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INFORMATION NOTE

from:	General Secretariat
to:	Permanent Representatives Committee/Council
Subject:	Proposal for a regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes - Outcome of the European Parliament's first reading (Strasbourg, 11 to 14 June 2012)

I. INTRODUCTION

The Rapporteur, Mrs Frédérique RIES (ALDE - BE), submitted a report on behalf of the Committee on the Environment, Public Health and Food Safety containing 82 amendments. In addition, the following political groups submitted a number of further amendments:

- the Greens/EFA and the S&D jointly: amendments 83-86;
- the ALDE, EPP, Greens/EFA, ECR and EUL/NGL jointly: amendments 87-89;
- the ALDE and EPP jointly: amendment 90;
- the ALDE, EPP and ECR jointly: amendment 91;
- the ALDE and EUL/NGL jointly: amendment 92; and
- the EPP alone: amendment 93.

II. DEBATE

The Rapporteur opened the debate, which took place on 14 June 2012, and:

- argued that the current legislation needs to be tidied up. Consumers are confused and cannot make an informed choice. The single market is impaired;
- supported the Commission's approach of simplifying legislation and abolishing the concept of dietetic foods;
- called for an extension of the scope in order to protect vulnerable groups such as obese patients subject to a diet of less than 1,200 calories a day and such as the 2% of the European Union's population who are gluten-intolerant;
- called for support for SMEs working in the gluten-free sector, who fear that the Commission is trying to overturn the 2006 food claims legislation and who find prohibitive the cost of applying for EFSA authorisation (on average €500,000-1,000,000). Such high fees prevent fair competition; and
- expressed her personal preference for some of the amendments tabled since the Committee vote, for example amendment 84 on pesticides. Nonetheless, she had given her word to adhere to the compromise package which had been agreed with the Shadow Rapporteurs and which had been adopted by the Committee. For this reason and because the pesticides issue was already adequately covered by the Committee's amendment 63, she would oppose amendment 84 and the other post-Committee amendments.

Commissioner DALLI:

- noted that some of the proposed amendments would extend the scope of the Regulation to include slimming foods intended to replace the total daily diet. Although he believed that such foods could be managed comprehensively under the horizontal rules of food law, he understood the Parliament's concerns and was open to considering their inclusion within the scope;
- opposed the inclusion of gluten-free foods within the scope of the Regulation because this is not necessary. It would be not be in the interest of coeliacs and it would not be consistent with the principles of better regulation and simplification. Whilst agreeing that it was important to maintain the existing rules on gluten-free foods, this could be achieved in a simpler and better way by transferring these rules to the recently adopted Regulation on Food Information to Consumers. Such a transfer would ensure that the existing rules would also apply to non-prepacked foods and would therefore provide better protection to coeliacs;
- stated that he could in principle accept several amendments on labelling provisions and restricted use of pesticides in baby foods, but argued that it would be better to address these points through delegated acts;
- expressed his support for the amendments concerning the preparation of reports on sports foods and growing-up milks;
- opposed the amendments regarding the establishment and update of the Union list of substances by delegated acts instead of implementing acts. The Commission's proposal was in accordance with the Lisbon Treaty and the Commission Guidelines on delegated acts. It should therefore remain unchanged; and
- argued that allowing Member States to apply further restrictions on advertising of foods for infants and young children, without distinction, would be disproportionate to the objectives of the proposed Regulation and could have an impact on the good functioning of the internal market.

Speaking on behalf of the Committee on Industry, Research and Energy, Mr Hannu TAKKULA (ALDE – FI) stressed the need to:

- revise legislation which had now become obsolete; and
- prevent misleading claims.

Speaking on behalf of the Committee on Internal Market and Consumer Protection, Mrs Iliana IVANOVA (EPP - BU) called for thorough research into the extent to which baby milk products really benefit children.

Speaking on behalf of the EPP political group, Mrs Esther DE LANGE (EPP - NL):

- called for greater clarity on whether gluten falls within or outside the scope of the proposed Regulation;
- called on the Commission and the Council to expedite their work on the proposal; and
- noted that there is debate as to whether baby milk is special baby food, just a vitamin-enhanced drink or even a harmful product which induces in babies a lifetime's dependence on sugar.

Speaking on behalf of the S&D political group, Mrs Daciana SÂRBU (S&D - RO):

- stated that there is no proof that baby milk has any added value. It is just more expensive and promoted by misleading advertising;
- defended the amendments on pesticides as a way of closing loopholes in existing EU legislation on pesticides.

Speaking on behalf of the ALDE political group, Mrs Antonyia PARVANOV (ALDE – BU) welcomed the proposed review clause.

Speaking on behalf of the Greens/EFA political group, Mr Carl SCHLYTER (Greens/EFA - SE):

- called for tighter rules on pesticides;
- argued that unuseful special categories of food should be eliminated; and
- called for the protection of those who are intolerant of gluten, soya and milk protein.

