Requirements

Section 1

Introductory provisions

Article 7

Introductory provision

Food referred to in Article 1(1) shall comply with requirements 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.~~ **[Am. 55]**

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 applying this Regulation.

Article 8a

Food for normal consumption

In the labelling, presentation and advertising of food for normal consumption the following shall be prohibited:

(a) the use of the expression 'specialised nutrition', either alone or in conjunction with other words, to designate such food;

(b) all other markings or any presentation likely to give the impression that the food belongs to one of the categories referred to in Article 1(1). **[Am. 56]**

Section 2

General requirements

Article 9

General composition 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 ***peer-reviewed and independently evaluated*** scientific data ***and medical opinion***. **[Am. 57]**

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 they are intended.

3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ~~provide adequate consumer information~~ ***be accurate, clear and easy to understand for consumers*** and shall not be misleading. ***It shall not attribute properties to such food for the prevention, treatment or cure of human disease, or imply such properties.*** **[Am. 58]**

Thursday 14 June 2012

3a. The labelling of infant formula and follow-on formula shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. Graphic representations for easy identification of the product and for illustrating methods of preparation shall, however, be permitted. Directive 2006/141/EC shall be amended accordingly. **[Am. 59]**

4. The dissemination of useful information or recommendations with reference to the categories of food referred to in ***points (a), (b), (c) and (ca)*** of Article 1 (1) may be made exclusively ~~by~~ ***to*** persons with qualifications in medicine, nutrition~~,~~ ***or*** pharmacy ~~or other~~***. Additional information disseminated by healthcare*** professionals ~~responsible for maternal and child health care~~ ***to the final consumer shall only be of a scientific and factual nature and shall not contain advertising.*** **[Am. 60]**

4a. In order to ensure efficient official monitoring, food business operators shall notify the competent authority of each Member State in which they place on the market food referred to in Article 1(1), by forwarding it a model of the product's label. **[Am. 61]**

4b. The use of pesticides in agricultural products intended for the production of food referred to in Article 1(1) shall be restricted as far as possible, without prejudice to Directive 2006/125/EC and Directive 2006/141/EC. **[Am. 62]**

4c. Specific requirements relating to food referred to in Article 1(1) that lay down limitations on the use of, or that ban, certain pesticides shall be updated regularly, with particular attention being paid to pesticides containing active substances, safeners or synergists classified under 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 [1] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, considered to have endocrine-disrupting properties that may cause adverse effects in humans, or active substances approved as 'candidate for substitution' pursuant to Article 24 of Regulation (EC) No 1107/2009. **[Am. 63]**

Section 3

Specific requirements

Article 10

Specific composition and information requirements

1. Food referred to in Article 1(1) shall comply with the requirements of Article 7 and composition and information requirements provided in Article 9.

2. Subject to the general requirements of Articles 7 and 9***, and to the specific requirements of Articles 10a and 10b,*** and taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC as well as any technical and scientific progress, ***in particular the results of risk evaluations and the precautionary principle as referred to in Article 6a,*** the Commission shall be empowered to adopt delegated ~~Regulations,~~ ***acts*** no later than … [2], in accordance with Article 15, with respect to the following: **[Am. 64]**

(a) the specific compositional requirements of food referred to in Article 1(1);

(b) the specific requirements on the use of pesticides in agricultural products intended for the production of such food and on pesticides residues in such food;

[1] ***OJ L 353, 31.12.2008, p. 1.***
[2] 2 years after the date of entry into force of this Regulation.

(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,~~ ***those requirements shall include the specific related rules already in force for food referred to in Article 1(1);*** **[Am. 66]**

(ca) the requirements for information to be provided on recommendations for appropriate use of food referred to in Article 1(1); **[Am. 67]**

(d) the notification procedure for the placing on the market of a 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 formulae;

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

(fa) ***a requirement for post-market monitoring of food referred to in Article 1(1), in order to verify whether the specific requirements are being complied with.*** **[Am. 68]**

3. Subject to the ***general*** requirements of Articles 7 and 9***, and to the specific requirements of Articles 10a and 10b,*** and taking into account relevant technical and scientific progress, ***in particular the results of new risk assessments and the precautionary principle as referred to in Article 6a,*** the Commission shall update the delegated ***acts*** mentioned in paragraph 2 of this Article in accordance with Article 15. **[Am. 69]**

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.

Article 10a

Food for people intolerant to gluten

1. In addition to the requirements of Article 9, food intended for people intolerant to gluten consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten, shall contain a level of gluten not exceeding 100 mg/kg in the food as sold to the final consumer.

