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Committee on the Environment, Public Health and Food Safety

2011/0156(COD)

26.1.2012

AMENDMENTS

168 - 282

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 168

Esther de Lange

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ha) 'foods intended for very low calorie diets (VLCD)' means specifically formulated foods which, when used as instructed by the manufacturer, replace the total daily diet and contain between 400 and 800 kcal per day.

Or. en

Amendment 169

Esther de Lange, Julie Girling

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ha) 'Formula intended for low birth weight and pre-term infants' means a formula specifically developed to meet the medically-determined nutrient requirements of infants who are born prematurely or at a low birth weight (less than 2 500 g body weight).

Or. en

Amendment 170

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

Proposal for a regulation

Article 2 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 to adapt the definitions of ‘infant formula’, ‘follow-on formula’, ‘processed cereal-based food’ and ‘baby food’, ‘food for special medical purposes’, **and ‘food for people intolerant to gluten’** 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 171
Oreste Rossi

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 to adapt the definitions of ‘infant formula’, ‘follow-on formula’, ‘processed cereal-based food’ and ‘baby food’, ‘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 technical and scientific progress and relevant developments at international level, as appropriate.

Amendment 172
Sophie Auconie

Proposal for a regulation
Article 2 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. fr

Justification

Food intended to meet expenditure for intense muscular effort is food specially processed or 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 173
Daciana Octavia Sârbu, Glenis Willmott, Christel Schaldemose

Proposal for a regulation
Article 3

Text proposed by the Commission

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

Amendment

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

Union law applicable to food.

2. Food imported into the Union for the purpose of being placed on the market there shall comply with the applicable provisions of Union food law. Food exported or re-exported from the Union for the purpose of being placed on the market in a third country shall comply with the applicable provisions of Union food law. Food exported to a third country shall be labelled in a language appropriate to that country.

3. Food referred to in Article 1(1) may be placed on the market only in pre-packaged form, as defined in Article 2(2)(e) of Regulation (EC) No 1169/2011.

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

Or. en

Justification

This amendment compliments the rapporteur's amendment (no.35) and reiterates that food exported to a third country must be labelled in a language appropriate to that country.

Amendment 174
Oreste Rossi

Proposal for a regulation
Article 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 175

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 3

Text proposed by the Commission

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

Amendment

Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation.
"Milks" or similar products shall not be marketed by making reference to special suitability for infants or young children.

Or. en

Justification

Currently, so-called "growth milks" or "children's milks" are marketed in some Member States. It is obvious that the selling of such products is highly misleading for the consumer as such products do not show any added benefit in the nourishment of young children compared to a normal diet suitable for children. They should therefore not be allowed on the market.

Amendment 176

Sophie Auconie

Proposal for a regulation

Article 3

Text proposed by the Commission

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

Amendment

Food referred to in Article 1(1) ***and (2)*** may be placed on the market only if it complies with the provisions of this Regulation.

Or. fr

Justification

Alignment with the introduction to Article 1(2). This provision should apply for all foods for

specialised nutrition.

Amendment 177
Christine De Veyrac

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

Text proposed by the Commission

Amendment

1a. All markings or any presentation likely to give the impression that one of the products referred to in Article 1(1) and 1(2) is involved, shall be prohibited in the labelling, presentation and advertising of foodstuffs for normal consumption.

However, the Commission shall be empowered to adopt delegated acts in accordance with Article 15 of this regulation in order to adopt measures enabling foodstuffs for normal consumption which are suitable for a particular nutritional use to indicate such suitability. Such provisions may lay down the arrangements for indicating that suitability.

Or. fr

Justification

To avoid misleading consumers, there is a need to maintain a provision similar to that in Article 2.2.b of the current Framework Directive ensuring that only products compliant with the regulations can be presented as conforming to the specific needs of the targeted populations.

Amendment 178
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

1a. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the words ‘specialised nutrition products’, either alone or in conjunction with other words, to designate those foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1(1) and 1(2) is involved.

Or. fr

Justification

Afin de ne pas induire en erreur le consommateur, il est nécessaire de maintenir une disposition similaire à celle de l'article 2.2.b de la directive-cadre actuelle, garantissant que seuls les produits conformes à ce règlement peuvent être présentés comme convenant aux besoins spécifiques des populations cibles. S'agissant des consommateurs vulnérables, un étiquetage approprié, qui leur fournisse les informations adéquates relatives à la composition de ces denrées alimentaires spécifiques, s'avère nécessaire. Une distinction claire doit être faite entre les étiquetages des denrées alimentaires nutritionnelles et les denrées alimentaires ordinaires, afin de garantir la sécurité aussi bien des consommateurs nécessitant des produits de nutrition spécialisée que des consommateurs ordinaires. Seules les denrées alimentaires ordinaires présentant des allégations nutritionnelles et de santé agréées devraient mentionner qu'elles conviennent à une alimentation particulière.

Amendment 179

Tiziano Motti

Proposal for a regulation

Article 3 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the words "specialised nutrition", either alone or in conjunction with other words, to designate those foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1(1) or 1(2) is involved.