Speaking on behalf of the ECR political group, Mrs Julie GIRLING (ECR - UK):

- stressed the need to simplify legislation;
- argued that the Committee's position on gluten does not help consumers. It merely helps certain manufacturers in certain countries;
- opposed the Committee's amendments on low calorie and very low calorie diets. No evidence had been provided to support the claim that it would be helpful to make it more difficult to obtain such products;

- stated that no evidence had been presented on the issue of advertising milk products. This debate should be evidence-based and not emotive;
- stated that no evidence had been presented in support of the pesticides amendments; and
- disagreed with the suggestion that gluten-intolerant consumers need more protection than is currently offered by the food claims regulation. The gluten amendments to the current proposal add no value.

Mrs Françoise GROSSETÊTE (EPP - FR) called for the scope of the Regulation to include gluten-free foods and low-calory diets.

Mrs Glenis WILLMOTT (S&D - UK) - supported by Mrs Åsa WESTLUND (S&D - SE), Mrs Karin KADENBACH (S&D - AT) and Mrs Judith MERKIES (S&D - NL) - stated that allowing advertising of follow-on formula milk intended for babies aged over six months creates a risk that parents might unintentionally purchase and supply such milk to younger babies. Parents should be allowed to decide on the basis of objective expert opinion, not advertising.

Commissioner DALLI once more took the floor and:

- acknowledged that there are differing opinions on the question of whether growing-up milks are needed to meet the nutritional requirements of young children. It is therefore necessary to consult EFSA on this point. He was also ready to look into the advertising point raised by Mrs Willmott and others;
- noted that the relevant legislation on pesticides had recently been reviewed and that it already takes account of vulnerable groups, including children. He agreed that the use of pesticides in products intended for infants and young children should be restricted as much as possible. The existing legislation on products for infants and young children already sets extremely low levels for pesticides - so low, in fact, that they are effectively prohibitive. The Commission could accept amendments on pesticides which are consistent with existing legislation;
- stressed the difference between the application and the presence of pesticides. The focus should be on the presence of pesticides in food, because a focus on application would not cover food grown on fields which had been contaminated in the past; and

- argued that the current proposal does not in any way reduce protection for coeliacs. On the contrary, such protection would be increased by maintaining the current compositional and labelling rules and by transferring those rules to a more appropriate legal text on food information to consumers. This would protect coeliacs in relation to both non-packed and packed foods. It would also ensure that all information related to gluten is covered by the same piece of legislation, because the Regulation on Food Information to Consumers already covers the labelling of the presence of gluten in the list of ingredients.

The Rapporteur once more took the floor and explained that the failure to secure a first-reading agreement was due in part to the need for a thorough scrutiny of the gluten question and also due to inter-institutional disagreement over delegated acts.

III. VOTE

When it voted on 14 June 2012, the Parliament adopted 83 amendments to the proposed Regulation (amendments 1-31, 33-41, 43-64, 66-72, 75-82 and 87-92).

The text of the amendments adopted and the European Parliament's legislative resolution are annexed to this note.

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

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))

(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 2011¹,
- 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.

¹ OJ C 24, 28.1.2012, p. 119.

Amendment 1

Proposal for a regulation Title

Text proposed by the Commission

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

Amendment

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**

Amendment 2

Proposal for a regulation Recital 2

Text proposed by the Commission

(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.**

Amendment

(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.**

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.

Amendment 4

Proposal for a regulation

Recital 3

Text proposed by the Commission

(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*.

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 *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 supplements¹, Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods², 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 food³ 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 consumers⁴, is a further factor making it necessary to thoroughly overhaul Directive 2009/39/EC.*

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.

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 1992¹, 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 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.***

(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 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.

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

(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.

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 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.

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.

Amendment 11

Proposal for a regulation Recital 15

Text proposed by the Commission

(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.

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 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

(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 international level, as appropriate.

Amendment

(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 (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 14

Proposal for a regulation Recital 17

Text proposed by the Commission

(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.

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 **and independent** review of the available scientific 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 market¹ 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.

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 origin¹, 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.

Amendment 19

Proposal for a regulation

Recital 18

Text proposed by the Commission

(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.

Amendment

(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.

Amendment 20

Proposal for a regulation

Recital 19

Text proposed by the Commission

(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 medical purposes laid down in this Regulation taking into account technical and scientific progress and relevant developments at international level***, to lay

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

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.

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.

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

(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 applicable **implementing** acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require.

Amendment

(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 uses¹, which does not apply to liquid or solid 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.

Amendment 23

Proposal for a regulation

Recital 21

Text proposed by the Commission

(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**.

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.

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.

Amendment 24

Proposal for a regulation
Recital 22

Text proposed by the Commission

(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.

Amendment

(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.**

Amendment 90

Proposal for a regulation
Recital 26

Text proposed by the Commission

(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 Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

Such 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 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 Regulation (EC) No 41/2009 be completed prior to the entry into application of this Regulation.

