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*Committee on the Environment, Public Health and Food Safety*

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**2011/0156(COD)**

30.11.2011

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# **DRAFT REPORT**

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Frédérique Ries

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

In amendments by Parliament, amendments to draft acts are highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the draft act which may require correction when the final text is prepared – for instance, obvious errors or omissions in a language version. Suggested corrections of this kind are subject to the agreement of the departments concerned.

The heading for any amendment to an existing act that the draft act seeks to amend includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend. Passages in an existing act that Parliament wishes to amend, but that the draft act has left unchanged, are highlighted in **bold**. Any deletions that Parliament wishes to make in such passages are indicated thus: [...].

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**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 2011<sup>1</sup>,
  - 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 (A7-0000/2011),
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.

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<sup>1</sup> OJ C 0, 0.0.0000, p. 0/ Not yet published in the Official Journal.

## 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 and on food for special medical purposes ***and energy-restricted diets***

Or. fr

#### *Justification*

*It is important to maintain specific legislation at EU level for energy-restricted diets in order to avoid any risk of disorders in dietary habits arising from certain unsupervised diets. The maintenance of this category of food in the Regulation's scope must therefore be reflected in the proposal's title.*

## Amendment 2

### Proposal for a regulation Recital 1

*Text proposed by the Commission*

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

*Amendment*

(1) Article 114**(3)** of the Treaty on the Functioning of the European Union (TFEU) provides that measures having as their object the establishment and functioning of the internal market and which concern inter alia health, safety and consumer protection must take as a base a high level of protection taking account in particular of any new development based on scientific facts. ***It is also important that any such scientific discoveries be the subject of a peer review.***

Or. fr

#### *Justification*

*In view of the range of scientific views, including in the field of food and nutrition, it would be*

*preferable to ensure that innovative products available on the market are clearly beneficial to the consumer, and that they are subject at least to a peer review in authoritative scientific reviews.*

### **Amendment 3**

#### **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 their free movement and the proper functioning of the internal market.***

Or. fr

*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 4**

#### **Proposal for a regulation**

##### **Recital 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**(2a) *In this context, given that the relevant EU legislation 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 categories concerned should be excluded from the composition of categories of foods covered by this Regulation.***

Or. fr

### *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 5**

### **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 this legislation and EU provisions adopted more recently, such as Directive 2002/46/EC of the European Parliament and the Council of 10 June on the approximation of the laws of the Member States relating to food supplements, Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods and Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to food and Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to***



**consumers, is a further factor making it necessary to thoroughly overhaul the directive.**

Or. fr

### *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 6**

### **Proposal for a regulation**

#### **Recital 7**

#### *Text proposed by the Commission*

(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.***

#### *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. ***At the same time the undertaking made by the Commission in Directive 2009/39/EC to meet the high demand from persons engaging in sports and to clarify the relevant labelling rules still applies, which certainly justifies the Commission's updating of the report of 28 February 2001 on the foods concerned.***

*Justification*

*Sportspersons, insofar as a common definition might be adopted at EU level, are not strictly speaking a category that requires a specific food diet. However, there is a genuine problem as regards harmonisation of this sector of the food market in Europe, which would justify the Commission looking further into the issue of food intended to meet the expenditure of intense muscular effort by means of a new assessment report.*

**Amendment 7****Proposal for a regulation****Recital 7 a (new)**

*Text proposed by the Commission*

*Amendment*

***(7a) A Commission report 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 not therefore the appropriate legal framework for this category of food. According to the Commission, it is more important, as regards persons with diabetes, to consider the quantity and model and food absorbed. This conclusion is in no way contrary to the establishment of an EU-wide strategy comprehensively targeting diabetes (Type 1 and Type 2), which affects more than 32 million EU citizens. These 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 EU 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 9

#### *Text proposed by the Commission*

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

#### *Amendment*

(9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure showed that difficulties may arise from different interpretations of the definition of foodstuffs for particular nutritional uses which appeared to be open to different interpretations by the national authorities. ***Similar food could thus at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption addressed to the population in general or to certain sub-groups thereof such as pregnant women, postmenopausal women, older adults, children, adolescents, variably active individuals and others. The Commission report*** therefore concluded that a revision of the scope of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of the Union legislation. ***Therefore, the concept of “foodstuffs for particular nutritional uses” should be abolished and Directive 2009/39/EC should be replaced by this Regulation.***

