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

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**2011/0156(COD)**

26.1.2012

# **AMENDMENTS 57 - 167**

**Draft report**  
**Frédérique Ries**  
(PE478.337v01-00)

Food intended for infants and young children and food for special medical purposes (PARNUTS)

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

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**EN**

*United in diversity*

**EN**



## Amendment 57

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Andrea Zanoni, Oreste Rossi, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

### 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 **and on foodstuffs for people intolerant to gluten**

Or. en

#### *Justification*

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

## Amendment 58

**Oreste Rossi**

### 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, food for special medical purposes **and other food for specialised nutrition**

**Amendment 59**  
**Esther de Lange**

**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 food for very low calorie diets***

Or. en

*Justification*

*VLCD should be covered by specific legislation.*

**Amendment 60**  
**Sophie Auconie**

**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, food for special medical purposes ***and other foods for specific nutritional purposes***

Or. fr

*Justification*

*Some essential guarantees have been removed, to the detriment of vulnerable consumers such*

*as obese or overweight people and people who are intolerant to gluten. Such consumers need foods which are specifically formulated to provide them with specialised nutrition and will help them manage their diet under specific conditions.*

#### **Amendment 61**

**Daciana Octavia Sârbu**

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

##### **Recital 6 a (new)**

*Text proposed by the Commission*

*Amendment*

***(6a) Having regard to the Council Resolution of 18th June 1992 on the marketing of breast-milk substitutes in third countries by Community-based manufacturers.***

Or. en

#### **Amendment 62**

**Françoise Grossetête, Christine De Veyrac, Esther de Lange**

#### **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

(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, ***in light of the report of 22 June 2000 by the European Commission's Scientific Committee on Food***, no successful conclusion could be reached as regards the

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<sup>9</sup> concludes that the scientific basis for setting specific compositional requirements is lacking.*

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. *Work on this needs to continue and the Commission should draw up a report on 'food intended to meet the expenditure of intense muscular effort' so that a coherent and effective strategy to protect consumers, manufacturers in the sector and the operation of the internal market may be produced. Taking the conclusions of this report as its basis, the Commission may submit proposals to amend the relevant Union legislation or may take new initiatives, where appropriate, on a sectoral basis.*

Or. fr

#### *Justification*

*The Commission will have to propose a report on the need for provisions on the composition and labelling of food intended to meet the expenditure of intense muscular effort to be harmonised in view of consumer protection requirements and requirements arising from the functioning of the internal market.*

#### **Amendment 63** **Julie Girling**

#### **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

##### *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.

nutritional uses:

**(i) ‘Food** intended to meet the expenditure of intense muscular effort, especially for sportsmen’. With regard to **this category**, no successful conclusion could be reached **on** the development of specific provisions due to widely diverging views among Member States and stakeholders concerning the scope of the specific legislation. **However, the undertaking made by the Commission in Directive 2009/39/EC to meet the specific requirements of sportspeople should still apply, as supported by the publication of EFSA Scientific Opinions on claims relevant to active individuals which justifies the review of general food law.**

**(ii) ‘Food** for persons suffering from carbohydrate metabolism disorders (diabetes)’. **In this regard**, a Commission report concludes that the scientific basis for setting specific compositional requirements is lacking.

Or. en

## Justification

*The report of the Scientific Committee on Food of 28 February 2001 on ‘food intended to meet the expenditure of intense muscular effort, especially for sportsmen’, as well as more recent Scientific Opinions by EFSA, have highlighted that sportspersons involved in intense muscular effort have additional nutritional needs when compared with the general population, therefore updating legislation in this would be appropriate.*

### **Amendment 64** **Oreste Rossi**

#### **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<sup>9</sup> 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 ***specialised nutrition***: ‘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 ***to date*** 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, ***the mandatory information for the safe use of food intended to meet the expenditure of intense muscular effort***, and the potential impact on innovation in product development. ***There is a genuine need for harmonisation of the category of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. Harmonisation will remove barriers to free movement of this category of food, while providing***



*sportsmen a high level of safety and guaranteeing the absence of doping substances, the latter being considered as a priority by the European Commission in its communication on Sports of 18th January 2011.* As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report<sup>9</sup> concludes that the scientific basis for setting specific compositional requirements is lacking.

Or. en

**Amendment 65**  
**Sophie Auconie**

**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

*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 ***specialised nutrition***: '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 ***has yet been*** 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, the number of sub-categories of the food to be included, the criteria for establishing composition requirements, ***compulsory information to ensure safe use of the food*** and the potential impact on innovation in product development. ***There is a real need for harmonisation of the category of food***

(diabetes), a Commission report concludes that the scientific basis for setting specific compositional requirements is lacking.

*intended to meet the expenditure of intense muscular effort, especially for sportsmen. Harmonisation would remove the barriers to the free movement of these products and provide sportsmen with a high level of safety, at the same time ensuring the absence of doping substances. The Commission considers the matter of doping to be a priority in its communication entitled ‘Developing the European Dimension in Sport’ of 18 January 2011.* 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.

Or. fr

#### *Justification*

*Lack of harmonisation among the Member States concerning food intended to meet the expenditure of intense muscular effort is creating a divided internal market and does not provide consumers with proper protection or security. It is also necessary in order to ensure the absence of doping substances in products consumed by athletes, an issue highlighted in the Commission Communication on Sport of 18 January 2011.*

#### **Amendment 66** **Sophie Auconie**

#### **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*

(13) The concept of ‘***food for specific uses***’ ***should therefore be maintained but strictly limited to products able to demonstrate their unique capacity to meet the specific nutritional needs of vulnerable groups of the population which would otherwise not be able to be placed on the market in a harmonised way under current EU law whilst fully***

*complying with the rules on free movement.* 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.

Or. fr

#### *Justification*

*It is necessary to re-introduce the concept of food intended for specialised nutrition.*

#### **Amendment 67** **Oreste Rossi**

#### **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*

(13) Therefore, the concept of '*specialised nutrition*' should be ***maintained but strictly limited to products that can demonstrate their unique ability to fulfil the specific nutritional needs of vulnerable groups of the population, which otherwise could not be placed on the market using current Union acts and where harmonisation ensures the free movement of such food in a satisfactory manner.*** 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.

Or. en

#### **Amendment 68** **Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Andrea Zanoni, Oreste Rossi, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**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 foods for people intolerant to gluten**. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC, **and Commission Regulation 41/2009** 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, food for special medical purposes, **and foods for people intolerant to gluten**, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC Commission Directive 1999/21/EC, **and Commission Regulation (EC) No 41/2009**.