Amendment

(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 Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

Those statements should be regulated solely by this Regulation and comply with requirements herein. Regulation (EC) No 41/2009 should therefore be repealed.

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

(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are ***currently*** considered as food

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.

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 rules¹, 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

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

Amendment

(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.*

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.

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 91

Proposal for a regulation Recital 29 c (new)

Text proposed by the Commission

Amendment

(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 European Food Safety Authority has been consulted.

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:

Amendment 34

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

Text proposed by the Commission

(c) food for special medical purposes.

Amendment

(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.

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.***

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.

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**;

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.

Amendment 92

Proposal for a regulation

Article 2 - paragraph 2 - point h

Text proposed by the Commission

(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.

Amendment

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. ***Foods for special medical purposes also include formula intended for low birth-weight and pre-term infants, which also have to comply with 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;

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;

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

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.

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).

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.

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.

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.

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

2. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

Amendment

deleted

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) .

Amendment 57

Proposal for a regulation Article 9 – paragraph 1

Text proposed by the Commission

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.

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 ***peer-reviewed and independently evaluated*** scientific data ***and medical opinion***.

Amendment 58

Proposal for a regulation Article 9 – paragraph 3

Text proposed by the Commission

3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ***provide adequate consumer information*** and must not be misleading.

Amendment

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

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**.

Amendment

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 mixtures¹ 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, with respect to the following:

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 **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 66

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(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;***

Amendment

(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);***

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

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

Regulations mentioned in paragraph 2 in accordance with Article 15.

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.

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.

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 87

Proposal for a regulation

Article 11 - paragraphs 1 and 2

Text proposed by the Commission

Article 11

Union list of permitted substances

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:

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).

Amendment

Article 11

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 ... [2 years after the date of entry into force of this Regulation], delegated acts in accordance with Article 15, in order to insert in Annex -1 a list of vitamins, minerals and other substances which may be added to each category of food referred to in Article 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;

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.

(The replacement of the term "Union list" by "Annex -I" applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

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

Amendment 88

Proposal for a regulation

Article 11 - paragraphs 3, 4 and 5

Text proposed by the Commission

Amendment

Article 11a

Updating of the list of permitted substances

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

1. The entry of a ***new*** substance ***into 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

also represent several interested parties (*hereinafter referred to as* the applicant).
Applications shall be sent to the Commission, in accordance with paragraph 4.

4. 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 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;
- (g) scientific evidence demonstrating that the substance is available for use by the human body;
- (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.*

interested parties (the 'applicant').

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.

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 is intended 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.

3. When a substance is already included in *Annex -1* 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 Annex - 1 and which shall require a separate application.*

4. If a substance that is in Annex -1 no longer meets the conditions referred to in Article 11(2) and (2a), the Commission

shall decide to remove that substance from Annex -1.

5. The entry for a substance into Annex -1 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 -1. 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.

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 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

The Commission, the Authority and the Member States shall, in accordance with 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

environment.

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.

Amendment 77

Proposal for a regulation Article 15 – paragraph 2

Text proposed by the Commission

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.]***

Amendment

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.]***

Amendment 78

Proposal for a regulation Article 15 – paragraph 3

Text proposed by the Commission

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.

Amendment

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.

Amendment 79

Proposal for a regulation

Article 15 – paragraph 5

Text proposed by the Commission

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 the European Parliament or the Council.

Amendment

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

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 89

**Proposal for a regulation
Annex -1 (new)**

Text proposed by the Commission

Amendment

*Annex -1
List of permitted substances*

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 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

<i>Potassium</i>	<i>(mg)</i>	<i>3 100</i>
<i>Iron</i>	<i>(mg)</i>	<i>16</i>
<i>Zinc</i>	<i>(mg)</i>	<i>9,5</i>
<i>Copper</i>	<i>(mg)</i>	<i>1,1</i>
<i>Iodine</i>	<i>(µg)</i>	<i>130</i>
<i>Selenium</i>	<i>(µg)</i>	<i>55</i>
<i>Sodium</i>	<i>(mg)</i>	<i>575</i>
<i>Magnesium</i>	<i>(mg)</i>	<i>150</i>
<i>Manganese</i>	<i>(mg)</i>	<i>1</i>

Table 2

AMINO ACID REQUIREMENT PATTERN (1)

	<i>g/100 g protein</i>
<i>Cystine + methionine</i>	<i>1,7</i>
<i>Histidine</i>	<i>1,6</i>
<i>Isoleucine</i>	<i>1,3</i>
<i>Leucine</i>	<i>1,9</i>
<i>Lysine</i>	<i>1,6</i>
<i>Phenylalanine + tyrosine</i>	<i>1,9</i>
<i>Threonine</i>	<i>0,9</i>
<i>Tryptophan</i>	<i>0,5</i>
<i>Valine</i>	<i>1,3</i>
<p><i>(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).</i></p>	