Or. fr

#### *Justification*

*This amendment includes the most explicit parts of recitals 10 to 13 of the proposal for a regulation, which the rapporteur is proposing to delete.*

## Amendment 9

### Proposal for a regulation Recital 10

*Text proposed by the Commission*

*Amendment*

***(10) A study report concerning the revision of the legislation on foodstuffs for particular nutritional uses confirms the findings of the Commission report on the implementation of the notification procedure and indicates that an increasing number of foodstuffs are today marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in Directive 2009/39/EC. The study report also points out that the type of food regulated under that legislation differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption addressed to the population in general or to certain sub-groups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out.***

***deleted***

Or. fr

## Amendment 10

### Proposal for a regulation Recital 11

*Text proposed by the Commission*

*Amendment*

***(11) It appears that other Union acts recently adopted are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and the Council of 10 June on the approximation of the laws of the Member States relating to food supplements, Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods and Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to foods. Furthermore, the provisions of these Union acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less administrative burden and more clarity as to the scope and objectives.*** ***deleted***

Or. fr

## Amendment 11

### Proposal for a regulation Recital 12

*Text proposed by the Commission*

*Amendment*

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

**Amendment 12****Proposal for a regulation****Recital 13***Text proposed by the Commission*

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

*Amendment**deleted***Amendment 13****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

*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 public health and consumer interests, while allowing** the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food, **sets out the precautionary principle as a provisional risk management measure** and establishes the structures and mechanisms for the scientific and technical evaluations which

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.

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.

Or. fr

#### *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 14**

#### **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.***

Or. en

#### *Justification*

*Linked with amendment 13*

## Amendment 15

### 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 ***and food intended for use in energy-restricted diets and they are presently covered by*** provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission Directive 1999/21/EC ***and Commission Directive 96/8/EC respectively. Experience has shown that those provisions*** 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 *focus* 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 ***and food intended for use in energy-restricted diets and that the specific compositional and information requirements for these categories of food should be laid down by the Commission in delegated regulations adopted pursuant to this Regulation, which take*** into account ***and replace*** Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC ***and Directive 96/8/EC.***



*The power to adopt acts in accordance with Article 290 of the Treaty should be delegated to the Commission in respect of laying down the specific compositional and information requirements for the categories of food covered by this Regulation, including additional labelling requirements to, or derogations from, the provisions of Directive 2000/13/EC and the authorisation of nutrition and health claims. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.*

Or. en

#### *Justification*

*See Amendment 1 on the incorporation of food for energy-restricted diets into the scope of this Regulation. To this has been added the final modified part of recital 19 on delegated acts.*

### **Amendment 16**

#### **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***

##### *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 **and Commission Directive 96/8/EC** should be transferred to this Regulation.

*appropriate.*

Or. en

*Justification*

*Consistent with Amendments 1 and 12, seeking to incorporate Directive 96/8/EC on foods intended for weight reduction into the scope of this legislative proposal.*

**Amendment 17**

**Proposal for a regulation**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) The use of pesticides and other toxic substances in agricultural products intended for the production of food referred to in Article 1 (1) should be prohibited.***

Or. en

*Justification*

*Linked with the proposal to ban at the article 10 (2) b) the use of pesticides in agricultural products intended for the production of food for infants, young children and persons with special medical needs.*

**Amendment 18**

**Proposal for a regulation**

**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) 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 referred to in Article 1(1) complies with the requirements of food law in general and of this Regulation in particular.***

Or. en

## 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 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 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*

*deleted*

***ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.***

Or. fr

*Justification*

*To avoid the repetition that appears in some parts of the text.*

**Amendment 20**

**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 for use in energy-restricted diets***, subject to certain criteria laid down in this Regulation. ***The list should be adopted taking due account of the specific dietary habits of the population groups concerned and should take into account 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, which does not apply to liquid or solid formulae for infants and young children, and replace them.*** 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.