Or. en

*Justification*

*Some essential guarantees that are offered in the current dietetic Framework Directive*

(2009/39/EC), in particular those concerning “food for people intolerant to gluten” have been removed from the scope of the proposed revision to the detriment of those suffering from Coeliac disease. These foods for specialised nutrition are recognized at international level by the recently revised Codex Standard 118-1979 rev 2008 for foods for special dietary use for persons intolerant to gluten.

**Amendment 69**  
**Oreste Rossi**

**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 intended for weight reduction and control, and food intended to meet the expenditure of intense muscular effort*. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC, *as well as Commission Directive 96/8/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, food for special medical purposes, *food intended for*

*weight reduction and control, and food intended to meet the expenditure of intense muscular effort, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC and Commission Directive 96/8/EC. In addition, the concept of 'specialised nutrition' should be maintained and strictly limited to products that demonstrate their unique ability to fulfil the specific nutritional needs of vulnerable groups of the population, which otherwise could not be placed on the market using current Union acts.*

Or. en

**Amendment 70**  
**Gilles Pargneaux**

**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

*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, ***milk-based drinks for young children*** 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

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 these three directives.

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, ***milk-based drinks for young children*** and food for special medical purposes, taking into account these three directives. ***Furthermore, the concept of ‘specialised nutrition products’ should be maintained and strictly limited to products able to demonstrate their unique capacity to meet the specific nutritional needs of vulnerable groups of the population, as without this said products would not be able to be placed on the market under current EU law.***

Or. fr

#### *Justification*

*Certaines garanties essentielles contenues dans l’actuelle directive-cadre relative aux aliments diététiques (2009/39/CE) et sous les directives verticales afférentes ont été retirées de cette proposition, au détriment des consommateurs vulnérables. Ces consommateurs exigent des préparations spéciales qui garantissent une alimentation spéciale et les aident à gérer leur état spécifique sur le plan diététique. La proposition de la Commission menace d’affaiblir la santé et la sécurité de ces groupes de consommateurs en restreignant le champ d’application du règlement proposé, et donc de limiter les possibilités d’innovations futures issues de développements scientifiques. Il est par conséquent nécessaire de réintroduire le concept de produits de nutrition spécialisée. Ceci, en conformité avec l’actuelle Norme de Codex pour les aliments diététiques ou de régime (146-1985). Les boissons à base de lait destinées aux enfants en bas âge contribuent de manière significative à l’équilibre alimentaire de ces derniers. Les recommandations nutritionnelles d’experts établissent que le lait et les produits laitiers constituent une part importante du régime alimentaire des enfants en bas âge. La prise en compte de cette catégorie de produits permettra d’imposer des critères de protection des enfants en bas âge en ce qui concerne les besoins nutritionnels et les règles de sécurité alimentaire spécifiques à cette tranche d’âge, en fixant par exemple des limites concernant l’ajout de nutriments, les risques microbiologiques et les contaminants. Ne pas inclure ces produits dans le champ d’application du présent règlement aura pour conséquence de voir ces produits réglementés en tant que produits d’alimentation générale et soumis aux critères définis pour la population adulte en termes de pureté et de nutrition, critères qui ne conviennent pas toujours aux enfants âgés de 12 à 36 mois.*

## Amendment 71

Françoise Grossetête, Christine De Veyrac

### 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 these three directives.

##### *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, ***milk-based drinks for young children*** 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, ***milk-based drinks for young children*** and food for special medical purposes, taking into account these three directives. ***Furthermore, the concept of 'special nutritional uses' should be maintained and strictly limited to products able to demonstrate their unique capacity to meet the specific nutritional needs of vulnerable groups of the population, as without this said products would not be able to be placed on the market under current EU law.***



*Justification*

*Growth milks for children aged 1-3 are products specifically designed to address these children's nutritional needs and they must meet very strict food safety requirements, notably with regard to pesticide-residue content. The level of safety currently applicable to baby foods must be applied to foods for children aged 1-3.*

**Amendment 72**  
**Esther de Lange**

**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,

*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 foods for 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 framework 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

Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.

cereal-based food and baby food for infants and young children and to food for special medical purposes **and foods intended for very low calorie diets**, while taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC **and amending Commission Directive 96/8/EC in order to cover VLCD**.

Or. en

### *Justification*

*VLCD should be covered by specific legislation.*

### **Amendment 73** **Tiziano Motti**

#### **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

##### *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, **milk based drinks intended for young children**, food for special medical purposes. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, **and** Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory

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.

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, baby food for infants and young children, *milk based drinks intended for young children*, 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 addition, the concept of "specialised nutrition" should be maintained and strictly limited to products that demonstrate their unique ability to fulfil the specific nutritional needs of vulnerable groups of the population, which otherwise could not be placed on the market using current Union acts.*

Or. en

**Amendment 74**  
**Mairead McGuinness**

**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

*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, *milk based drinks intended for young children*, food for special medical

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.

purposes. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC, ***Commission Regulation 41/2009, as well as Commission Directive 96/8/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, baby food for infants and young children, ***milk based drinks intended for young children***, food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC Commission Directive 1999/21/EC, ***Commission Directive 96/8/EC and Commission Regulation (EC) No 41/2009***. ***In addition, the concept of "specialised nutrition" should be maintained and strictly limited to products that demonstrate their unique ability to fulfil the specific nutritional needs of vulnerable groups of the population, which otherwise could not be placed on the market using current Union acts.***

Or. en

**Amendment 75**  
**Sophie Auconie**

**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

*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 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 these three directives.

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, ***as well as food intended to meet the expenditure of intense muscular effort.*** 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, ***as well as food intended to meet the expenditure of intense muscular effort,*** taking into account these three directives. ***The concept of ‘food for specific uses’ should therefore be maintained but strictly limited to products able to demonstrate their unique capacity to meet the specific nutritional needs of vulnerable groups of the population which would otherwise not be able to be placed on the market in a harmonised way under current EU law whilst fully complying with the rules on free movement.***

Or. fr

#### *Justification*

*Foods for intense muscular effort are foods specially formulated to ensure healthy nutrition in extreme sport and other physical activities. To help it prepare, produce and recover from intense or high-level effort, the human body needs specially formulated products promoting*

*an adequate and effective supply of liquids and nutrients such as carbohydrates.*

#### **Amendment 76**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

#### **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, **and Commission Regulation 41/2009** 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, **and foods for people intolerant to gluten** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.

Or. en

##### *Justification*

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

#### **Amendment 77**

**Renate Sommer**

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

#### **Recital 16**

*Text proposed by the Commission*

(16) To ensure legal certainty, definitions laid down in Commission Directives 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 Directives 2006/141/EC, 2006/125/EC, 1999/21/EC **and 2009/41/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.

Or. de

**Amendment 78**  
**Esther de Lange**

**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 and Commission Directive 1999/21/EC **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, and food for special medical purposes **and foods intended for very low calorie diets** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.