Or. en

Justification

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

Amendment 180
Sophie Auconie

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

Text proposed by the Commission

Amendment

1a. The composition, presentation and labelling of food referred to in Article 1(1) and 1(2) satisfy the nutritional requirements of the persons for whom they are intended. They give consumers sufficient information to promote risk-free use of these products and safe food, in line with generally-accepted scientific data.

Or. fr

Justification

Provisions on suitable nutritional composition, product safety and labelling are essential for consumers of specialised nutrition products. It is vital that there be suitable labelling for

vulnerable consumers to ensure they are given adequate information on the composition of specific nutrition products and their safe use.

Amendment 181
Sophie Auconie

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

Text proposed by the Commission

Amendment

1b. In the labelling, presentation and advertising of foodstuffs for normal consumption the following shall be prohibited:

(a) the use of the words ‘specialised nutrition’, either alone or in conjunction with other words, to designate those foodstuffs;

(b) all other markings or any presentation likely to give the impression that one of the products referred to in Article 1(1) and 1(2) is involved.

Or. fr

Justification

To avoid misleading consumers, there is a need to maintain a provision similar to that in Article 2.2.b of the current Framework Directive ensuring that only products compliant with the regulations can be presented as conforming to the specific needs of the targeted populations. It is vital that there be suitable labelling for vulnerable consumers.

Amendment 182
Oreste Rossi

Proposal for a regulation
Article 6 – paragraph 1

Text proposed by the Commission

Amendment

1. Where it is evident that a food referred to in Article 1(1) is likely to constitute a

1. Where it is evident that a food referred to in Article 1(1) **and 1(1a)** is likely to

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

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

Or. en

Amendment 183
Sophie Auconie

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Food referred to in Article 1 shall comply with any requirement of Union law applicable to food, ***save as regards changes made to them to ensure their conformity with the definitions given in Article 1.***

Or. fr

Justification

The products covered by this Regulation are foods for specialised nutrition. Their composition and presentation must therefore be appropriate for the needs of the persons for whom they are intended.

Amendment 184
Oreste Rossi

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Food referred to in **Article 1** shall comply with any requirement of Union law applicable to food, **save as regards changes made to them to ensure their conformity with the definitions given in Article 1.**

Or. en

Amendment 185
Kartika Tamara Liotard

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.

Amendment

1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted **peer-reviewed** scientific data.

Or. en

Amendment 186
Oreste Rossi

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs

Amendment

1. The composition of food referred to in Article 1(1) **and 1(1a)** shall be such that it is appropriate to satisfy the **specific**

of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.

nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted scientific data.

Or. en

Amendment 187
Kartika Tamara Liotard

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons to whom they are intended.

Amendment

2. Food referred to in Article 1(1) shall not contain any substance ***which endangers, or which is*** in such quantity as to endanger, the health of the persons to whom they are intended.

Or. en

Amendment 188
Oreste Rossi

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission

2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons to whom they are intended.

Amendment

2. Food referred to in Article 1(1) ***and 1(1a)*** shall not contain any substance in such quantity as to endanger the health of the persons to whom they are intended.

Or. en

Amendment 189
Claudiu Ciprian Tănăsescu

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Food referred to in Article 1(1)(a) and (b) shall not contain genetically modified organisms (GMOs), ingredients or additives originating from GMOs that are currently used in the production of food. Strict traceability and labelling rules shall be applied.

Or. en

Amendment 190
Carl Schlyter
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. With the exception of products authorised in accordance with Article 16 (1) of Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products, pesticides and other toxic substances shall 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 191

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. Foods referred to in Article 1(1) shall not contain residues of pesticides above the level of detection.

Or. en

Justification

For some of the foods referred to in Article 1(1), specific requirements regarding pesticide residues already exist. As all foods covered by this Regulation are intended to the most vulnerable population, and as test methods are evolving, it is appropriate to require such foods not to contain any pesticide residues above the detection limit.

Amendment 192

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 2 c (new)

Text proposed by the Commission

Amendment

2c. Genetically modified organisms as defined under Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed and products produced from animals that have been fed with genetically modified feeding stuffs shall not be used 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 193

Oreste Rossi

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The labelling, presentation and advertising of food referred to in Article 1(1) **and 1(1a)** shall provide adequate consumer information and must not be misleading **and shall not attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.**

Or. en

Amendment 194

Carl Schlyter

on behalf of the Verts/ALE Group

Christel Schaldemose

Proposal for a regulation

Article 9 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. The labelling of infant formulae and follow-on formulae as well as all other foods intended for infants or young children shall not include pictures of infants or young children, nor shall it include other pictures or text which may idealise the use of the product.

Or. en

Justification

Requirement taken over from Directive 2006/141/EC on infant formulae and follow-on formulae. In order not to confuse consumers or to possibly advantage the use of "special" children food to a normal diet suitable for children, the strict requirements on labelling which apply today for infant formulae should be extended to all foods intended for infants and young children.