2. Food intended for people intolerant to gluten sold to the final consumer which contain a level of gluten:

— not exceeding 100 mg/kg may be labelled 'very low gluten content';

— not exceeding 20 mg/kg may be labelled 'gluten free'.

3. Food intended for people intolerant to gluten shall also comply with the following criteria:

— it shall provide roughly the same amount of vitamins and mineral salts as the foodstuffs they are replacing,

Thursday 14 June 2012

— it shall be prepared with special care, in compliance with good manufacturing practice (GMP), to avoid gluten contamination,

— where the terms 'very low gluten content' or 'gluten free' are used, they shall appear in proximity to the name under which the food is marketed. **[Am. 70]**

Article 10b

Foods intended for use in low calorie diets and very low calorie diets

1. LCD and VLCD products shall comply with the compositional requirements set out in Annex II to this Regulation.

2. All individual components making up LCD and VLCD products, as sold, shall be contained in a single package.

3. The name under which LCD and VLCD products are sold shall be:

(a) for VLCD products,

'Total diet replacement for use in very low calorie diets';

(b) for LCD products,

'Total diet replacement for use in low calorie diets'.

4. The labelling of LCD and VLCD products shall bear, in addition to those provided for in Chapter IV of Regulation (EU) No 1169/2011, the following mandatory particulars:

(a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

(b) the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of AnnexII, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;

(c) instructions for appropriate preparation, when necessary and a statement as to the importance of following those instructions;

(d) if a product provides a daily intake of polyols in excess of 20 g per day, when used as instructed by the manufacturer, there shall be a statement to the effect that the food may have a laxative effect;

(e) a statement on the importance of maintaining an adequate daily fluid intake;

(f) a statement that the product provides adequate amounts of all essential nutrients for the day;

(g) a statement that the product should not be used for more than three weeks without medical advice.

5. The labelling, advertising and presentation of LCD and VLCD products concerned shall not make any reference to the rate or amount of weight loss which may result from their use. **[Am. 71]**

Article 10c

Access for SMEs to the internal market

The Commission shall, in close cooperation with all stakeholders and the Authority, adopt appropriate guidelines and provide technical guidance to enable undertakings, in particular SMEs, to comply with this Regulation and assist them in the preparation and presentation of the application for scientific assessment. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to adopt those guidelines. **[Am. 72]**

Chapter IV

~~Union~~ List of permitted substances

Article 11

~~Union~~ ***Establishment of a*** list of permitted substances

1. ***Taking account of Directives 2006/141/EC and 2006/125/EC and Regulation (EC) No 953/2009, the Commission shall be empowered to adopt, no later than … (*), delegated acts in accordance with Article 15, in order to insert in Annex I a list of vitamins, minerals and other substances which may be added to each category of food referred to in Article 1(1).***

~~1.~~***2.*** Vitamins, minerals, amino acids and other substances may be added to food referred to in Article 1(1), provided that such substances meet the following conditions:

(a) they do not, on the basis of the ***generally accepted and peer-reviewed*** scientific evidence available, pose a safety concern to the health of the consumer; ~~and,~~

(b) they are available for use by the human body;

(ba) they are suitable for the nutritional use for which they are intended; and

(bb) they have, on the basis of generally accepted scientific evidence, a nutritional or physiological effect.

~~2. No later than *[2 years after the date of the entry into force of this Regulation]*, the Commission shall establish and subsequently update a Union list of permitted substances that meet the conditions of paragraph 1, by means of implementing Regulations. The entry of a substance in the Union list shall include a specification of the substance, and, where appropriate, specify the conditions of use and the applicable purity criteria. Those implementing Regulations shall be adopted in accordance with the examination procedure referred to in Article 14(2). On duly justified grounds of extreme urgency relating to emerging health risks, the Commission shall adopt immediately applicable implementing acts updating the Union list in accordance with Article 14(3).~~

2a. For substances referred to in paragraph 2 that are engineered nanomaterials, the following additional conditions shall apply:

(a) the condition in point (a) of paragraph 2 has been demonstrated on the basis of adequate test methods; and

(b) their nutritional value and the suitability for the persons for whom they are intended has been shown. **[Am. 87]**

(*) ***2 years after the date of entry into force of this Regulation***

Thursday 14 June 2012

Article 11a

Updating of the list of permitted substances

~~3.~~ ***1.*** The addition of a ***new*** substance ~~in the Union list referred to in paragraph 2~~ ***to Annex I*** may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may also represent several interested parties (~~hereinafter referred to as~~ the 'applicant'). ~~Applications shall be sent to the Commission, in accordance with paragraph 4.~~

1a. The applicant shall submit an application to the Commission in accordance with paragraph 2. The Commission shall acknowledge receipt in writing within 14 days of its receipt.