Or. en

*Justification*

*VLCD should be covered by specific legislation.*

**Amendment 79**

**Sophie Auconie**

**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 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, food for special medical purposes **and food intended to meet the expenditure of intense muscular effort** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.

Or. fr

*Justification*

*Foods for intense muscular effort are foods specially formulated to ensure healthy nutrition in extreme sport and other physical activities. To help it prepare, produce and recover from intense or high-level effort, the human body needs specially formulated products promoting an adequate and effective supply of liquids and nutrients such as carbohydrates.*

**Amendment 80**

**Oreste Rossi**

**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 **and Commission Directive 96/8/EC** should be transferred to this Regulation. However, the definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, food for special medical purposes, **food intended for weight reduction and control, and food intended to meet expenditure for intense muscular effort** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.

Or. en

**Amendment 81**

**Carl Schlyter**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

**(17a) With the exception of products authorised in accordance with Article 16 (1) of Regulation 834/2007, pesticides and other toxic substances should not be used for the production of food referred to in Article 1(1).**

Or. en

*Justification*

*Based on AM 17 by the Rapporteur. Reg. 834/2007 on organic production and labelling of organic products enables the Commission to lay down a list of products and substances which*

*may be used in organic farming. This very limited list is laid down in Annex II of the respective implementing Reg. No 889/2008. Since pesticides permitted for use in organic farming are generally considered to be harmless it would be wise to limit the permitted pesticides for the vulnerable to only such substances.*

**Amendment 82**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) Maximum concentrations of pesticide residue defined by the applicable Community legislation, in particular Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in products of plant and animal origin<sup>1</sup>, should be without prejudice to the specific provisions established by this Regulation. The principle of prohibiting the use of pesticides should therefore be maintained whenever possible and in all cases of the use of pesticides or metabolites of pesticides with an acceptable daily intake of less than 0.0005 mg/kg body weight in the production of agricultural products intended for infant and follow-on formulae. This principle, which is set out in Directive 2006/141/EC, is also applicable to processed cereal-based food and baby food covered by Directive 2006/125/EC and should be extended to other categories of foodstuffs for particular nutritional uses.***

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<sup>1</sup> *OJ L 70, 16.3.2005, p. 1.*

Or. fr

## *Justification*

*This Regulation must ensure the protection primarily of infants' health and young children but also that of other vulnerable groups. This approach will be achieved through strict selection of raw materials – including imported raw materials – and by determining, as set down in current legislation, a concentration for all pesticides which corresponds to the minimum concentration detectable in foodstuffs for particular nutritional uses.*

### **Amendment 83**

**Esther de Lange, Christa Klaß, Julie Girling**

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

##### **Recital 17 a (new)**

*Text proposed by the Commission*

*Amendment*

***(17a) Maximum levels for pesticide residues set out in relevant Community legislation, in particular as taken up in Regulation (EC) No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, should apply without prejudice to specific provisions set out in this Regulation and its delegated acts.***

Or. en

### **Amendment 84**

**Frédérique Ries**

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

##### **Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) It is important for pesticides authorised by Annex IX of Directive 2006/141/EC and Annex VI of Directive 2006/125/EC and which do not satisfy the safety conditions set out in Articles 4 and 6 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the***

***placing of plant protection products<sup>1</sup> on the market to be banned from the market and not be carried over into this Regulation.***

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

Or. fr

*Justification*

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

**Amendment 85**

**Carl Schlyter**

on behalf of the Verts/ALE Group

**Proposal for a regulation**

**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) The use of genetically modified organisms pursuant to Regulation (EC) No 1829/2003 as well as products produced from animals that have been fed with genetically modified feedingstuffs should be prohibited in the production of food referred to in Article 1(1).***

Or. en

*Justification*

*In accordance with the precautionary principle, it is appropriate to prohibit GMOs or products produced thereof in the production of foods intended for the most vulnerable parts of the population.*

**Amendment 86**  
**Esther de Lange, Christa Klaß, Julie Girling**

**Proposal for a regulation**  
**Recital 17 b (new)**

*Text proposed by the Commission*

*Amendment*

***(17b) However, given the vulnerable nature of infants and young children, severe limitations on pesticide residues are required in infant and follow-on formulae and food for infants and young children. Specific maximum residue limits for these products are set in Commission Directive 2006/141/EC and Commission Directive 2006/125/EC.***

Or. en

**Amendment 87**  
**Renate Sommer**

**Proposal for a regulation**  
**Recital 18**

*Text proposed by the Commission*

*Amendment*

(18) General labelling requirements are laid down in **Directive 2000/13/EC** of the European Parliament and of the Council of **20 March 2000 on the approximation of the law of the Member States relating to labelling, presentation and advertising of foodstuffs**<sup>1</sup>. Those general labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, the provisions of **Directive 2000/13/EC**, where necessary, in order to meet the specific objectives of this Regulation.

(18) General labelling requirements are laid down in **Regulation 1169/2011/EC** of the European Parliament and of the Council of **25 October 2011 on the provision of food information to consumers**<sup>1</sup>. 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 1169/2011/EC**, where necessary, in order to meet the specific objectives of this Regulation.

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<sup>1</sup> **OJ L 184, 17.7.1999, p. 23.**

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<sup>1</sup> **OJ L 304, 22.11.2011, p. 18.**

**Amendment 88**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**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 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

*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, **and foods for people intolerant to gluten**, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC, **Commission Regulation (EC) No 41/2009**. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, **and foods for people intolerant to gluten** 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

and appropriate transmission of relevant documents to the European Parliament and Council.

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.

Or. en

### *Justification*

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

## **Amendment 89** **Gilles Pargneaux**

### **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 down the specific compositional and information requirements with respect to the categories

#### *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, ***milk-based drinks for young children*** 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, ***milk-based drinks for young children*** 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

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.

compositional and information requirements ***and the procedure for placing on the market foodstuffs resulting from scientific and technological innovations*** 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.

Or. fr

#### *Justification*

*Il apparaît indispensable d'inclure les boissons à base de lait destinées aux enfants en bas âge au champ d'application du présent règlement, afin de garantir que ces produits respectent les règles de sécurité les plus strictes en matière d'alimentation, de risques microbiologiques, de pesticides et de contaminants, ainsi que d'agents colorants et édulcorants. Ne pas englober ces produits dans le champ d'application du présent règlement aura pour conséquence de les voir réglementés en tant que produits d'alimentation générale et ainsi soumis aux critères définis pour la population adulte en termes de pureté et de nutrition, critères qui ne conviennent pas aux enfants âgés de 12 à 36 mois.*

#### **Amendment 90**

**Françoise Grossetête, Christine De Veyrac**

#### **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 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.

*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, ***milk-based drinks for young children*** 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, ***milk-based drinks for young children*** 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 ***and the procedure for placing on the market foodstuffs resulting from scientific and technological innovations*** 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.