Or. fr

### *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 newborn baby.*

## **Amendment 21**

### **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 this scientific opinion and in view of the particular sensitivity of the categories for which foods for particular uses are intended,*** engineered nanomaterials should not be included in the Union list for the categories of food covered by this Regulation ***so long as their safety and nutritional value have not been demonstrated by the Authority.***

*Justification*

*Responsible and safe development of nanotechnologies in Europe is essential. The best response to the growing fear being expressed by the general public and the scientific community with regard to the possible introduction into daily products of artificial nanomaterials, e.g. babyfood, is therefore to demonstrate not only their safety but also the scientific value of including nutrients in nanocapsules.*

**Amendment 22****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. ***This extension may not take place without an evaluation by the Authority and the intervention of the European Parliament and the Council as co-legislator.***

*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 23****Proposal for a regulation****Recital 25***Text proposed by the Commission*

(25) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health

*Amendment*

(25) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health

claims made on foods establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or non-legislative acts adopted pursuant to this Regulation.

claims made on foods establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or non-legislative acts adopted pursuant to this Regulation, ***as is already the case for foods included in infant formulae and follow-on formulae which are covered by special rules on nutrition claims.***

Or. fr

### *Justification*

*Directive 2006/141/EC on infant formulae and follow-on formulae has its own rules on nutrition and health claims set out in Annex IV, which ought to be maintained.*

## **Amendment 24**

### **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

#### *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. For the sake of ***consistency***, those statements should be regulated solely by Regulation (EC) No 1169/2011 ***on the provision of food information to consumers (repealing Directives 90/496/EEC and 2000/13/EC)*** and comply with requirements therein, ***which already provides, in particular, for the possible establishment of criteria for information on allergens. Regulation (EC) No 41/2009 should therefore be repealed. The extension to the statements 'lactose-free' and 'very low lactose', which are other common forms of food***

into application of this Regulation.

***intolerance, should also be provided for in this Regulation.***

Or. fr

### *Justification*

*The Member States have expressed considerable reservations about the Commission's proposal to incorporate the regulation on food for people with coeliac disease into the regulation on nutrition and health claims. Hence this alternative proposal to ensure greater legal certainty.*

## **Amendment 25**

### **Proposal for a regulation Recital 27**

#### *Text proposed by the Commission*

(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.***

#### *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. ***Against this 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 European Food Safety 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. It is therefore necessary to maintain specific provisions in this Regulation on food for use in energy-restricted diets. This is an important nutrition and health safety tool for people seeking to lose weight.***



*Justification*

*Linked to Amendments 1, 12 and 13: 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 26****Proposal for a regulation  
Recital 29 a (new)***Text proposed by the Commission**Amendment*

***(29a) To ease access of small and medium-sized undertakings (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 to help undertakings, in particular SMEs, to comply with the requirements laid down in this Regulation and thus facilitate competitiveness and innovation.***

Or. en

*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 27****Proposal for a regulation  
Recital 29 b (new)***Text proposed by the Commission**Amendment*

***(29b) This Regulation cannot be fully effective as regards protection of the most***

*vulnerable consumers and, a fortiori, its nutritional benefits, unless it is backed up by a robust and independent assessment system (composition, labelling, reformulation) before and after the marketing of food products, responsibility for which lies principally with the European Food Safety Authority, in cooperation with the competent national authorities.*

Or. fr

*Justification*

*Legislative measures must be supplemented by consistent health control measures from farm gate to plate.*

**Amendment 28**

**Proposal for a regulation**

**Article 1 - paragraph 1 – introductory part**

*Text proposed by the Commission*

1. This Regulation establishes compositional and information requirements for the following categories of food:

*Amendment*

1. This Regulation, **complementing EU legislation on foodstuffs**, establishes compositional and information requirements for the following categories of food:

Or. fr

*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 29

### Proposal for a regulation

#### Article 1 - paragraph 1- point d (new)

*Text proposed by the Commission*

*Amendment*

***(d) food intended for use in energy-restricted diets for weight reduction.***

Or. fr

*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 health claims made for foodstuffs (Regulation (EC) No 1924/2006).*

## Amendment 30

### 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 update 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.***

Or. fr

*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 31

### Proposal for a regulation Article 1 - paragraph 3 (new)

*Text proposed by the Commission*

*Amendment*

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

Or. fr

#### *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 32

### 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 ***specialy 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 foods for use in very low energy diets supplying daily requirements of essential nutrients intended for the exclusive feeding of individuals with moderate or severe***

*obesity.*

Or. en

*Justification*

*Very low calories diet products intended for obese people as their solely food consumption shall be included both in the definition of 'food for special medical purposes' and in the scope of this Regulation.*

**Amendment 33**

**Proposal for a regulation**

**Article 2 - paragraph 2 - point i (new)**

*Text proposed by the Commission*

*Amendment*

*i) 'foods for use in energy-restricted diets for weight reduction' are specially formulated foods which, when used as instructed by the manufacturer, replace all or part of the total daily diet. They are divided in two categories:*

*i) products presented as replacing all of the total daily diet;*

*ii) products presented as replacing one or more of the meals making up the total daily diet.*

Or. fr

*Justification*

*Linked to Amendment 26 and the retention within the scope of the regulation of foods intended for use in energy-restricted diets for weight reduction.*

**Amendment 34**

**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*

*deleted*

*'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.*

Or. fr

#### *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 35**

#### **Proposal for a regulation Article 3**

##### *Text proposed by the Commission*

Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation.

