AMENDMENTS 001-082
by the Committee on the Environment, Public Health and Food Safety

Report
Frédérique Ries **A7-0059/2012**
Food intended for infants and young children and food for special medical purposes

Proposal for a regulation (COM(2011)0353 – C7-0169/2011 – 2011/0156(COD))

Amendment 1

Proposal for a regulation
Title

Text proposed by the Commission	*Amendment*
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	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on food intended for infants and young children**,** 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***

Justification

Some essential guarantees that are offered in the current dietetic Framework Directive (2009/39/EC) and under its relevant Vertical Directives have been removed in this proposal to the detriment of vulnerable consumers. These consumers require foods that are specially formulated to provide specialised nutrition and to help them in the dietary management of specific conditions. It is therefore necessary to re-introduce the concept of food intended for specialised nutrition. This is aligned with the current Codex standard for foods for special dietary uses (146-1985).

Amendment 2

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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.***	(2) The ***safety*** of food***, especially when it is intended for vulnerable groups, such as infants, young children and persons with special diseases,*** is an essential ***prerequisite for the free movement of such persons and the proper functioning of the internal market.***

Justification

The focus needs to be shifted: if we are to expect the internal market to work properly, we cannot afford to disregard the health of the more vulnerable members of society.

Amendment 3

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(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 categories of foods covered by this Regulation.

Justification

The current EU legislation must not allow the presence of pesticide residues in formulae for infants under the age of 12 months or children under the age of 3. Early exposure to such toxic products may prove to have irreversible effects. There is an urgent need to apply the principle of prohibiting the use of pesticides in products of animal origin such as milk, but also to impose more stringent checks.

Amendment 4

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses 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***.	(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses 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 ***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[1], 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[2], 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 other substances to food[3] 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[4], is a further factor making it necessary to thoroughly overhaul Directive 2009/39/EC.***

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[1] OJ L 83, 12.07.2002, p. 51.

[2] OJ L 404, 30.12.2006, p.9.

[3] 2 OJ L 404, 30.12.2006, p.26.

[4] OJ L 304, 22.11.2011, p. 18.

Justification

The rapporteur shares the Commission's view that the framework directive on foodstuffs for particular nutritional uses needs to be thoroughly overhauled. Operators have taken advantage of the variety of laws available to them to market similar products under different names.

Amendment 5

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) According to the Council Resolution of 18 June 1992[1], the Union should contribute to the application of appropriate practices for the marketing of breast-milk substitutes in third countries by Community-based manufacturers.
	[1] OJ C 172, 8.7.1992, p. 1.

Amendment 6

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(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***	(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 regards the development of specific provisions due to widely diverging views among Member States and stakeholders concerning the scope of the specific legislation. ***Nevertheless, the undertaking made by the Commission in Directive 2009/39/EC to recognise the nutritional requirements of sportspeople should still***

product development. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report concludes that the scientific basis for setting specific compositional requirements is lacking.	***apply, as supported by scientific opinions of the European Food Safety 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.***

Amendment 7

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) The Commission report of 26 June 2008 on food for persons suffering from carbohydrate metabolism disorders (diabetes) 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.

Justification

This Regulation is not the appropriate legal framework for examining the whole range of aspects of the important issue of diabetes at EU level.

Amendment 8

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) There is therefore a need to remove differences in interpretation and to tackle difficulties for Member States and 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 SMEs.

Amendment 9

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(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 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 European Food Safety Authority (hereinafter referred to as '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.	(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 establishes common principles and definitions for Union food law in order to ensure a high level of protection ***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 European Food Safety Authority (hereinafter referred to as '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.

Justification

The precautionary principle, considered as a provisional risk management measure, forms part of the general principles set out in the general legislation on food of 28 January 2002.

Amendment 10

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Justification

Linked with amendment 9.

Amendment 11

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(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	(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. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission 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. It is therefore 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, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.	formulae, processed cereal-based food and baby food***,*** food for special medical purposes, ***food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission 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. ***VLCD products are currently not covered by Commission Directive 96/8/EC but solely by Directive 2009/39/EC.*** It is therefore 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***,*** food for special medical purposes***, food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, ***while*** taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.