Or. fr

## *Justification*

*Growth milks for children aged 1-3 are products specifically designed to address these children's nutritional needs and they must meet very strict food safety requirements, notably with regard to pesticide-residue content. The level of safety currently applicable to baby foods must be applied to foods for children aged 1-3.*

### **Amendment 91**

**Carl Schlyter**

on behalf of the Verts/ALE Group

### **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 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

#### *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 lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

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.

Or. en

### *Justification*

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

## **Amendment 92** **Esther de Lange**

### **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 down the specific compositional and information

#### *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 ***and foods intended for very low calorie diets***, 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

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.

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

Or. en

### *Justification*

*VLCD should be covered by specific legislation.*

## **Amendment 93** **Tiziano Motti**

### **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

#### *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, baby food, ***milk based drinks intended for young children***, and food for special medical purposes, taking into account Commission Directive 2006/141/EC,

Directive 1999/21/EC. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes laid down in this Regulation taking into account technical and scientific progress and relevant developments at international level, to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, including for additional **labelling** requirements to, or derogations from, the provisions of Directive 2000/13/EC and for the authorisation of nutrition and health claims, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Commission Directive 2006/125/EC, Commission Directive 1999/21/EC. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, **milk based drinks intended for young children**, 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 **and the process for placing on the market of food resulting from scientific and technological innovations** 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.

Or. en

**Amendment 94**  
**Oreste Rossi**

**Proposal for a regulation**  
**Recital 19**

*Text proposed by the Commission*

(19) This Regulation should provide the

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

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 intended for weight reduction and control, and food intended to meet expenditure of intense muscular effort**, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC **and Commission Directive 96/8/EC**. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, **food intended for weight reduction and control, and food intended to meet the expenditure of intense muscular effort** 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 **and the process for placing on the market of food resulting from scientific and technological innovations** 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.

Or. en

**Amendment 95**  
**Mairead McGuinness**

**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 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.

*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, baby food, *milk based drinks intended for young children*, and food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC, *Commission Directive 96/8/EC and Commission Regulation (EC) No 41/2009*. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, *milk based drinks intended for young children*, 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 *and the process for placing on the market of food resulting from scientific and technological innovations* 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.

Or. en

**Amendment 96**  
**Sophie Auconie**

**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 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

*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, **as well as food intended to meet the expenditure of intense muscular effort**, 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, food for special medical purposes and **food intended to meet the expenditure of intense muscular effort** 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 **and the procedure and timetable for placing on the market foodstuffs resulting from scientific and technological innovations**, including for additional labelling



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.

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.

Or. fr

#### *Justification*

*Foods for intense muscular effort are foods specially formulated to ensure healthy nutrition in extreme sport and other physical activities. To help it prepare, produce and recover from intense or high-level effort, the human body needs specially formulated products promoting an adequate and effective supply of liquids and nutrients such as carbohydrates.*

#### **Amendment 97** **Julie Girling**

#### **Proposal for a regulation** **Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) In order to take into account technical and scientific progress and other relevant developments at Union or international level, the requirements applying to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, and food for special medical purposes should be regularly updated to enable consumers to benefit rapidly from such progress and developments. Data***

*supporting such updates may be provided by interested parties (e.g. scientific bodies, consumer organisations, food business operators).*

Or. en

#### *Justification*

*The current legal framework provides a possibility for innovation (Art. 4.2. of Directive 2009/39/EC) allowing to deviate from compositional criteria laid down in specific directives. As science is moving fast for example on adequate intake and nutrient quality in early infancy and childhood (incl. obesity research), consumers including infants and young children should be able to benefit rapidly from relevant technical and scientific progress.*

#### **Amendment 98** **Oreste Rossi**

#### **Proposal for a regulation** **Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) Whereas food controlled by this Regulation is specialised food distinguishable from foodstuffs intended for normal consumption, and which is governed by specific compositional criteria and which is required to provide additional mandatory labelling information to foodstuffs intended for normal consumption, it is appropriate to provide derogations, where appropriate, to those mandatory labelling requirements laid down in Regulation (EU) No 1169/2011.***

Or. en

#### **Amendment 99** **Esther de Lange**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) It is furthermore required to clarify the status of so-called 'growing-up milks' (GUMs), which are currently notified in 26 Member States through Directive 2009/39/EC, which is to be repealed. To this end, the Commission will present a report, and if necessary legislative proposals, at the latest one year before the repeal of Directive 2009/39/EC.***

Or. en

**Amendment 100**  
**Bogusław Sonik**

**Proposal for a regulation**  
**Recital 19 a (new)**

*Text proposed by the Commission*

*Amendment*

***(19a) Most often, patients who consume dietary foods for special medical purposes covered by this regulation require advice from healthcare professionals qualified in medicine, nutrition, pharmacy or child and maternal healthcare, on their specific nutritional and/or dietary requirements. This includes advice on safe and appropriate use. It is therefore necessary to allow manufacturers to provide information and recommendations, in addition to label information, directly to healthcare professionals. It is also the case that healthcare professionals will advise manufacturers on the needs of their patients in order to formulate products and to collect the appropriate scientific data in order to meet the objectives of this regulation.***

Or. en

## *Justification*

*Dietary foods for special medical purposes that fall within the scope of the proposed Regulation are used under the supervision of Healthcare Professionals. It is essential for the safe use of these products that manufacturers can provide useful information, in addition to labelling, in order to inform Healthcare Professionals of the composition and safe and appropriate use of these products.*

### **Amendment 101**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

### **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 substances that may be added ***for specific nutritional purposes*** to infant formula, follow-on formula, processed cereal-based food and baby ***foods, food for special medical purposes, and foods for people intolerant to gluten, taking into account Regulation (EC) No. 953/2009, Commission Directives 2006/141/EC and 2006/125/EC***, 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.

Or. en

### *Justification*

*Existing Regulation (EC) No 953/2009, Directives 2006/141/EC and 2006/125/EC regulates substances that may be added for specific nutritional purposes. Retaining this terminology avoids confusion on the scope and purpose of the Union list of substances. The simplified and consolidated list of substances that may be added for specific nutritional purposes must take into account those substances that are currently permitted under the existing rules.*

## **Amendment 102** **Oreste Rossi**

### **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 substances that may be added **for specific nutritional purposes** to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes **and food intended for weight reduction and control, taking into account Regulation 953/2009, Commission Directive 2006/141/EC and Commission Directive 2006/125/EC**, 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.