##### *Amendment*

**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 there 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 pre-packaged form, as defined in Article 2(2)(e) of Regulation (EC) No 1169/2011.*

**4.** *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.***

Or. fr

*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 36**

**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.***

Or. fr

*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 37**

**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.***

Or. fr

### *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 38**

#### **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 chosen, necessary to ensure the high level of protection of the vulnerable categories of population specified in this regulation.***

Or. en

### *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 39**

### **Proposal for a regulation Article 7 - paragraph 1**

*Text proposed by the Commission*

*Amendment*

**1. Introductory provisions** *deleted*

***Food referred to in Article 1(1) shall  
comply with any requirement of Union  
law applicable to food.***

Or. fr

*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 40**

### **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*

Or. fr

*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 41**

### **Proposal for a regulation Article 9 - paragraph 3**

*Text proposed by the Commission*

*Amendment*

3. The labelling, presentation and

3. The labelling, presentation and

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

advertising of food referred to in Article 1(1) shall provide adequate consumer information, must not be misleading **and shall neither attribute to such products properties for the prevention, treatment or cure of human disease nor imply such properties.**

Or. en

*Justification*

*The new paragraph reflects the existing rules of Article 8 of "the Framework Directive on dietetic foods" (2009/39/EC).*

**Amendment 42**

**Proposal for a regulation  
Article 9 - paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. No product other than infant formulas may be represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life.***

Or. fr

*Justification*

*This key provision of Directive 92/52/EC concerning infant and follow-up formulas intended for export to third countries must be retained in the proposal for a regulation under consideration here, on the grounds that it defines clearly the nature of infant formulas.*

**Amendment 43**

**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

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.**

by persons having qualifications in medicine, nutrition, pharmacy or **intended exclusively for them.**

Or. fr

#### *Justification*

*The aim is to remain faithful to the spirit of Framework Directive 2009/39/EC and, in particular, Article 8(2) thereof, as regards the issue of the dissemination of information to medical professionals.*

#### **Amendment 44**

##### **Proposal for a regulation**

##### **Article 10 - paragraphs 1 and 2**

*Text proposed by the Commission*

*Amendment*

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

2. **Subject to** the general requirements of Articles 7 and 9 and **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. **Taking into account** the general requirements of Articles **6a** and 9 and Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC **and Directive 98/6/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:

Or. fr

#### *Justification*

*When it uses delegated acts to amend existing legislation, the Commission must respect the letter of the text in force and always seek to improve consumer protection. The precautionary principle laid down in Article 6a (new) is one of the fundamental principles which must guide food safety policy.*

## Amendment 45

### Proposal for a regulation

#### Article 10 - paragraph 2 - point b

*Text proposed by the Commission*

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

*Amendment*

b) the specific requirements on pesticides residues in such food;

Or. fr

#### *Justification*

1. *European legislators must force the food industry to take steps to ensure that they are placing on the market products which are entirely free of pesticides. That is the thinking behind this amendment, which establishes the principle of a ban on pesticides in foods for particular nutritional uses, even if the presence of traces of the substances concerned can never be ruled out completely.*

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

## Amendment 46

### 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), including the authorisation of nutrition and health claims thereof, ***with the exception of the types of food referred to in Article 1(1)(a);***

Or. fr

#### *Justification*

1. *European legislators must force the food industry to take steps to ensure that they are placing on the market products which are entirely free of pesticides. That is the thinking behind this amendment, which establishes the principle of a ban on pesticides in foods for particular nutritional uses, even if the presence of traces of the substances concerned can never be ruled out completely.*

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

#### **Amendment 47**

##### **Proposal for a regulation**

##### **Article 10 - paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

**2a. Pesticides and other toxic substances shall not be used in agricultural products intended for the production of food referred to in Article 1(1).**

Or. en

##### *Justification*

*European legislators must force the food industry to take steps to ensure that they are placing on the market products which are entirely free of pesticides. That is the thinking behind this amendment, which establishes the principle of a ban on pesticides in foods for particular nutritional uses, even if the presence of traces of the substances concerned can never be ruled out completely.*

#### **Amendment 48**

##### **Proposal for a regulation**

##### **Article 10 - paragraph 3**

*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 requirements of Articles **6a** 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.