Amendment 12

Proposal for a regulation
Recital 16

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

international level, as appropriate.	***(LCD) and very low calorie diets (VLCD)*** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.

Amendment 13

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(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 infants 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.

Amendment 14Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(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.	(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.

Justification

The scientific data on the nutritional adequacy of the special food must be not only systematic, but also based on independent evaluation, to guarantee the high reliability and general acceptance of such data.

Amendment 15

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(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.
	_____
	[1] OJ L 309, 24.11.2009, p. 1.

Justification

Cadusafos, which is a member of the organophosphate family of chemicals, has been banned in the territory of the EU since 2008. It must therefore be deleted from the list of the five active substances for which the maximum content of pesticide residue or metabolites in formulae for infants and children under three is fixed. Fipronil, the harmful effects of which have been pointed out by a number of national health authorities, should also be withdrawn.

Amendment 16

Proposal for a regulation
Recital 17 b (new)

Text proposed by the Commission	*Amendment*
	(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[1], should apply without prejudice to specific provisions set out in this Regulation and the delegated acts adopted in accordance with this Regulation.

[1] OJ L 70, 16.3.2005, p. 1.

Amendment 17

Proposal for a regulation
Recital 17 c (new)

Text proposed by the Commission	*Amendment*
	(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 food for infants and young children. Specific maximum residue levels for such 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.

Amendment 18

Proposal for a regulation
Recital 17 d (new)

Text proposed by the Commission	*Amendment*
	(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.

Justification

The principle of liability of all actors of the food production chain has to be emphasized in this Regulation.

Amendment 19

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(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***. 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***, where necessary, in order to meet the specific objectives of this Regulation.	(18) General labelling requirements are laid down in ***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 ***Regulation (EU) No 1169/2011***, where necessary, in order to meet the specific objectives of this Regulation.

Justification

Since the adoption of the Commission's proposal for a Regulation on food intended for infants and young children and on food for special medical purposes, 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 has been replaced by 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.

Amendment 20

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission 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***	(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***, food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC. In

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.	order to lay down the specific compositional and information requirements with respect to the categories of food covered by 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. 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.

Justification

It is not appropriate to allow for delegated acts for the updating of the definitions, as the definitions are an essential part of the Regulation which should only be allowed to be changed by the ordinary legislative procedure. The establishment and updating of the list is an act of general application to supplement or amend certain non-essential elements of the legislative act. Moreover the conditions laid down in Article 11(1) are very open. Therefore delegated acts should be applied.

Amendment 21

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 22

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) It is appropriate to establish and update a Union list 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, subject to certain criteria laid down in this Regulation. Given the fact that the adoption of the list ***implies the*** 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***. The Commission should adopt immediately	(20) It is appropriate to establish and update a Union list of vitamins, minerals and other substances that may be added to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes ***and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, subject to certain criteria laid down in this Regulation. ***The 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[1], which does not apply to liquid or solid***

applicable ***implementing*** acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require.	***formula for infants and young children.*** Given the fact that the adoption ***and updating*** of the list ***is a measure of general*** application ***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 ***delegated*** acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require. _____ ***[1] OJ L 269, 14.10.2009, p. 9.***

Justification

While the Commission's idea of aiming at a simplified and consolidated model for a single positive list of vitamins, minerals and other nutritional substances is to be supported, it is equally important to specify its content in order to preserve the specific dietary habits of each category. An added nutriment may be good for a sick person, but not necessarily for a new-born baby.

Amendment 23

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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***, engineered nanomaterials should not be included in the Union list for the categories of food covered by this Regulation, ***until an evaluation*** by the Authority ***is carried out***.	(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. ***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 for the categories of food covered by this Regulation ***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.

Justification

Based on AM 21 by the Rapporteur. Nanomaterials can only be assessed by specific test-methods.

Amendment 24

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) In the interests of ***efficiency and*** legislative simplification, there should be a medium-term examination of the question whether to extend the scope of the Union list to other categories of food governed by other specific Union legislation.	(22) In the interests of 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 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.***

Justification

Linked to Amendment 17: any future decision to extend the list to other food categories should be taken subject to the expert assessment of the EFSA and under appropriate democratic scrutiny.