Or. en

**Amendment 103**  
**Kartika Tamara Liotard**

**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, 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. ***For sake of legal clarity and avoiding legal gaps, it must be made clear that when a substance which is already included in the Union list and which undergoes a significant change in the production methods or if there is a change in particle size, for example through nanotechnology, the substance shall be removed from the Union list and considered a substance requiring an application as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.*** 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. en

## **Amendment 104**

**Carl Schlyter**

on behalf of the Verts/ALE Group

### **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, 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 *and updating* of the list *is a measure of general application to supplement or amend certain non-essential elements of the legislative act, 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.

*Justification*

*The establishment and updating of the list is an act of general application to supplement or amend certain non-essential elements of the legislative act. Moreover the requirements laid down in Article 11(1) are very open. Therefore delegated acts should be applied.*

**Amendment 105**  
**Sophie Auconie**

**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 substances that may be added ***for particular nutritional requirements*** to infant formula, follow-on formula, processed cereal-based food and baby food ***for infants and young children***, food for special medical purposes and ***food intended to meet the expenditure of intense muscular effort***, 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.



## *Justification*

*Foods for intense muscular effort are foods specially formulated to ensure healthy nutrition in extreme sport and other physical activities. To help it prepare, produce and recover from intense or high-level effort, the human body needs specially formulated products promoting an adequate and effective supply of liquids and nutrients such as carbohydrates.*

### **Amendment 106**

**Carl Schlyter**

on behalf of the Verts/ALE Group

### **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 **as long as their safety, based on adequate and sufficient test methods, their nutritional value and their suitability for the persons to whom it is intended have not been demonstrated** by the Authority.

Or. en

## *Justification*

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

**Amendment 107**  
**Kartika Tamara Liotard**

**Proposal for a regulation**  
**Recital 24 a (new)**

*Text proposed by the Commission*

*Amendment*

***(24a) It is necessary to re-evaluate the benefits of follow-on formula and growing-up milks and whether follow-on formula should be treated as food for a specific nutritional purpose. Therefore, the Commission should no later than [Two years after the entry into force of this Regulation] and after having reviewed the scientific opinion of the Authority on this matter, present a report on follow-on formula and growing-up milk to the European Parliament and Council, where appropriate, followed by a legislative proposal.***

Or. en

**Amendment 108**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 25**

*Text proposed by the Commission*

*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.

(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, ***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*

*Technical amendment intended to replace the rapporteur's original Amendment 23. 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 109**  
**Christine De Veyrac**

**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. ***Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers<sup>1</sup> provides for the possible adoption by the Commission of implementing acts regulating voluntary information on the possible and unintentional presence in food of substances or products causing allergies or intolerances. For reasons of coherence and simplification of the legal framework, the Commission should be granted a mandate under Regulation (EU) No 1169/2011 to adopt implementing acts concerning gluten-free or lactose-free foods. It is necessary that the Regulation in question be amended to***

*that effect and that the required implementing provisions be adopted by the Commission prior to the entry into application of this Regulation. The implementing act covering food for people intolerant to gluten should take over and replace all the provisions on labelling and composition set out in Regulation (EC) No 41/2009 in order to ensure the same level of consumer protection.*

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<sup>1</sup> OJ L 304, 22.11.2011, p. 18.

Or. fr

### *Justification*

*The change regarding gluten-free foods in Regulation No 1169/2011 is not sufficient to protect coeliac disease sufferers. The INCO regulation is not as strict as Regulation 49/2009 on the composition of products (residual gluten content, production method, product identification). It is important for Commission implementing acts to take into account Regulation 49/2009 in order to ensure the same level of consumer protection.*

## **Amendment 110** **Frédérique Ries**

### **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

#### *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 ***judicial and health security***, those statements should be regulated solely by ***this Regulation in terms of food meeting specific nutritional and physiological needs. It forms the best***

*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.*

*judicial framework for the specific requirements of food for people intolerant to gluten in terms of composition and labelling. In particular, only products with a gluten content of not more than 20 mg/kg in the food sold to final consumers should be allowed to be labelled 'gluten free', and only products with a gluten content of not more than 100 mg/kg in the food sold to final consumers should be allowed to be labelled 'very low gluten content'. Regulation (EC) No 41/2009 should therefore be repealed.*

Or. fr

#### *Justification*

*This amendment is intended to replace Amendment 24, as the rapporteur considers that the present legislative framework is the most suitable in terms of defining specific rules on labelling and composition which will enable patients suffering from gluten intolerance to continue to eat in complete safety, and thus to encourage gluten-free foods to be put on the market in order to protect this group of people suffering from a life-long complaint.*

**Amendment 111**  
**Françoise Grossetête**

**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*

*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. *Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers<sup>1</sup> provides for the adoption by the Commission of*

***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.***

***implementing acts regulating voluntary information on the possible and unintentional presence in food of substances or products causing allergies or intolerances. For reasons of coherence and simplification of the legal framework, the Commission should be granted a mandate under Regulation (EU) No 1169/2011 to also adopt implementing acts regulating voluntary information on the absence or reduced presence in food of substances causing intolerances, such as gluten and lactose, and to withdraw Commission Regulation (EC) No 41/2009. It is necessary that Regulation (EU) No 1169/2011 be amended to that effect and that the required implementing provisions be adopted by the Commission prior to the entry into application of this Regulation. The implementing act concerned should maintain on the foods in question the statements 'gluten-free' and 'very low gluten' and their associated conditions of use, as well as an indication of the persons for whom the foods are intended, as currently regulated under Regulation (EC) No 41/2009, and hence provide for the same level of consumer protection.***

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<sup>1</sup> OJ L 304, 22.11.2011, p. 18.

Or. fr

#### *Justification*

*People intolerant to gluten and lactose must have a regulatory framework tailored to their specific needs.*

#### **Amendment 112**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**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 **foods for specialised nutrition intended for people intolerant to gluten** under the rules specified in **article 3 of** Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. **In addition, the statement 'gluten-free' may be used for foodstuffs for normal consumption and other foods for specialised nutrition suitable for people intolerant to gluten under the rules specified in article 4 of Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten which do not allow the use of the statement 'very low gluten' for these foods. Such foods for specialized nutrition intended for people intolerant to gluten shall be maintained in this Regulation, as providing such safe foods intended for people intolerant to gluten and informing coeliacs about the absence of gluten is vital to the management of the disease. This is in line with the international standard for foods for special dietary use for persons intolerant to gluten (CODEX STAN 118-1979 revised in 2008). Also the conditions of use of the claim "gluten-free" for foods for normal consumption should be maintained in the Regulation (CE) 41/2009.**

Or. en

*Justification*

*Some essential guarantees that are offered in the current dietetic Framework Directive (2009/39/EC), in particular those concerning "food for people intolerant to gluten," have been removed from the scope of the proposed revision to the detriment of those suffering from*