Amendment 195

Carl Schlyter, Christel Schaldemose

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3b. The labelling of infant formulae and follow-on formulae as well as all other foods intended for infants or young children may bear nutrition and health claims only in the cases listed in Annex IV of Directive 2006/141/EC and in accordance with the conditions set out therein.

Or. en

Justification

Requirement taken over from Directive 2006/141/EC on infant formulae and follow-on formulae. In order not to confuse consumers or to possibly advantage the use of "special" children food to a normal diet suitable for children, the requirements on nutrition and health claims which apply today for infant formulae should be extended to all foods intended for infants and young children.

Amendment 196

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 3 c (new)

Text proposed by the Commission

Amendment

3c. Advertising of infant formulae, follow-on formulae and of any other kind of food intended for infants or young children shall be prohibited. This includes advertisements in publications, point-of-sale advertising, giving samples or any other promotional device to induce sales directly to the consumer.

Or. en

Justification

Today, Directive 2006/141/EC on infant formulae and follow-on formulae constraints the advertising of infant formulae. In order not to advantage the use of "special" children food to a normal diet suitable for children, the advertising of all kinds of foods intended for infants and young children should be prohibited.

Amendment 197

Daciana Octavia Sârbu, Glenis Willmott, Christel Schaldemose

Proposal for a regulation

Article 9 – paragraph 4

Text proposed by the Commission

Amendment

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care. **Such information shall not constitute advertising or promotional material.**

Or. en

Amendment 198
Oreste Rossi

Proposal for a regulation
Article 9 – paragraph 4

Text proposed by the Commission

4. **The** dissemination of any useful information or recommendations **with reference to the categories of food referred to in Article 1 (1) may be made** exclusively **by** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Amendment

4. **Paragraph 3 shall not prevent the** dissemination of any useful information or recommendations exclusively **intended for** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Or. en

(See Directive 2009/39/EC, Article 8(2).)

Amendment 199
Kartika Tamara Liotard

Proposal for a regulation
Article 9 – paragraph 4

Text proposed by the Commission

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Amendment

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition, pharmacy or **by** other **independent qualified** professionals responsible for maternal and child health care, **or intended exclusively for them.**

Or. en

Amendment 200
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 9 – paragraph 4

Text proposed by the Commission

4. **The dissemination** of any useful information or recommendations **with reference to the categories of food referred to in Article 1 (1) may be made exclusively by** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Amendment

4. **Paragraph 3 shall not prevent the dissemination** of any useful information or recommendations exclusively **intended for** persons having qualifications in medicine, nutrition **and** pharmacy or other professionals responsible for maternal and child health care.

Or. en

Justification

Reference is made to Article 8 of Directive 2009/39/EC, where, for safety reasons, it is required that foods for specialised nutrition carry along additional information for Healthcare Professionals.

Amendment 201
Julie Girling

Proposal for a regulation
Article 9 – paragraph 4

Text proposed by the Commission

4. **The dissemination** of any useful information **or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Amendment

4. **Paragraph 3 shall not prevent the communication** of any useful information **intended for** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Or. en

Justification

The new paragraph reflects the existing rules of Article 8 of Directive 2009/39/EC. It is essential that Health Care professionals can be furnished with the relevant information and documentation associated with these products, as well as being able to provide patients with access to these products under their supervision.

Amendment 202 **Esther de Lange**

Proposal for a regulation **Article 9 – paragraph 4**

Text proposed by the Commission

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively **by** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Amendment

4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in **points (a), (b) and (c) of** Article 1 (1) may be made exclusively **to** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care.

Or. en

Amendment 203 **Boguslaw Sonik**

Proposal for a regulation **Article 9 – paragraph 4**

Text proposed by the Commission

4. The dissemination of any useful information or recommendations **with reference to the categories of food referred to in Article 1 (1) may be made** exclusively **by** persons having qualifications in medicine, nutrition, pharmacy **or other professionals responsible for maternal and child health care**.

Amendment

4. **Paragraph 3 shall not prevent** the dissemination of any useful information or recommendations exclusively **intended for** persons having qualifications in medicine, nutrition **and** pharmacy.

Justification

The new paragraph reflects the existing rules of Article 8 of Directive 2009/39/EC. 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 the products that manufacturers can provide useful information, in addition to the labelling, in order to inform Healthcare Professionals of the composition and safe and appropriate use of the products.

Amendment 204

Kartika Tamara Liotard

Proposal for a regulation

Article 9 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. A food business operator placing on the market foods referred in Article 1(1) shall notify the competent authority of the Member State on which territory such foods are placed.

Or. en

Amendment 205

Julie Girling

Proposal for a regulation

Article 9 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. To permit efficient official monitoring, a food business operator placing the foods referred in the Article 1(1) on the market shall notify the competent authority of the Member State of the placing of such foods on the market by forwarding it a model of the label used for the product.

Justification

The competent authority of the Member State shall make the rules of notification publicly available.