Amendment 25

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 26

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are considered as food for particular nutritional uses and are 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 between food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statements 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 '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.	(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 (VLCD) 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 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 calorie diets (LCD) and very low calorie diets (VLCD). 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 calorie diets (LCD) and very low calorie diets (VLCD), 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.

Amendment 27

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 28

Proposal for a regulation
Recital 27 b (new)

Text proposed by the Commission	*Amendment*
	(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.
	[1] OJ L 165, 30.4.2004, p. 1.

Amendment 29

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) Adequate ***transitional*** measures ***are necessary*** to enable ***food business operators*** to adapt to the requirements of this Regulation.	(29) ***The Commission should take*** adequate measures ***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 ***them*** to adapt to the requirements of this Regulation.

Justification

Account must be taken of the fact that the regulatory adjustments resulting from this proposal may create a legal vacuum, albeit during a transitional period.

Amendment 30

Proposal for a regulation
Recital 29 a (new)

Text proposed by the Commission	*Amendment*
	(29a) To ease access of small and medium-sized enterprises (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.

Justification

The European Union has to think small first and should facilitate, although with appropriate legal provisions, the access for SMEs to the internal market.

Amendment 31

Proposal for a regulation
Recital 29 b (new)

Text proposed by the Commission	*Amendment*
	(29b) In order to facilitate market access for operators – especially SMEs – wishing to sell foods resulting from scientific and technological innovations, 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.

Amendment 32

Proposal for a regulation
Recital 29 c (new)

Text proposed by the Commission	*Amendment*
	(29c) A procedure should be laid down which allows the Commission, by means of delegated acts, to authorise food resulting from scientific and

	technological innovations 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 category of food concerned. However, in the interests of consumer health protection, marketing authorisation may be granted only after the Authority has been consulted.

Justification

It is important – to enable them to respond as effectively as possible to the specific nutrition needs of vulnerable groups of people – that manufacturers in the sector should have optimal guidance on the steps to be followed. The groups concerned could thus benefit swiftly from relevant technical and scientific progress.

Amendment 33

Proposal for a regulation
Article 1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation establishes compositional and information requirements for the following categories of food:	1. This Regulation***, complementing Union law on food,*** establishes compositional and information requirements for the following categories of food:

Justification

Your rapporteur takes the view that substitute meals replacing all or part of a person's daily food intake (meeting nutritional needs in terms of vitamins, minerals, protein, essential fatty acids, fibre, etc.) should continue to be the subject of specific legislation. This is the best way of retaining some control over the composition of the foods in question and of ensuring that there is no confusion with the aspects linked to the health claims made for foodstuffs (Regulation (EC) No 1924/2006).

Amendment 34

Proposal for a regulation
Article 1 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) food for special medical purposes**.**	(c) food for special medical purposes, ***including formula intended for low birth-weight and pre-term infants.***

Amendment 35

Proposal for a regulation
Article 1 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) food for people intolerant to gluten.

Justification

Regulation (EC) No 41/2009, which came into force on 1 January 2012, sets out provisions for labelling and composition for products for people intolerant to gluten. It would therefore be logical to maintain these specific rules by including them in this proposal for a regulation, which covers all the categories of food for specific nutritional purposes intended for vulnerable groups, such as sufferers of coeliac disease.

Amendment 36

Proposal for a regulation
Article 1 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) foods intended for use in low calorie diets (LCD) and very low calorie diets (VLCD).

Amendment 37

Proposal for a regulation
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation provides the rules for the establishment and *update* of a Union list of vitamins, minerals and other substances that can be added to the categories of food referred to in paragraph 1.	2. This Regulation provides the rules for the establishment and *updating* of a ***clearly defined*** Union list 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***.

Justification

It is important to make clear that this regulation concerns foods which are intended to meet a range of very specific dietary needs and which account for only 1 to 2 % of the European food market. Paragraph 3 reproduces verbatim Article 7(2) of the proposal for a regulation, dealing with introductory provisions, which has been deleted.

Amendment 38

Proposal for a regulation
Article 1 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

Justification

It is important to make clear that this regulation concerns foods which are intended to meet very specific and clearly defined nutritional needs and which account for only 1 to 2 % of the European food market. Paragraph 3 reproduces verbatim Article 7(2) of the proposal for a regulation, dealing with introductory provisions, which has been deleted.