*Coeliac disease. These foods for specialised nutrition are recognized at international level by the recently revised Codex Standard for foods for special dietary use for persons intolerant to gluten.*

## **Amendment 113**

**Anja Weisgerber, Renate Sommer**

### **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. ***Gluten-free foods are the only food source for coeliac disease sufferers. The composition of foods is decisive in managing the condition. However, neither Regulation (EC) No 1924/2006 nor Regulation (EC) No 1169/2011 takes account of the particular requirements for the composition of these foods. Foods intended for people intolerant to gluten should therefore come under the scope of this Regulation.***

Or. de

##### *Justification*

*Coeliac disease is an auto-immune disorder which can only be managed by strict avoidance of foods containing gluten. Failure to adhere to a strict regime can lead to associated conditions such as cancer of the intestine. As the Commission states in recital 15, it is essential to maintain the intended nutritional adequacy for certain groups of the population.*



**Amendment 114**  
**Esther de Lange**

**Proposal for a regulation**  
**Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

***(26a) It is important that the change in regulatory framework is carried out without changing the current definition and composition of 'gluten-free' and 'very low gluten' products, so as not to confuse the end-users of these products.***

Or. en

**Amendment 115**  
**Frédérique Ries**

**Proposal for a regulation**  
**Recital 26 a (new)**

*Text proposed by the Commission*

*Amendment*

***(26a) Labelling indicating 'lactose free' and 'very low lactose content' currently have no legal cover at EU level: neither under Regulation (EC) No 1924/2006 nor under specific provisions to deal with different kinds of food intolerance. These indicators are, however, important for people who are intolerant to lactose. They should therefore be covered by the new Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers<sup>1</sup>, which makes possible the establishment of criteria for including allergens on labelling.***

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<sup>1</sup> OJ L 304, 22.11.2011, p. 18.

Or. fr

## Justification

*Like gluten intolerance, lactose intolerance is one of the most common intolerances. However, whilst gluten intolerance can be fatal if a strict regime is not adhered to, lactose intolerance does not generally cause 'harm' to the human body. This medical distinction is enough to justify different treatment in the regulations. It would be worth including lactose intolerance in Regulation 1169/2011 on food labelling.*

### **Amendment 116** **Esther de Lange**

#### **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 **currently** considered as food for particular nutritional uses and are governed by specific rules adopted under Directive 96/8/EC, **while foods intended for 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. 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 should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein, **with the exception of foods intended for very low calorie diets (VLCD), which should in future be regulated under Directive 96/8/EC.** 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.

Or. en

### *Justification*

*VLCD replacing the entire daily diet, and providing only 400-800 kcal per day should be governed by a separate specific Directive, while LCD products can be governed by general food legislation.*

## **Amendment 117** **Oreste Rossi**

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

*Text proposed by the Commission*

*Amendment*

*(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are considered as food for particular nutritional uses and are governed by specific rules adopted under Directive 96/8/EC. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. In order to eliminate any potential confusion between food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'total diet replacement for*

*deleted*

*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.*

Or. en

**Amendment 118**  
**Sophie Auconie**

**Proposal for a regulation**  
**Recital 27 a (new)**

*Text proposed by the Commission*

*Amendment*

*(27a) Low-calorie diets pursued in particular with specific food programmes are becoming more popular, a trend which is encouraged by modern lifestyles and media development. Such diets can cause nutritional imbalances and inequalities in the supply of the most essential nutrients (too little or too much) which are likely to endanger the health of those involved. Scientific studies point to clinical, biological, behavioural and psychological risks when these diets are based on misleading, erroneous or scientifically invalidated recommendations. The Commission must submit a report on low-calorie diets, taking into account Member States' experience and after consulting the European Food Safety Authority. The report should aim to assess the impact of suitable measures to enable consumers wishing to undertake such diets to enjoy an appropriate level of protection.*

Or. fr

**Amendment 119**  
**Françoise Grossetête, Esther de Lange**

**Proposal for a regulation**  
**Recital 29 a (new)**

*Text proposed by the Commission*

*Amendment*

***(29a) A procedure should be laid down which allows foodstuffs resulting from scientific and technological innovations to be placed on the market on a temporary basis in order that proper benefit may be derived from the fruits of industry research pending the amendment of the specific directive concerned. However, on the grounds of consumer health protection, marketing authorisation may be granted only after the European Food Safety Authority has been consulted.***

Or. fr

*Justification*

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

**Amendment 120**  
**Françoise Grossetête, Esther de Lange**

**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 foods on the market on a temporary basis.*

Or. fr

**Amendment 121**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**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 establishes compositional and information requirements for the following categories of food *for specialised nutrition*:

Or. en

**Amendment 122**

**Oreste Rossi**

**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 establishes compositional and information requirements for the following categories of food *for specialised nutrition*:

Or. en

**Amendment 123**

**Mairead McGuinness**

**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 establishes compositional and information requirements for the following categories of food ***for specialised nutrition***:

Or. en

**Amendment 124**  
**Sophie Auconie**

**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 establishes compositional and information requirements for categories of food ***for specific nutritional purposes***:

Or. fr

**Amendment 125**  
**Mairead McGuinness**

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

*Text proposed by the Commission*

(a) infant formula and follow-on formula;

*Amendment*

(a) infant formula and follow-on formula ***for infants in good health***;

Or. en

**Amendment 126**  
**Oreste Rossi**

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

*Text proposed by the Commission*

(a) infant formula and follow-on formula;

*Amendment*

(a) infant formula and follow-on formula  
***for infants in good health;***

Or. en

**Amendment 127**  
**Esther de Lange, Julie Girling**

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

*Text proposed by the Commission*

(a) infant formula and follow-on formula;

*Amendment*

(a) infant formula and follow-on formula  
***for infants in good health;***

Or. en

**Amendment 128**  
**Anja Weisgerber, Renate Sommer**

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

*Text proposed by the Commission*

*Amendment*

***(ba) other foods for infants and young children;***

Or. de

*Justification*

*Many foods for infants and young children, such as baby tea and foods for premature infants, are available on the market. These foods should be covered by this Regulation in order to ensure maximum consumer protection.*