Amendment 206
Esther de Lange

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

Text proposed by the Commission

Amendment

4a. The dissemination of any useful information or recommendations with reference to the category of food referred to in point (ca) of Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition or pharmacy.

Or. en

Amendment 207
Oreste Rossi

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 208

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 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC **and** Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Amendment

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC **and Regulation (EC) No 41/2009**, as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations **for foods covered by Article 1(1)** no later than [2 years after the date of the entry into force of this Regulation] in accordance with Article 15, with respect to the following:

Or. en

Justification

The current dietetic Framework Directive (2009/39/EC) offers essential guarantees to coeliacs. The procedure of notification (article 11 of the Directive 2009/39/EC) guarantees an effective control by the controlling bodies and therefore protection for consumers who are coeliac sufferers, who are damaged by even the smallest traces of gluten. It is therefore necessary to maintain for food for people intolerant to gluten the procedure of notification (point d of article 10, paragraph 2) that guarantees an effective control by the controlling bodies and therefore protection for consumers who are coeliac.

Amendment 209

Oreste Rossi

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Subject to the general requirements of Articles 7 and 9 and taking into account

Amendment

2. Subject to the general requirements of Articles 7 and 9 and taking into account

Directive 2006/141/EC, Directive 2006/125/EC **and** Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC **and Directive 96/8/EC** as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations **for foods covered by Article 1(1)**, no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Or. en

Amendment 210
Gilles Pargneaux

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

Text proposed by the Commission

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Amendment

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC, as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations **for foods referred to in Article 1(1)** no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Or. fr

Amendment 211
Tiziano Motti

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

Text proposed by the Commission

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC **and** Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than ~~2~~ years after the date of the entry into force of this Regulation~~,~~ in accordance with Article 15, with respect to the following:

Amendment

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC, as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations **for foods covered by Article 1(1)** no later than 2 years after the date of the entry into force of this Regulation in accordance with Article 15, with respect to the following:

Or. en

Amendment 212
Mairead McGuinness

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

Text proposed by the Commission

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC **and** Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than ~~2~~ years after the date of the entry into force of this Regulation~~,~~ in accordance with Article 15, with respect to the following:

Amendment

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC, as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations **for foods covered by Article 1(1)** no later than 2 years after the date of the entry into force of this Regulation in accordance with Article 15, with respect to the following:

Or. en

Amendment 213
Esther de Lange, Christa Klauß

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

Text proposed by the Commission

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

Amendment

(b) the specific requirements on the ***lowest possible maximum*** pesticides residues in such food;

Or. en

Amendment 214
Mairead McGuinness

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

Text proposed by the Commission

Amendment

(ba) the process for the placing on the market of food referred to in Article 1(1) resulting from scientific and technological innovations which do not comply with the rules as to composition laid down by the delegated regulations.

Or. en

Amendment 215
Kartika Tamara Liotard

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

Text proposed by the Commission

Amendment

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), ***including the authorisation of nutrition and health claims thereof;***

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1);

Or. en

Justification

Regulation (EC) No 1924/2006 deals with the authorisation of nutrition and health claims on foodstuffs.

Amendment 216
Frédérique Ries

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

Text proposed by the Commission

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims thereof;

Amendment

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims thereof, ***with the exception of infant formulae with their own rules regarding such claims;***

Or. fr

Justification

Technical amendment to replace the rapporteur's original Amendment 46. It highlights the importance of retaining the single, specific provisions contained in Annex IV of Directive 2006/141/EC on infant formulae.

Amendment 217
Renate Sommer

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

Text proposed by the Commission

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), ***including the authorisation of nutrition and health claims thereof;***

Amendment

(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1); ***special rules already in force for food referred to in Article 1(1) will be transferred;***

Or. de

Amendment 218
Mairead McGuinness

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

Text proposed by the Commission

Amendment

(ca) the requirements for information to be provided on recommendations for appropriate use of the foods referred to in Article 1(1).

Or. en

Amendment 219
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

(ca) due to the additional specific requirements for mandatory information to be provided on labels of certain foods referred to in Article 1(1) of this Regulation, derogations from the minimum font size and from other legibility requirements set out in Article 13(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 relating to the provision of food information to consumers¹;

¹ OJ L 304, 22.11.2011, p. 18.

Or. fr

Amendment 220
Oreste Rossi

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

Text proposed by the Commission

Amendment

(ea) the process for the placing on the market of food referred to in Article 1(1) resulting from scientific and technological innovations which do not comply with the rules as to composition laid down by the delegated regulations;

Or. en

Amendment 221
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

(ea) the process for the placing on the market of food referred to in Article 1(1) resulting from scientific and technological innovations which do not comply with the rules on composition established by the delegated Regulations;

Or. fr

Amendment 222
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

(fa) the requirements for information to be provided on recommendations for

*appropriate use of foods referred to in
Article 1(1);*

Or. fr

Amendment 223

Oreste Rossi

Proposal for a regulation

Article 10 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

*(fa) the requirements for information to
be provided on recommendations for
appropriate use of the foods referred to in
Article 1(1).*

Or. en

Amendment 224

Kartika Tamara Liotard

Proposal for a regulation

Article 10 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

*(fa) the need to include, inter alia, follow-
on formula and growing-up milk as a
category of food in this Regulation,*

Or. en

Justification

The Commission should, after having studied the scientific opinion of the Authority, review whether follow-on formula and growing-up milk still need to be considered as food with a specific nutritional purpose and therefore fall under this Regulation, or whether it should be considered as normal food.