Amendment 39

Proposal for a regulation
Article 2 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the definitions of **'**food**'** and **'**placing on the market**'** set out in Articles 2 and 3(8) of Regulation (EC) No 178/2002;	(a) the definitions of ***'***food***', 'retail'*** and ***'***placing on the market***'*** set out in Articles 2 and ***3(7) and*** 3(8) of Regulation (EC) No 178/2002;

Amendment 40

Proposal for a regulation
Article 2 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the definitions of 'labelling' ***and*** '***pre-packaged foodstuff***' in points ***(a)*** and ***(b)*** of Article ***1(3)*** of ***Directive 2000/13/EC***;	(b) the definitions of ***'prepacked food' and*** 'labelling' ***set out*** in points ***(e)*** and ***(j)*** of Article ***2(2)*** of ***Regulation (EU) No 1169/2011***;

Justification

Alignment to the recently adopted Regulation (EU) No 1169/2011 on food information to consumers, which replaces Directive 2000/13/EC.

Amendment 41

Proposal for a regulation
Article 2 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the definition of 'engineered nanomaterial' set out in point (t) of Article 2(2) of Regulation (EU) No 1169/2011.

Justification

As engineered nanomaterials are referred to both in the Commission proposal (Recital 21) and in several amendments, it is appropriate to add the definition.

Amendment 42

Proposal for a regulation
Article 2 – paragraph 2 – point h

Text proposed by the Commission	*Amendment*
(h) 'food for special medical purposes' means food 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 with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet.	h) 'food for special medical purposes' means food 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 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, which also have to comply with the requirements of Directive 2006/141/EC.***

Amendment 43

Proposal for a regulation
Article 2 – paragraph 2 – point h a (new)

Text proposed by the Commission	*Amendment*
	(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.

Amendment 44

Proposal for a regulation
Article 2 – paragraph 2 – point h b (new)

Text proposed by the Commission	*Amendment*
	(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;

Justification

Some essential guarantees that are offered in the current dietetic Framework Directive (2009/39/EC), in particular those concerning "food for people intolerant to gluten" have been removed from the scope of the proposed revision to the detriment of those suffering from Coeliac disease. These foods for particular nutritional uses are recognized at international level by the recently revised Codex Standard 118-1979 rev 2008 for foods for special dietary use for persons intolerant to gluten.

Amendment 45

Proposal for a regulation
Article 2 – paragraph 2 – point h c (new)

Text proposed by the Commission	*Amendment*
	(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;

Justification

Some essential guarantees that are offered in the current dietetic Framework Directive (2009/39/EC), in particular those concerning "food for people intolerant to gluten" have been removed from the scope of the proposed revision to the detriment of those suffering from Coeliac disease. These foods for particular nutritional uses are recognized at international level by the recently revised Codex Standard 118-1979 rev 2008 for foods for special dietary use for persons intolerant to gluten.

Amendment 46

Proposal for a regulation
Article 2 – paragraph 2 – point h d (new)

Text proposed by the Commission	*Amendment*
	(hd) 'food intended for use in low calorie diets (LCD)' and 'food intended for use in very low calorie diets (VLCD)' 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 1200 kcal per day.

Amendment 47

Proposal for a regulation
Article 2 – paragraph 2 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Food for special medical purposes within the meaning of point (h) of the first subparagraph fall into one of the following three categories:
	(i) nutritionally complete foods with a standard nutrient formulation which, 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, 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.

Amendment 48

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	***deleted***

Justification

Linked to Amendment 13 to recital 16. Parliament and the Council must be able to exercise democratic scrutiny over the definitions laid down in Article 2, which are fundamental to this proposal for a regulation.

Amendment 49

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation.	***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 imported into the Union for the purpose of being placed on the market shall comply with the applicable provisions of Union food law. Food 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 only be placed on the market 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.

Justification

It is essential that the same safety and quality rules should be laid down for food imported into the Union as for food intended for export, as specified, for example, in Articles 11 and 12 of the General Food Law Regulation of 28 January 2002. To make the text more coherent, the provisions governing 'pre-packaged food' and 'free movement of goods' have been combined in the article headed 'placing on the market'.