**Amendment 129**

**Esther de Lange, Julie Girling**

**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.*

Or. en

**Amendment 130**

**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**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.*

Or. en

*Justification*

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

**Amendment 131**

**Oreste Rossi**

**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.***

Or. en

**Amendment 132**

**Frédérique Ries**

on behalf of the Committee on the Environment, Public Health and Food Safety

**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.***

Or. fr

*Justification*

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

**Amendment 133**

**Kartika Tamara Liotard**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point c a (new)**

*Text proposed by the Commission*

*Amendment*

***(ca) products designed for weakened elderly people.***

Or. en

**Amendment 134**  
**Esther de Lange**

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

*Text proposed by the Commission*

*Amendment*

***(ca) foods intended for use in very low calorie diets (VLCD).***

Or. en

*Justification*

*VLCD should be covered by specific legislation.*

**Amendment 135**  
**Anja Weisgerber, Renate Sommer**

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

*Text proposed by the Commission*

*Amendment*

***(ca) foods for people intolerant to gluten (gluten-free foods).***

Or. de

*Justification*

*Coeliac disease is an auto-immune disorder which can only be managed by strict avoidance of foods containing gluten. Failure to adhere to a strict regime can lead to associated conditions such as cancer of the intestine. As the Commission states in recital 15, it is essential to maintain the intended nutritional adequacy for certain groups of the population.*

**Amendment 136**  
**Mairead McGuinness**

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

*Text proposed by the Commission*

*Amendment*

***(ca) formula intended for low birth-weight and pre-term infants.***

Or. en

**Amendment 137**  
**Sophie Auconie**

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

*Text proposed by the Commission*

*Amendment*

***(ca) foods intended to meet the expenditure of intense muscular effort.***

Or. fr

**Amendment 138**  
**Anja Weisgerber, Renate Sommer**

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

*Text proposed by the Commission*

*Amendment*

***(cb) food intended to meet the requirements of extreme physical activity.***

Or. de

*Justification*

*People engaged in intense muscular effort need special foods which satisfy nutritional requirements. Until now these foods have been regulated in the Framework Directive on dietetic foods (2009/39/EC). If such foods did not come under the scope of this Regulation, they would cease to be marketable in many Member States owing to lack of authorisation.*

**Amendment 139**  
**Oreste Rossi**

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

*Text proposed by the Commission*

*Amendment*

***(cb) food intended for weight reduction  
and control;***

Or. en

**Amendment 140**  
**Oreste Rossi**

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

*Text proposed by the Commission*

*Amendment*

***(cc) food intended to meet the expenditure  
of intense muscular effort.***

Or. en

**Amendment 141**  
**Sophie Auconie**

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

*Text proposed by the Commission*

*Amendment*

***1a. This Regulation establishes rules for  
placing on the market of other foods for  
specialised nutritional purposes.***

Or. fr

*Justification*

*In order to enable future innovation on the basis of specific scientific evidence, the category*

*'other foods for specialised nutritional purposes' needs to be created to take into account the development of scientific knowledge and consumer needs.*

**Amendment 142**  
**Oreste Rossi**

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

*Text proposed by the Commission*

*Amendment*

***1a. This Regulation establishes rules for the placing on the market of other food for specialised nutrition.***

Or. en

**Amendment 143**  
**Kartika Tamara Liotard**

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

*Text proposed by the Commission*

*Amendment*

***2a. Without prejudice to Regulation (EC) No 178/2002, the requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.***

Or. en

*Justification*

*This paragraph reproduces Article 7(2) of the Commission proposal, but moved into Article 1 for clarity. Regulation (EC) No 178/2002 is the basic food law of the European Union, which should prevail over all sectoral food legislation.*

**Amendment 144**  
**Kartika Tamara Liotard**

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

*Text proposed by the Commission*

(a) the definitions of ‘food’ and ‘placing on the market’ set out in Articles 2 and 3(8) of Regulation (EC) No 178/2002;

*Amendment*

(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;

Or. en

**Amendment 145**  
**Kartika Tamara Liotard**

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

*Text proposed by the Commission*

(b) the definitions of ‘labelling’ and ‘pre-packaged foodstuff’ in points (a) and (b) of Article 1(3) of Directive 2000/13/EC;

*Amendment*

(b) the definitions of ‘labelling’ and ‘pre-packaged foodstuff’ **set out** in points (a) and (b) of Article 1(3) of Directive 2000/13/EC;

Or. en

**Amendment 146**  
**Julie Girling**

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

*Text proposed by the Commission*

***(d) the definition of ‘other substance’ set out in Article 2(2) of Regulation (EC) No 1925/2006.***

*Amendment*

***deleted***

Or. en

### *Justification*

*Alignment with the categories introduced in Article 11 (1). In order to guarantee legal clarity of the Union list the types of substances should be clearly defined as categories taking into account existing legislation (Directives 2006/121/EC, 2006/125/EC and Regulation (EC) No 953/2009).*

#### **Amendment 147**

**Carl Schlyter**

on behalf of the Verts/ALE Group

#### **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.***

Or. en

### *Justification*

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

#### **Amendment 148**

**Sophie Auconie**

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

**Article 2 – paragraph 2 – point a a (new)**

*Text proposed by the Commission*

*Amendment*

***(aa) 'food for specialised nutritional purposes' means foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to***



*indicate such suitability;*

Or. fr

*Justification*

*There needs to be a clear distinction between foods intended to meet a specific nutritional purpose and foodstuffs for normal consumption in order to ensure the safety of all consumers: those with particular nutritional requirements and those who have no specific needs.*

**Amendment 149**

**Oreste Rossi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point a a(new)**

*Text proposed by the Commission*

*Amendment*

*(aa) 'food for specialised nutrition' means foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.*

Or. en

**Amendment 150**

**Gilles Pargneaux**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

*(ii) milk intended for young children;*

*deleted*

Or. fr

### *Justification*

*Les boissons à base de lait destinées aux enfants en bas âge sont des produits riches en nutriments spécialement conçus pour contribuer aux besoins nutritionnels des enfants âgés de 12 à 36 mois. Les exclure du présent règlement entraînera un assouplissement des mesures de sécurité alimentaire, une composition nutritionnelle non spécifique et un manque d'harmonisation entre tous les États membres de l'UE. En conséquence, ces produits seront réglementés en tant que produits d'alimentation générale et seront ainsi soumis aux critères de sécurité édictés pour les adultes, inappropriés pour les enfants âgés de 12 à 36 mois.*

#### **Amendment 151**

**Oreste Rossi**

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

#### **Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

**(ii) milk intended for young children;**

**deleted**

Or. en

#### **Amendment 152**

**Françoise Grossetête, Christine De Veyrac**

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

#### **Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

**(ii) milk intended for young children;**

**deleted**

Or. fr

### *Justification*

*Growth milks for children aged 1-3 are products specifically designed to address these children's nutritional needs and they must meet very strict food safety requirements, notably with regard to pesticide-residue content. The level of safety currently applicable to baby foods must be applied to foods for children aged 1-3.*

**Amendment 153**  
**Paolo Bartolozzi, Elisabetta Gardini**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

***(ii) milk intended for young children;***                      ***deleted***

Or. en

*Justification*

*Milk Based Drinks Intended for Young Children are specifically designed nutrient dense products, which contribute to young children’s nutritional needs from 12-36 months. Excluding these products from the Regulation will result in reduced food safety measures, non-specific nutritional composition and their regulation as general foods, thus subject to the nutritional and safety criteria laid down for adults, which are not appropriate for children aged 12-36 months.*