~~4.~~ ***2.*** The application shall include:

(a) the name and the address of the applicant;

(b) the name and a clear description of the substance

(c) the composition of the substance;

(d) the proposed use of the substance and conditions thereof;

(e) a systematic review of the scientific data and appropriate ***peer-reviewed*** studies performed following generally accepted expert guidance on the design and conduct of such studies;

(f) scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it isintended and its suitability for the intended uses;

(g) scientific evidence demonstrating that the substance is available for use by the human body ***and has a nutritional or physiological effect***;

(h) a summary of the content of the application.

~~5.~~ ***3.*** If a substance is already included in ~~the Union list~~ ***Annex I*** and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods ***or with a change in particle size*** shall be considered as a different substance ~~and the Union listbe modified accordingly before it can be placed on the Union market.~~ ***A separate application shall be required for its inclusion in Annex I***.

4. If a substance that is in Annex I no longer meets the conditions referred to in Article 11(2) and (2a), the Commission shall decide to remove that substance from Annex I.

5. The entry for a substance into Annex I shall include:

— ***a specification of the substance;***

— ***where appropriate, a specification of the conditions of use; and***

— ***where appropriate, a specification of the applicable purity criteria.***

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to update Annex I. 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. **[Am. 88]**

Article 12

Confidential information relating to applications

1. Among the information provided in the application referred to in Article 11, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of the applicant.

2. Information relating to the following shall not, in any circumstances, be regarded as confidential:

(i) the name and address of the applicant;

(ii) the name and description of the substance;

(iii) the justification for the use of the substance in or on specific food;

(iv) information that is relevant to the assessment of the safety of the substance;

(v) where applicable, the analysis method(s) used by the applicant;

(va) any scientific data gathered from animal testing for the assessment of the safety of the substance. **[Am. 75]**

3. Applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

4. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.

5. After being informed of the Commission's position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.

Chapter V

Confidentiality

Article 13

General *transparency and* confidentiality clause

The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [1], ***guarantee the broadest possible access to documents and, in particular, shall assist members of the public with, and inform them about, the procedures for submitting applications for access to documents. They shall also*** take the necessary

[1] OJ L 145, 31.5.2001, p. 43.

measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment. **[Am. 76]**

Chapter VI

Procedural provisions

Article 14

Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. 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.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

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 ~~delegation of~~ power ***to adopt delegated acts*** referred to in Articles ~~2(3) and 10~~ ***3(4a), 10(2) and (3), 10c, 11(1)*** and ***11a(6)*** ~~of this Regulation~~ shall be conferred for ~~an indeterminate~~ ***a*** period ~~of time from the (*) [(*) Date of entry into force of the basic legislative act or from any other date set by the legislator.]~~ ***of 5 years from … (*). 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.*** **[Am. 77]**

3. The ~~delegation of powers~~ ***power to adopt delegated acts*** referred to in Articles ~~2(3) and 10~~ ***3(4a), 10(2) and (3), 10c, 11(1) and 11a(6)*** may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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. **[Am. 78]**

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

(*) ***Date of entry into force of this Regulation.***

5. A delegated act adopted pursuant to ***Articles*** ~~2(3)~~ ***3(4a), 10(2) and (3), 10c, 11(1) and*** ~~10~~ ***11a(6)*** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 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 2 months at the initiative of the European Parliament or the Council. **[Am. 79]**

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 the Council.

Chapter VII

Final provisions

Article 16a

Food for people intolerant to lactose

By … (*), the Commission shall present a report, if appropriate accompanied by a legislative proposal, to the European Parliament and to the Council, in order to clarify the status of labelling indications of 'lactose free' and 'very low lactose content' under general food law. **[Am. 80]**

Article 16b

Milks intended for young children

By … (*), the Commission shall, after consulting the Authority, submit a report to the European Parliament and to the Council assessing the need for special provisions regarding the composition and labelling of milks intended for young children. This report shall consider the nutritional needs, the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of these young children. The report shall also consider whether these milks have any nutritional benefits when compared to a normal diet for a child who is being weaned. In the light of the conclusions of that report, the Commission shall either:

(a) decide that there is no need for special provisions regarding the composition and labelling of milks intended for young children; or

(b) if appropriate, submit, in accordance with the ordinary legislative procedure and on the basis of Article 114 of the TFEU, a legislative proposal.