Or. fr

##### *Justification*

*1. European legislators must force the food industry to take steps to ensure that they are*

*placing on the market products which are entirely free of pesticides. That is the thinking behind this amendment, which establishes the principle of a ban on pesticides in foods for particular nutritional uses, even if the presence of traces of the substances concerned can never be ruled out completely.*

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

## **Amendment 49**

### **Proposal for a regulation – amending act Article 10 - paragraph 3 a (new)**

*Text proposed by the Commission*

*Amendment*

***3a. In order to enable foodstuffs intended for particular nutritional uses and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting the European Food Safety Authority, authorise for a two-year period the placing on the market of foodstuffs which do not comply with the rules as to composition laid down by this Regulation and by the delegated regulations for groups of foodstuffs for particular nutritional uses referred to in Article 1(1). These measures shall be adopted in accordance with the delegation procedure referred to in Article 15.***

Or. fr

#### *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 50

### Proposal for a regulation

#### Article 11 - paragraphs 1 and 2

*Text proposed by the Commission*

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*

***1. Taking account of the provisions of Directives 2006/141/EC and 2006/125/EC and Regulation (EC) No 953/2009, no later than [2 years after the date of entry into force of this Regulation] the Commission shall establish a Union list of vitamins, minerals and other substances which may be added to the types of food referred to in Article 1(1) ('the Union list'). That list shall be different for each category of food referred to in Article 1(1).***

***2. Only the substances included in the Union list may be added to the types of food referred to in Article 1(1).***

3. 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.

***4. The Commission shall establish the Union list by means of implementing regulations. Those implementing regulations shall be adopted in accordance with the examination procedure referred to in Article 14(2).***

Or. fr

*(Paragraph 1 of the Commission text has become paragraph 3 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 51**

### **Proposal for a regulation**

#### **Article 11 – paragraphs 3, 4 and 5**

*Text proposed by the Commission*

**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).

*Amendment*

#### ***Article 11a***

##### ***Updating of the Union list***

**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



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.

with **paragraph 2**.

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 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.

3. **Where** a substance is already included in the Union list and there is a significant change in the production methods, the substance prepared by those new methods shall be considered as a different substance and **shall be removed from the Union list unless** the Union list **is** modified accordingly before it can be placed on the Union market.

4. **If a substance that is on the Union list no longer meets the conditions referred to in Article 11(3), 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 update the Union list by means of implementing Regulations. Those implementing Regulations shall be adopted in accordance with the examination procedure referred to in Article 14(2). On duly justified imperative grounds of urgency relating to emerging health risks, the Commission shall adopt immediately applicable implementing acts updating the Union list in accordance with Article 14(3)***

Or. en

#### *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) and then this list 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.*

#### **Amendment 52**

##### **Proposal for a regulation Article 13**

###### *Text proposed by the Commission*

General confidentiality clause

13. 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

###### *Amendment*

General ***transparency and*** confidentiality clause

13. 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***

circumstances so require in order to protect human health, animal health or the environment.

***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.

Or. fr

#### *Justification*

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

### **Amendment 53**

#### **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 delegation of power referred to in Articles 10 ***and 18a*** shall be conferred for ***a period of 5 years from the 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.***

Or. fr

#### *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.*

## Amendment 54

### 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 delegation of powers referred to in **Articles 10 and 18a** 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.

Or. fr

*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 SMUs, the delegation of powers to the Commission can be justified more easily.*

## Amendment 55

### Proposal for a regulation Article 17 - paragraph 2

*Text proposed by the Commission*

**2. Directive 96/8/EC and** Regulation (EC) No 41/2009 **are** repealed from [the first day of the month 2 years after the date of the entry into force of this Regulation].

*Amendment*

2. Regulation (EC) No 41/2009 **is** repealed from [the first day of the month 2 years after the date of the entry into force of this Regulation].