Amendment 225

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(fa) a requirement for post-market monitoring in order to ensure that the specific legislative requirements e.g. regarding pesticides, contaminants, labelling and advertising are met.

Or. en

Justification

A FVO-evaluation report on infant and baby foods from 2010 (DG(SANCO)/2010-8768) revealed that the "general official controls of the specified foods were inadequate to ensure that the relevant specific legislative requirements regarding pesticides, contaminants and labelling were complied with." In order to improve this situation, a regular post-market monitoring is useful.

Amendment 226

Oreste Rossi

Proposal for a regulation

Article 10 – paragraph 2 – subparagraph 1a (new)

Text proposed by the Commission

Amendment

Due to the additional specific requirements on mandatory information to be provided on labels of certain foods referred to in Article 1(1) of this Regulation, the Commission may, if appropriate, establish by means of the delegated regulations referred to in paragraph 2, derogations from the minimum font size and other legibility requirements established in Article 13(2) of Regulation (EU) No 1169/2011;

Amendment 227
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

2a. without prejudice to the criteria for certain contaminants levels laid down in Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs¹, the microbiological criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs² shall apply to milk-based drinks intended for young children on the market during the transition period laid down in Article 18;

¹ OJ L 364, 20.12.2006, p. 5.

² OJ L 288, 19.10.2006, p. 43.

Or. fr

Justification

Afin de garantir une utilisation sûre, les aliments relevant du champ d'application du présent règlement doivent fournir d'importantes informations additionnelles à celles requises par les dispositions en matière d'étiquetage de l'alimentation générale. Les dispositions spécifiques en matière d'étiquetage applicables à ces groupes de produits seront revues et remaniées sous la forme d'actes délégués. Il convient, à ce stade, d'examiner les besoins d'information spécifiques au consommateur et les exigences de lisibilité applicables à ces produits, lesquels peuvent nécessiter une dérogation à la taille de la police minimale et à certains autres critères de lisibilité prévus pour l'alimentation générale. Les actes délégués prévus dans le règlement proposé établiront des dispositions en matière de composition spécifiques aux catégories d'aliments couverts par le présent règlement. Il est crucial que les produits sûrs et validés relevant du champ d'application du présent règlement, issus d'innovations technologiques et scientifiques, puissent être mis sur le marché de manière opportune. Ceci s'inscrit dans le droit fil de l'objectif du présent règlement de tenir compte des progrès

techniques et scientifiques, et reflète l'article 4, paragraphe 2, de la directive-cadre 2009/39/CE qui vise à encourager l'innovation et à introduire de nouveaux développements scientifiques opportuns pour les consommateurs et les patients. Étant donné que les produits actuellement sur le marché, y compris les boissons à base de lait destinées aux enfants en bas âge, remplissent les critères relatifs à la sécurité alimentaire définis pour les enfants en bas âge, ces dispositions devraient être maintenues jusqu'à la présentation de l'avis de l'EFSA afin de continuer à garantir un degré élevé de sécurité, approprié pour ce groupe de consommateurs vulnérables.

Amendment 228

Daciana Octavia Sârbu, Glenis Willmott, Christel Schaldemose

Proposal for a regulation

Article 10 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. No later than 2 years after the entry into force of this regulation, the European Food Safety Authority shall publish a report on milk-based drinks intended for young children in which it shall assess whether such milks have any added nutritional benefits over cow's milk as part of a diet in which complementary feeding has been introduced. The Commission may, on the basis of this report from the European Food Safety Authority, make any legislative proposals which may be necessary.

Or. en

Justification

There is no proof that milks intended for young children have any extra benefits over cows' milk as children no longer rely on milk as their only source of nutrients and can obtain their nutritional requirements from a varied diet. EFSA should assess whether these milks provide any additional nutritional benefits, in order to inform future policy decisions.

Amendment 229

Paolo Bartolozzi, Elisabetta Gardini

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

Text proposed by the Commission

Amendment

2a. Without prejudice to the criteria for certain contaminants levels laid down in Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, the microbiological criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs shall apply to milk-based drinks intended for young children currently on the market during the transition period laid down in Article 18 of this Regulation.

Or. en

Justification

The delegated acts that are foreseen within the proposed regulation will set down compositional provisions specific to the categories of foods covered by this Regulation. It is crucial that safe and validated products falling under the scope of this Regulation, developed as a result of scientific and technological progress, can be placed on the market in a timely manner.