Prior to the preparation of the Commission report referred to in the first paragraph, the milks intended for young children shall continue to fall within the scope of the relevant Union legislation such as Regulation (EC) No 178/2002, Regulation (EC) No 1925/2006 and Regulation (EC) No 1924/2006. **[Am. 81]**

(*) ***1 year after entry into force of this Regulation.***

Thursday 14 June 2012

Article 17

Repeal

1. Directive 92/52/EEC and Directive 2009/39/EC are repealed from … (*). References to the repealed acts shall be construed as references to this Regulation.

2. Directive 96/8/EC and Regulation (EC) No 41/2009 are repealed from … (*).

Article 18

Transitional measures

Food not complying with this Regulation but complying with Directives 2009/39/EC and 96/8/EC, Regulations (EC) No 41/2009 and (EC) No 953/2009, and labelled prior to … (**) may continue to be marketed after that date until stocks are exhausted.

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 … (***).

This Regulation shall 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*

(*) the first day of the month 2 years after the date of the entry into force of this Regulation.
(**) 2 years after the date of the entry into force of this Regulation.
(***) the first day of the month 2 years after the date of the entry into force of this Regulation.

Thursday 14 June 2012

Annex I

List of permitted substances **[Am. 89]**

Annex II

Compositional requirements for LCD and VLCD products

These specifications refer to LCD and VLCD products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

1.1. The energy provided by a VLCD product shall not be less than 1 680 kJ (400 kcal) and shall not exceed 3 360 kJ (800 kcal) for the total daily ration.

1.2. The energy provided by a LCD product shall not be less than 3 360 kJ (800 kcal) and shall not exceed 5 040 kJ (1 200 kcal) for the total daily ration.

2. Protein

2.1. The protein contained in LCD and VLCD products shall provide not less than 25 % and not more than 50 % of the total energy of the product. In any event the amount of protein of these products shall not exceed 125 g.

2.2. Point 2.1 refers to a protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein set out in Table 2. If the chemical index is lower than 100 % of the reference protein, the minimum protein levels shall be correspondingly increased. In any event the chemical index of the protein shall at least be equal to 80 % of that of the reference protein.

2.3. The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.

2.4. In every event, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. Fat

3.1. The energy derived from fat shall not exceed 30 % of the total available energy of the product.

3.2. The linoleic acid (in the form of glycerides) shall not be less than 4,5 g.

4. Dietary fibre

The dietary fibre content of LCD and VLCD products shall not be less than 10 g and shall not exceed 30 g for the daily ration.

5. Vitamins and minerals

The LCD and VLCD products shall provide for the whole of the daily diet at least: 100 % of the amounts of vitamins and minerals specified in Table 1.

Thursday 14 June 2012

Table 1

Vitamin A	*(µg RE)*	*700*
Vitamin D	*(µg)*	*5*
Vitamin E	*(mg-TE)*	*10*
Vitamin C	*(mg)*	*45*
Thiamin	*(mg)*	*1,1*
Riboflavin	*(mg)*	*1,6*
Niacin	*(mg-NE)*	*18*
Vitamin B6	*(mg)*	*1,5*
Folate	*(µg)*	*200*
Vitamin B12	*(µg)*	*1,4*
Biotin	*(µg)*	*15*
Pantothenic acid	*(mg)*	*3*
Calcium	*(mg)*	*700*
Phosphorus	*(mg)*	*550*
Potassium	*(mg)*	*3 100*
Iron	*(mg)*	*16*
Zinc	*(mg)*	*9,5*
Copper	*(mg)*	*1,1*
Iodine	*(µg)*	*130*
Selenium	*(µg)*	*55*
Sodium	*(mg)*	*575*
Magnesium	*(mg)*	*150*
Manganese	*(mg)*	*1*

Table 2

AMINO ACID REQUIREMENT PATTERN [1]

	g/100 g protein
Cystine + methionine	*1,7*
Histidine	*1,6*
Isoleucine	*1,3*
Leucine	*1,9*
Lysine	*1,6*
Phenylalanine + tyrosine	*1,9*
Threonine	*0,9*
Tryptophan	*0,5*
Valine	*1,3*

[1] *World Health Organisation. Energy and protein requirements. Report of a Joint FAO/WHO/UNU Meeting. Geneva: World Health Organisation, 1985. (WHO Technical Report Series, 724).*

[Am. 82]