Or. fr

*Justification*

*In keeping with the retention within the scope of the regulation of foods used in energy-*

*restricted diets, which are currently covered by Directive 96/8/EC.*

## **Amendment 56**

### **Proposal for a regulation**

#### **Article 18 a (new)**

*Text proposed by the Commission*

*Amendment*

#### **Article 18a**

##### ***Access to internal market for SMEs***

***The Commission shall, in close cooperation with all stakeholders, adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in this Regulation. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to adopt those guidelines.***

Or. en

#### *Justification*

*Reducing administrative burden and facilitating access to internal market for SMEs are also important goals to achieve with this piece of legislation.*

## EXPLANATORY STATEMENT

### **1. Background**

The first piece of European legislation dealing with dietetic foods was a directive adopted back in 1977. That directive was subsequently amended several times and then consolidated in a framework directive based on the concept of ‘foodstuffs intended for particular nutritional uses’, which was adopted in 2009.

Thirty-four years later, following a comprehensive review of the legislation in force in this extremely competitive sector (which accounts for between 1 and 2% of the overall market), the Commission has reached the following stark conclusion: both consumers and controlling authorities are finding it hard to distinguish between foodstuffs for normal consumption and foodstuffs intended for specific population groups. The Commission provides a number of specific examples (muscle-building protein bars for sportspersons, food supplements for pregnant women, calcium- and vitamin D-enriched foods suitable for older people and slimming products).

The impact assessment highlights a number of reasons for this confusing situation, including disparities in the interpretation and implementation of the framework directive in the Member States, administrative constraints, compositional and labelling changes, innovation, competitiveness, price and consumer protection and information. There is therefore a clear need for the legislation on foodstuffs intended for specific population groups to be recast.

### **2. Abolition of the concept of ‘dietetic food’: a key aspect of the proposal for a regulation**

Following the consultations with Member States begun in 2007, the Commission submitted this proposal for a regulation on food intended for infants and young children and on food for special medical purposes in June 2011. The new regulation will repeal the following pieces of legislation:

- Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (recasting the 1989 framework directive);
- Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries;
- Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction;
- Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

A desire for simplification lies behind this overhaul of the legislation, as is illustrated by the establishment of a single list of substances that may be added to the foods covered by the proposal (the ‘Union list’). Care must, however, be taken to ensure that this consolidation does not pave the way for an increase in the number of vitamins, minerals and other

substances added to these highly specific foodstuffs.

### **3. Rapporteur's remarks**

#### Scope of the regulation

The Commission has rightly chosen to confine the scope of this regulation to a limited number of foods for particular nutritional uses. Infants, children under three years of age and people for whom a special diet is vital on medical grounds clearly require special attention and uniform treatment within the EU. The rapporteur shares the Commission's view that the current legal framework should be maintained for these vulnerable population groups.

So what happens to the other types of foodstuff that are not, or are no longer, covered by a 'tailor-made' legal framework? The Commission's abolition of the concept of 'dietetic food' will have an impact on other pieces of legislation currently in force, foremost among them being Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. 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).

Conversely, foodstuffs intended for sportspersons should not be included in the new regulation's scope. There are objective difficulties in defining exactly what constitutes a 'sportsperson' and in distinguishing between a food for intense muscular effort and what might be considered a stimulant or doping agent. Given that, generally speaking, they are not intended to meet special dietary needs, sports-related foods should therefore be covered by the general food provisions (Regulation (EC) No 178/2002 of 28 January 2002).

The EU's 32 million diabetics also require special attention, but this should not necessarily take the form of specific food legislation. The Commission's approach in this area – which is in keeping with the views expressed by diabetes associations – should therefore also be endorsed. In this connection, attention should be drawn to the alarming projections for 2030, by which time the incidence of diabetes is expected to have increased by 16% by 2030, owing in particular to endemic obesity and the ageing of the population in the EU.

#### Including very low calorie diets for obese patients

The idea is to bring very low calorie diet products (VLCDs) within the regulation's scope by including them in the definition of food for special medical purposes. Unlike many other kinds of weight-loss diet (generally between 800 and 1200 kcals/day), very low calorie diets (between 400 and 800 kcals/day) must be of strictly limited duration (in general, no more than four weeks) and must not be embarked upon without proper medical authorisation and supervision, owing to the possibility of side-effects.

## Legal cover for people with a food intolerance

Another of the key aspects of this proposal is the incorporation of Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten into the legislative framework for nutrition and health claims made on foods (Regulation (EC) No 1924/2006).