Amendment 230
Paolo Bartolozzi, Elisabetta Gardini

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

Text proposed by the Commission

Amendment

2b. By the end of the transition period set out in Article 18(1), the Commission shall, after consulting the European Food Safety Authority, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition and labelling of milk-based drinks intended for young

children with regard to the nutritional needs, the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of young children taking into account the different legislation that governs normal foods and foods intended for infants and young children. In the light of the conclusions of that report, the Commission shall either:

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

(b) present, in accordance with the procedure laid down in Article 114 TFEU, appropriate proposals for amendments to this Regulation, and amend the relevant delegated acts to include the special provisions concerned, in accordance with Article 15.

Or. en

Justification

To continue to provide a high level of protection for a group of particularly vulnerable consumers it would therefore be useful to have EFSA's scientific opinion on the desirability to include specific compositional and labelling requirements for these products in the Commission's delegated acts.

Amendment 231
Frédérique Ries

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

Text proposed by the Commission

Amendment

2a. There are specific compositional and labelling requirements for foodstuffs intended for people intolerant to gluten referred to in Article 1(1)ca.

The foodstuffs referred to in the first

subparagraph, consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten, shall not contain a level of gluten exceeding 100 mg/kg in the food as sold to the final consumer.

Foodstuffs sold to the final consumer which contain a level of gluten not exceeding 100 mg/kg may be labelled 'very low gluten content'.

Foodstuffs sold to the final consumer which contain a level of gluten not exceeding 20 mg/kg may be labelled 'gluten free'.

Foodstuffs referred to in this paragraph shall also comply with the following criteria:

- they shall provide roughly the same amount of vitamins and mineral salts as the foodstuffs they are replacing,*
- they shall be prepared with special care, in compliance with good manufacturing practice (GMP), to avoid gluten contamination,*
- appropriate labelling is provided, indicating 'very low gluten content' or 'gluten free' close to the name under which the product is marketed.*

Or. fr

Justification

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

Amendment 232
Tiziano Motti

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

Text proposed by the Commission

Amendment

2a. By the end of the transition period set out in article 18 (1), the Commission shall, after consulting the European Food Safety Authority, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition and labelling of milk-based drinks intended for young children with regard to the nutritional needs, the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of young children taking into account the different legislation that governs normal foods and foods intended for infants and young children. In the light of the conclusions of that report, the Commission shall either:

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

(b) present, in accordance with the procedure laid down in Article 114 TFEU, appropriate proposals for amendments to this Regulation, and amend the relevant delegated acts to include the special provisions concerned, in accordance with Article 15.

Or. en

Amendment 233
Esther de Lange, Christa Kläß

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

Text proposed by the Commission

Amendment

2a. The use of pesticides in agricultural products intended for the production of food referred to in Article 1(1) shall be limited as far as possible, while respecting the provisions referred to in Commission Directive 2006/125/EC and Commission Directive 2006/141/EC.

Or. en

**Amendment 234
Mairead McGuinness**

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

Text proposed by the Commission

Amendment

2a. Due to the additional specific requirements on mandatory information to be provided on labels of certain foods referred to in Article 1(1) of this Regulation, the Commission may, if appropriate, establish by means of the delegated regulations referred to in paragraph 2, derogations from the minimum font size and other legibility requirements established in Article 13(2) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

Or. en

**Amendment 235
Mairead McGuinness**

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

Text proposed by the Commission

Amendment

2a. Without prejudice to the criteria for certain contaminant levels laid down in Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs, the microbiological criteria laid down in Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs shall apply to milk-based drinks intended for young children currently on the market during the transition period laid down in Article 18 of this Regulation.

Or. en

Amendment 236
Mairead McGuinness

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

Text proposed by the Commission

Amendment

2a. By the end of the transition period set out in Article 18(1), the Commission shall, after consulting the European Food Safety Authority, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition and labelling of milk-based drinks intended for young children in regard to the nutritional needs, the pattern of consumption, the nutritional intake, quality criteria required for young children taking into account the different legislation that governs normal foods and foods intended for infants and young children. In the light of the conclusions of that report, the Commission shall either:

(i) decide that there is no need for special provisions regarding the composition and

labelling of milk-based drinks intended for young children; or

(ii) present, in accordance with the procedure laid down in Article 114 TFEU, appropriate proposals for amendments to this Regulation, and amend the relevant delegated acts to include the special provisions concerned, in accordance with Article 15.

Or. en

Amendment 237
Gilles Pargneaux

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

Text proposed by the Commission

Amendment

2b. By the end of the transition period as defined in Article 18 (1), the Commission shall, after consulting the European Food Safety Authority, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition and labelling of milk-based drinks intended for young children in regard to the nutritional needs, the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of young children taking into account the different legislation that governs normal food and food intended for infants and young children. In the light of the conclusions of that report, the Commission shall either:

(a) decide that there is no need for special provisions regarding the composition and labelling of milk-based drinks intended for young children, or

(b) present, in accordance with the procedure laid down in Article 114 of the Treaty on the Functioning of the

European Union, appropriate proposals with a view to amending this regulation and amend the delegated acts concerned so as to include the relevant specific provisions, in accordance with Article 15.