Amendment 50

Proposal for a regulation – amending act
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. 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), which does not comply with the rules on composition laid down by this Regulation and by the delegated acts adopted pursuant to this Regulation for food referred to in Article 1(1).

Justification

The current legislation contains an innovation clause providing for an accelerated procedure under EFSA supervision. Although it is used only rarely, such a procedure must be retained in the proposal under consideration here.

Amendment 51

Proposal for a regulation
Article 4

Text proposed by the Commission	*Amendment*
Article 4	***deleted***
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.	

Justification

It is essential that the same safety and quality rules should be laid down for food imported into the Union as for food intended for export, as specified, for example, in Articles 11 and 12 of the General Food Law Regulation of 28 January 2002. To make the text more coherent, the provisions governing 'pre-packaged food' and 'free movement of goods' have been combined in the article headed 'placing on the market'.

Amendment 52

Proposal for a regulation
Article 5

Text proposed by the Commission	*Amendment*
Article 5	***deleted***
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.	

Justification

It is essential that the same safety and quality rules should be laid down for food imported into the Union as for food intended for export, as specified, for example, in Articles 11 and 12 of the General Food Law Regulation of 28 January 2002. To make the text more coherent, the provisions governing 'pre-packaged food' and 'free movement of goods' have been combined in the article headed 'placing on the market'.

Amendment 53

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	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.

Justification

It is important to incorporate a provision based on the precautionary principle into the regulation, which is aimed at a particularly vulnerable group of consumers: newborns, infants, sick people and the obese.

Amendment 54

Proposal for a regulation
Article 6 b (new)

Text proposed by the Commission	*Amendment*
	Article 6b
	Oversight
	The national competent authorities shall ensure that an adequate system of oversight is put in place to ensure that market operators comply with this Regulation and with the relevant health requirements.

Amendment 55

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.	***deleted***

Justification

For the sake of legal clarity, this article has been deleted and its provisions incorporated into Articles 1 and 3 of the proposal.

Amendment 56

Proposal for a regulation
Article 8 a (new)

Text proposed by the Commission	*Amendment*
	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) .

Justification

To avoid misleading the consumer, there is a need to maintain a provision similar to that in Article 2.2.b of the current Framework Directive ensuring that only products compliant with the regulation can be presented as covering the specific needs of the targeted populations. Vulnerable consumers require proper labelling in order to receive adequate information about the composition of these specific foods. A clear distinction must be made between foods for labelling nutrition and foodstuffs for normal consumption.

Amendment 57

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	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***.

Justification

See justification for AM 1.

Amendment 58

Proposal for a regulation
Article 9 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ***provide adequate consumer information*** and must not be misleading.	3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ***be accurate, clear and easy to understand for consumers*** and must not be misleading. ***It shall not attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.***

Amendment 59

Proposal for a regulation
Article 9 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 60

Proposal for a regulation
Article 9 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively ***by*** persons having qualifications in medicine, nutrition***,*** pharmacy ***or other*** professionals ***responsible for maternal and child health care.***	4. The dissemination of any 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 ***to*** persons having qualifications in medicine, nutrition ***or*** pharmacy***. Additional information disseminated by healthcare*** professionals ***to the final consumer shall only be of a scientific and factual nature and shall not contain advertising.***

Amendment 61

Proposal for a regulation
Article 9 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 62

Proposal for a regulation
Article 9 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	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.

Amendment 63

Proposal for a regulation
Article 9 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*
	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.
	[1] OJ L 353, 31.12.2008, p. 1.

Amendment 64

Proposal for a regulation
Article 10 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. Subject to the general requirements of Articles 7 and 9 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, the Commission shall be empowered to adopt delegated ***Regulations,*** no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15,	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

with respect to the following:	empowered to adopt delegated ***acts for foods referred to in Article 1(1)*** no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Amendment 65

Proposal for a regulation
Article 10 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the process for the placing on the market of food referred to in Article 1(1) resulting from scientific and technological innovations which do not comply with the composition requirements laid down pursuant to point (a);

Amendment 66

Proposal for a regulation
Article 10 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(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***;	(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1); ***those requirements shall include the specific related rules already in force for food referred to in Article 1(1);***

Justification

It is important to retain the single, specific provisions contained in the legislation on infant and follow-up formulas.