The rapporteur does not agree with the Commission's approach in this matter, because it does not provide a suitable legal framework for people with a gluten intolerance or one of the other common food intolerances. There are a number of reasons for this, the first being the fact that, in its present form, Regulation (EC) No 1924/2006 still makes no provision for nutritional profiles, which may be seen as the 'DNA' of foodstuffs and are of decisive importance in determining whether or not a claim may be made for a given foodstuff. The second reason stems indirectly from the fact that Regulation (EC) No 1924/2006 is based on the principle of exhaustive lists, meaning that anything that is not specifically included in the lists is banned. Accordingly, unless the Commission adds the statement 'lactose-free' – which is of essential importance to people with a lactose intolerance (more common in the Mediterranean countries than in Northern Europe) to the annex to Regulation (EC) No 1924/2006, there is every reason to believe that use of that statement would be banned.

With a view to clarifying this grey area, the rapporteur considers that it would be more appropriate to incorporate the rules governing statements relating to gluten and lactose into the new Regulation (EU) No 1169/2011 on food labelling. Article 36 of this cross-cutting regulation already provides for the possibility of laying down criteria relating to information on the presence of products causing allergies.

## Faster, less costly procedures

It is essential for the notification procedure (which is faster and less costly) to continue to be the standard procedure, with marketing authorisations being granted at national level and there being an option to supplement this procedure with additional rules on labelling and composition. It is also only logical for stricter rules than those applying under the prior authorisation procedure based on an opinion delivered by the EFSA to be maintained for claims relating to foods for infants and children between the ages of one and three (Annex IV to Directive 2006/141/EC).

## Other key aspects: facilitating market access for SMEs and stimulating innovation

Facilitating access by SMEs to the internal market is one of the key strands of the Europe 2020 strategy launched by the Commission. However, this statement of intent must be followed up by the inclusion in every legislative proposal of provisions specifically designed to make it easier for SMEs to gain such access. This is particularly important in view of the fact that both EU and world markets for foods for particular nutritional uses are dominated by a very small number of industrial groups. This is why the rapporteur considers that the new regulation should do more than 'not impact disproportionately on small businesses' (as the



Commission puts it in its impact assessment and its comments relating to Objective 4: Small Businesses and Innovation) and should have a genuinely positive impact on SMEs, which form a dynamic, job-creating sector of the EU economy.

#### No pesticides in foods intended for vulnerable population groups

The current legislation is unsatisfactory. EU lawmakers need to require industry to ensure that the products it places on the market for infants and young children contain no pesticides or other toxic substances. That is the thinking behind the amendments which establish the principle of a ban on pesticides in foods for particular nutritional uses while accepting that some traces of chemicals may be accidentally present. This is because, given that the environment is contaminated by various pesticides, pesticide residues may, unfortunately, be found in some products.

#### **4. Preliminary conclusions**

The rapporteur agrees with the Commission that the legislation on foodstuffs for particular nutritional uses needs to be thoroughly overhauled and that the concept of ‘dietetic food’, which in most cases means very little from a nutritional point of view, should be done away with. She nonetheless considers that industry and the vulnerable population groups that are the subject of this regulation should be afforded greater legal certainty. This must necessarily involve regular democratic scrutiny by Parliament of the definitions of foods intended for infants, children under the age of three and people with certain medical conditions, for whom a special diet is of vital importance, and of the rules governing the composition of such foods. This simplified but more protective legal framework must apply to imported and exported foods alike and makes it easier for the precautionary principle to be applied. 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.

#### **5. Legislative footprint**

Your rapporteur is grateful for the explanations provided by the Commission through DG SANCO, as well as for the many suggestions made by the shadow rapporteurs, the Polish Presidency of the Council, the future Danish Presidency and representatives of the Belgian and French Governments. She would also like to express her thanks for the proposals put forward by: the food-sector companies Nestlé, Danone and Unilever; the manufacturers of foods for particular nutritional uses the European Dietetic Food Industry Association (IDACE), the Medical Nutrition International Industry (MNI), the European Specialist Sports Nutrition Alliance (ESSNA) and the European Natural Soyfoods Manufacturers Association (ENSA); and the European Consumers’ Organisation (BEUC) and the UK organisation Baby Milk Action. Special thanks must go to Parliament’s lawyer-linguists, who have helped to ensure that the policy proposals set out in this report are legally sound.