Or. fr

Justification

Les boissons à base de lait destinées aux enfants en bas âge, également appelées laits de croissance, sont actuellement disponibles sur le marché européen selon les dispositions prévues par la directive-cadre 2009/39/CE. Toutefois, il n'existe pas à ce jour de consensus parmi les États membres de l'UE quant aux modalités de régulation de ces produits. Afin de continuer de garantir un niveau élevé de protection à un groupe de consommateurs particulièrement vulnérables, il serait dès lors utile de requérir l'avis scientifique de l'EFSA sur l'opportunité d'inclure des exigences spécifiques relatives à l'étiquetage et à la composition pour ces produits dans les actes délégués de la Commission.

Amendment 238
Julie Girling

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

Text proposed by the Commission

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

Amendment

Subject to the requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, ***which may be based on data provided by interested parties***, the Commission shall update the delegated Regulations mentioned in paragraph 2 in accordance with Article 15.

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 239

Françoise Grossetête, Christine De Veyrac

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

Milks intended for young children

Before the end of the transition period as defined in Article 18(1), the Commission shall, after consulting the European Food Safety Authority, submit to the European Parliament and the Council a report stating whether specific measures are needed on the composition and labelling of milk-based drinks for young children. together with, if necessary, a legislative proposal.

Or. fr

Justification

To continue to ensure a high level of protection for a particularly vulnerable consumer category, the EFSA should be asked for a scientific opinion on whether to include specific labelling and composition requirements for such milk products in the Commission's delegated acts.

Amendment 240

Daciana Octavia Sârbu, Glenis Willmott, Christel Schaldemose

Proposal for a regulation

Article 10 a (new)

Commission Directive 2006/141/EC

Article 14

Article 10 a

Article 14 of Commission Directive 2006/141/EC is amended as follows:

"Article 14

1. Advertising of infant formulae *and follow-on formulae* shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements for infant formulae *and follow-on formulae* shall be subject to the conditions laid down in Article 13(3) to (7) and Article 13(8)(b) and contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula *or follow-on formulae* directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formulae *and follow-on formulae* shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers."

Or. en

Justification

Current advertising restrictions which apply to infant formulae should be extended to follow-on formulae. There is widespread confusion between these products which manufacturers can

exploit in order to indirectly advertise infant formulae. This allows extensive promotion of milk formulae products. A restriction on advertising would help send the message that breast milk is the best option for infants whilst still allowing the necessary information on alternatives to be available through the appropriate channels.

Amendment 241
Julie Girling

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. Vitamins, minerals, amino acids and other substances ***belonging to the categories defined by the implementing acts adopted pursuant to Article 11(2)*** may be added to food referred to in Article 1(1), provided that such substances meet the following conditions:

Or. en

Justification

A simple reference to “other substances” as defined in Regulation (EC) 1925/2006 would result in legal uncertainty as to the scope of the Union list. Categories are introduced for the purpose of efficiency and legislative simplification.

Amendment 242
Mairead McGuinness

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

1. ***The nutritional*** substances ***belonging to the categories defined by implementing acts adopted pursuant to Article 11 (2)*** may be added to food referred to in Article 1(1), provided that such substances meet the following conditions:

Amendment 243
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 244
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 245
Carl Schlyter
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) they show an added benefit to the consumer.

Justification

It is appropriate to ask for an added benefit to the consumer for substances which will be allowed in the production of food referred to in Article 1(1).

Amendment 246
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 1 – point b b(new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 247
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 1 – point b c (new)

Text proposed by the Commission

Amendment

(bc) they do not pose an ethical concern, animal welfare concern or environmental concern;

Or. en

Amendment 248
Carl Schlyter
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission

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

Amendment

2. No later than [2 years after the date of the entry into force of this Regulation], the Commission shall establish and subsequently update a Union list of permitted substances that meet the conditions of paragraph 1, by means of **delegated acts**. The entry of a substance in the Union list shall include a specification of the substance, and, where appropriate, specify the conditions of use and the applicable purity criteria. Those **delegated acts** shall be adopted in accordance with the procedure referred to in **Article 15**. On duly justified grounds of extreme urgency relating to emerging health risks, the Commission shall adopt immediately applicable **delegated** acts updating the Union list in accordance with **Article 16**.

Or. en

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 conditions laid down in Article 11(1) are very open. Therefore it is appropriate to apply delegated acts.

Amendment 249
Julie Girling

Proposal for a regulation
Article 11 – paragraph 3

Text proposed by the Commission

3. The entry of a substance in the Union list referred to in paragraph 2 may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member

Amendment

3. The entry of a substance in the Union list referred to in paragraph 2 **or the extension of the Union list to a new category** may be initiated either on the initiative of the Commission or following

State or by an interested party, who may also represent several interested parties (hereinafter referred to as the applicant). Applications shall be sent to the Commission, in accordance with paragraph 4.

an application. Applications may be made by a Member State or by an interested party, who may also represent several interested parties (hereinafter referred to as the applicant). Applications shall be sent to the Commission, in accordance with paragraph 4.