Amendment 67

Proposal for a regulation
Article 10 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the requirements for information to be provided on recommendations for appropriate use of food referred to in

Article 1(1).

Amendment 68

Proposal for a regulation
Article 10 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) a requirement for post-market monitoring in order to verify whether the specific requirements are being complied with.

Amendment 69

Proposal for a regulation
Article 10 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
3. Subject to the requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, the Commission shall update the delegated Regulations mentioned in paragraph 2 in accordance with Article 15.	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.

Justification

'Delegated acts' is the agreed standard wording to be used in provisions of this kind

Amendment 70

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission	*Amendment*
	Article 10a
	Food for people intolerant to gluten
	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.

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'.

Food intended for people intolerant to gluten sold to the final consumer which contain a level of gluten not exceeding 20 mg/kg may be labelled 'gluten free'.

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

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

– they 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 product is marketed.

Justification

There should be a specific article setting out the main provisions in the current Regulation (EC) No 41/2009 on composition and labelling in order to address the dietary needs of people who are intolerant to gluten.

Amendment 71

Proposal for a regulation
Article 10 b (new)

Text proposed by the Commission	*Amendment*
	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 the Annex 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 the Annex to this Regulation, 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, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, 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.

Amendment 72

Proposal for a regulation
Article 10 c (new)

Text proposed by the Commission	*Amendment*
	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 small and medium-sized enterprises, to comply with the requirements laid down in 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.

Amendment 73

Proposal for a regulation
Article 11 – paragraphs 1 and 2

Text proposed by the Commission	*Amendment*
1. 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:	1. ***Taking account of Directives 2006/141/EC and 2006/125/EC and Regulation (EC) No 953/2009, the Commission shall, no later than ... [2 years after the date of entry into force of this Regulation] establish a Union list of***

vitamins, minerals and other substances which may be added to each category of food referred to in Article 1(1) ('the Union list').

a) they do not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer; ***and***

b) they are available for use by the human body.

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).

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

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

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

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.
	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to establish the Union list.

(Paragraph 1 of the Commission text has become paragraph 2 and paragraph 2 of the Commission text has become paragraph 1, with modifications.)

Justification

It is essential that, in addition to being safe and absorbable by the human body, enriched foods should offer consumers nutritional added value. This is particularly important if, as in the context of this proposal for a regulation, the persons primarily affected are newborns or hospital patients, for whom this type of food is often vital. In addition, and in order to prevent a legal vacuum being created, it is important to draw a distinction between the current list of substances and the list which will probably be updated in two years' time.

Amendment 74

Proposal for a regulation
Article 11 – paragraphs 3, 4 and 5

Text proposed by the Commission	*Amendment*
	Article 11a
	Updating of the Union list
3. The entry of a substance in the Union list ***referred to in paragraph 2*** 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.***	***1.*** The entry of a substance in the Union list 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 (the 'applicant'). Applications shall be sent to the Commission, in accordance with ***paragraph 2.***

	1a. The applicant shall submit an application to the Commission. The Commission shall acknowledge receipt in writing within 14 days of its receipt.
4. The application shall include:	***2.*** The application shall include:
(a) the name and the address of the applicant;	(a) the name and the address of the applicant;
(b) the name and a clear description of the substance;	(b) the name and a clear description of the substance;
(c) the composition of the substance;	(c) the composition of the substance;
(d) the proposed use of the substance and conditions thereof;	(d) the proposed use of the substance and conditions thereof;
(e) a systematic review of the scientific data and appropriate studies performed following generally accepted expert guidance on the design and conduct of such studies;	(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 is intended and its suitability for the intended uses;	(f) scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it is intended and its suitability for the intended uses;
(g) scientific evidence demonstrating that the substance is available for use by the human body;	(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.	(h) a summary of the content of the application.
5. When a substance is already included in the Union list 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 shall be considered as different substance ***and*** the ***Union*** list shall ***be modified accordingly before it can be placed on the Union market***.	3. When a substance is already included in the Union list 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 ***which is not included in*** the list ***and which*** shall ***require a separate application***.
	4. If a substance that is on the Union list no longer meets the conditions referred to in Article 11(2) and (2a), the Commission shall decide to remove that substance from the Union list.
	5. The entry for a substance in the Union

	list 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 the Union list. 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.