**Amendment 154**  
**Anja Weisgerber, Renate Sommer**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

***(ii) milk intended for young children;***                      ***deleted***

Or. de

*Justification*

*‘Children’s milk’ or ‘growth milk’ should come under the scope of the Directive, like all foods intended for infants and young children.*

**Amendment 155**  
**Tiziano Motti**

**Proposal for a regulation**  
**Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

**(ii) milk intended for young children;**

**deleted**

Or. en

## **Amendment 156**

**Mairead McGuinness**

### **Proposal for a regulation**

#### **Article 2 – paragraph 2 – point g – point ii**

*Text proposed by the Commission*

*Amendment*

**(ii) milk intended for young children;**

**deleted**

Or. en

#### *Justification*

*Milk Based Drinks Intended for Young Children, also known as Toddlers Milks or Growing Up Milks, are specifically designed, nutrient dense products, which contribute to young children's nutritional needs from 12-36 months. International standards confirm that infants aged 6 to 36 months require specialised formulae, and this has been reflected since 1987 in the Codex Standard for follow-up formula intended for infants and young children. Excluding these products from the Regulation will result in, non-specific nutritional composition and a lack of harmonization across EU Member States. As a result, these products will be regulated as general foods, thus subject to the nutritional and quality criteria laid down for adults, which are not appropriate for children aged 12-36 months. An independent scientific assessment from the European Food Safety Authority should clarify the nutritional needs of this vulnerable category of consumers.*

## **Amendment 157**

**Christine De Veyrac**

### **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

(h) 'food for special medical purposes' means food ***specialy processed or designed and*** intended for the dietary

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.

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 **of their ingredients or metabolites**, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet. **Food for special medical purposes is classified under the three following categories:**

**(a) 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;**

**(b) 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;**

**(c) 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.**

**The foods referred to in points (a) and (b) may also be used as a partial replacement of a person's diet.**

Or. fr

#### *Justification*

*In the absence of a new scientific opinion from the Food Safety Authority, and applying the precautionary principle, it is important to maintain the definition set out in Directive 1999/21/EC in its entirety. The creation of three categories obviates varying interpretations*

*in different Member States.*

## **Amendment 158**

**Esther de Lange, Julie Girling**

### **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 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. ***Foods for special medical purposes also include formula intended for low birth-weight and pre-term infants.***

Or. en

## **Amendment 159**

**Sophie Auconie**

### **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***

*Amendment*

(h) ‘food for special medical purposes’ means food ***specially treated 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

*contained therein*, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet.

ordinary food or certain *of their ingredients or metabolites*, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet. *Dietary foods for special medical purposes are classified in the following three categories:*

*(a) 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;*

*(b) 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;*

*(c) 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.*

*The foods referred to in points (a) and (b) may also be used as a partial replacement or as a supplement to the patient's diet.*

Or. fr

#### *Justification*

*In the absence of a new scientific opinion from the European Food Safety Authority (EFSA), and applying the precautionary principle, the definition set out in Directive 1999/21/EC on dietary foods for special medical purposes should be maintained in its entirety in order to distinguish such foods from normal food and to avoid different interpretations between Member States.*

**Amendment 160**  
**Julie Girling**

**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 intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet. ***Food for special medical purposes fall into one of the following three categories:***

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

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

***– 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.***

Or. en



## *Justification*

*To avoid any confusion on the part of notifying authorities, patients and healthcare professionals, FSMPs should remain clearly categorised in the new EU rules, as defined in Directive 1999/21/EC.*

### **Amendment 161**

**Daciana Octavia Sârbu, Christel Schaldemose**

#### **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 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. ***Foods for special medical purposes fall into one of the following three categories:***

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

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

***– 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.*

Or. en

*Justification*

*It is important to keep the same, specific definitions of foods for special medical purposes established under regulation 1999/21 EC.*

**Amendment 162**  
**Oreste Rossi**

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

*Text proposed by the Commission*

*Amendment*

*(ha) 'food intended for weight reduction and control' means food specially formulated, when used as instructed by the manufacturer, to replace the whole or part of the total daily diet:*

*(i) for use in energy-restricted diets for weight reduction. They are divided in two categories:*

*– products presented as a replacement for the whole of the daily diet (low calorie diet and very low calorie diet);*

*– products presented as a replacement for one or more meals of the daily diet (meal replacement);*

*(ii) for weight control (products presented as a dish or part of a meal or light meal or snack).*

Or. en

**Amendment 163**  
**Elisabetta Gardini, Paolo Bartolozzi, Sergio Berlato, Lorenzo Fontana, Cristiana**

**Muscardini, Oreste Rossi, Andrea Zanoni, Patrizia Toia, Antonio Cancian, Amalia Sartori, Mario Pirillo, Tiziano Motti, Salvatore Tatarella, Lara Comi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) 'food for people intolerant to gluten' means foodstuffs for particular nutritional uses which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten;***

Or. en

*Justification*

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

**Amendment 164**

**Frédérique Ries**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) ‘gluten’ means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof, to which some persons are intolerant and which is insoluble in water and 0.5 M sodium chloride solution;***

Or. fr

*Justification*

*Reintroduction of the definition of gluten as set out in the Codex Alimentarius standards and in Regulation No 41/2009/EC.*

**Amendment 165**

**Sophie Auconie**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) 'food intended to meet the expenditure of intense muscular effort' means food specifically formulated and presented to compensate for expenditure sustained during intense muscular effort, in particular for sportsmen.***

Or. fr

*Justification*

*Foods for intense muscular effort are foods specially formulated to ensure healthy nutrition in extreme sport and other physical activities. To help it prepare, produce and recover from intense or high-level effort, the human body needs specially formulated products promoting an adequate and effective supply of liquids and nutrients such as carbohydrates.*

**Amendment 166**

**Oreste Rossi**

**Proposal for a regulation**

**Article 2 – paragraph 2 – point h a (new)**

*Text proposed by the Commission*

*Amendment*

***(ha) 'food intended to meet the expenditure of intense muscular effort' means food specially formulated and presented to meet the expenditure of intense muscular effort, especially for sportsmen.***

**Amendment 167**  
**Frédérique Ries**

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

*Text proposed by the Commission*

*Amendment*

***(hb) ‘foodstuffs for people intolerant to gluten’ means foodstuffs for particular nutritional uses which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten;***

Or. fr

*Justification*

*Incorporating specific provisions on composition and labelling in the scope of this Regulation justifies adding a definition for gluten-free foods included in Regulation No 41/2009.*