Justification

Since the Regulation will only apply after 2 years after the entry into force it seems that the Commission first shall establish a list (Article 11) which then could be updated on the initiative of the Commission or following an application (Article 11a). Concerning this updated list, it is good sense to set up provisions not only for addition of substances but also for deletion of certain substances in the specific foodstuff.

Nanomaterials can only be assessed by specific test-methods. It should therefore only be possible to include substances in the list which have been proven as safe.

Amendment 75

Proposal for a regulation
Article 12 – paragraph 2 – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) any scientific data gathered from animal testing for the assessment of the safety of the substance.

Amendment 76

Proposal for a regulation
Article 13

Text proposed by the Commission	*Amendment*
General confidentiality clause	General ***transparency and*** confidentiality clause
The Commission, the Authority and the Member States shall, in accordance with	The Commission, the Authority and the Member States shall, in accordance with

Regulation (EC) No 1049/2001, take the necessary 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.	Regulation (EC) No 1049/2001, ***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 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.

Justification

More transparent Community procedures and easier public access to documents are essential.

Amendment 77

Proposal for a regulation
Article 15 – paragraph 2

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

Justification

As regards delegated acts, and with a view to maintaining legal consistency between Community acts, this amendment reproduces the wording of Regulation (EU) No 1169/2011 on the provision of food information to consumers.

It is not appropriate to allow for delegated acts for the updating of the definitions, as they are an essential part of the Regulation which should only be allowed to be changed by the ordinary legislative procedure. The establishment and updating of the list is an act of general

application to supplement or amend certain non-essential elements of the legislative act.

Amendment 78

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The ***delegation of powers*** referred to in Articles ***2(3) and 10*** of this Regulation 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.	3. The ***power to adopt delegated acts*** referred to in Articles ***3(1a), 10(2) and (3), 10c, 11(3) and 11a(6)*** of this Regulation 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.

Justification

Strengthened democratic scrutiny is essential in connection with the definitions laid down in Article 2(3), given that this is an area where, for more obviously technical reasons linked to the composition of products and the dissemination of information about them and to the specific provisions to assist SMEs, the delegation of powers to the Commission can be justified more easily.

Amendment 79

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission	*Amendment*
5. A delegated act adopted pursuant to ***Articles 2(3)*** and ***10*** of this Regulation 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	5. A delegated act adopted pursuant to ***Articles 3(1a), 10(2) and (3), 10c, 11(3) and 11a(6)*** of this Regulation 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

the European Parliament or the Council.	extended by 2 months at the initiative of the European Parliament or the Council.

Justification

It is not appropriate to allow for delegated acts for the updating of the definitions, as the definitions are an essential part of the Regulation which should only be allowed to be changed by the ordinary legislative procedure. The establishment and updating of the list is an act of general application to supplement or amend certain non-essential elements of the legislative act. Moreover the requirements laid down in Article 11(1) are very open. Therefore delegated acts should be applied.

Amendment 80

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	Article 16a
	Food for people intolerant to lactose
	By ... [1 year after entry into force of this Regulation], 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.

Amendment 81

Proposal for a regulation
Article 16 b (new)

Text proposed by the Commission	*Amendment*
	Article 16b
	Milks intended for young children
	By ... [1 year after the date of the entry into force of this Regulation], 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

between one and three years. 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) submit, if appropriate, in accordance with the ordinary legislative procedure and on the basis of Article 114 of the TFEU, any appropriate legislative proposal.

Prior to the preparation of the above Commission report the milks intended for young children between one and three years 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;

Amendment 82

Proposal for a regulation
Annex (new)

Text proposed by the Commission	*Amendment*
	Annex
	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 1680 kJ (400 kcal) and shall not exceed 3360 kJ

(800 kcal) for the total daily ration.

1.2. The energy provided by a LCD product shall not be less than 3360 kJ (800 kcal) and shall not exceed 5040 kJ (1200 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.

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 B_6	***(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).	