Or. en

Amendment 250

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 11 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. For substances referred to in paragraph 1 that are engineered nanomaterials, the following additional conditions shall apply:

(a) the requirement of point (a) of paragraph 1 has been demonstrated on the basis of adequate and sufficient test methods; and

(b) their nutritional value and the suitability for the persons to whom it is intended has been shown.

Or. en

Justification

Nanomaterials can only be assessed by specific test-methods. It should therefore only be possible to include substances in the list which have been proven as safe, on the basis of adequate test methods. As the Regulation covers food for the most vulnerable parts of the population, it is appropriate to ask for a demonstration of suitability for such persons.

Amendment 251

Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 4 – point e

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 252
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 4 – point g

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 253
Kartika Tamara Liotard

Proposal for a regulation
Article 11 – paragraph 5

Text proposed by the Commission

5. When a substance is already included in the Union list and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods shall be considered as different substance and the

Amendment

5. When a substance is already included in the Union list and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods shall be considered as different substance and

Union list shall be ***modified accordingly before it can be placed on the Union market.***

removed from the Union list ***and the substance shall be considered as a substance requiring an application as a novel food under Regulation (EC) No 258/97.***

Or. en

Justification

This Regulation must not become a legal loophole for avoiding the appropriate application procedure for substances as a novel food under Regulation (EC) No 258/97.

Amendment 254

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 11 – paragraph 5

Text proposed by the Commission

5. When a substance is already included in the Union list and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods shall be considered as different substance ***and the Union list shall be modified accordingly before it can be placed on the Union market.***

Amendment

5. When a substance is already included in the Union list and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods ***or with a change in particle size shall be considered as different substance which is not included in the list and which shall require a separate application.***

Or. en

Justification

Clarification of the Commission proposal.

Amendment 255

Julie Girling

Proposal for a regulation
Article 11 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The Commission in cooperation with the Authority, shall provide appropriate technical guidance to assist food business operators, in particular SMEs, in the preparation and presentation of the application for scientific assessment.

Or. en

Justification

Experience on other pieces of food legislation has shown that specific guidance is often needed for such applications.

Amendment 256

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation
Article 11 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The presence of substances included in the Union list shall not be used to advertise the benefits of a product.

Or. en

Justification

Adding vitamins, minerals or other substances to food must not make people believe it could replace a healthy and balanced diet.

Amendment 257

Julie Girling

Proposal for a regulation
Article 11 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5b. The application shall be submitted to the Commission. The Commission shall acknowledge receipt in writing within 14 days of its receipt.

Or. en

Justification

Receipt of applications to the Commission should be communicated to applicants.

Amendment 258
Kartika Tamara Liotard

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

Text proposed by the Commission

Amendment

(va) any scientific data gathered from animal testing for the assessment of the safety of the substance.

Or. en

Amendment 259
Carl Schlyter
on behalf of the Verts/ALE Group

Proposal for a regulation
Chapter 5 – title

Text proposed by the Commission

Amendment

CONFIDENTIALITY

TRANSPARENCY

Or. en

Justification

Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents stipulates the right to access to documents. Exceptions to this general rule are also laid down in the Regulation. It is therefore appropriate to reverse the logic of the Commission proposal and grant transparency as a general rule, and ask for confidentiality in exceptional cases only.

Amendment 260

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – title

Text proposed by the Commission

Amendment

General **confidentiality** clause

General **transparency** clause

Or. en

Justification

Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents stipulates the right to access to documents. Exceptions to this general rule are also laid down in the Regulation. It is therefore appropriate to reverse the logic of the Commission proposal and grant transparency as a general rule, and ask for confidentiality in exceptional cases only.

Amendment 261

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13

Text proposed by the Commission

Amendment

The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure **appropriate confidentiality of** the information received by them under this Regulation, **except for**

The Commission, the Authority and the Member States shall, in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure **transparency regarding** the information received by them under this Regulation, **e.g.** in order to

information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

protect human health, animal health or the environment. ***Measures to ensure confidentiality of the information received can be taken in the exceptional cases laid down in Regulation (EC) No 1049/2001.***

Or. en

Justification

Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents stipulates the right to access to documents. Exceptions to this general rule are also laid down in the Regulation. It is therefore appropriate to reverse the logic of the Commission proposal and grant transparency as a general rule, and ask for confidentiality in exceptional cases only.

Amendment 262
Kartika Tamara Liotard

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in **Articles 2(3) and 10** of this Regulation shall be conferred for an indeterminate period of time from the (*) [(*) Date of entry into force of the basic legislative act or from any other date set by the legislator.]

Amendment

2. The delegation of power referred to in **Article 10** of this Regulation shall be conferred for an indeterminate period of time from the (*) [(*) Date of entry into force of the basic legislative act or from any other date set by the legislator.]

Or. en

Amendment 263
Carl Schlyter
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The delegation of power referred to in **Articles 2(3) and 10** of this Regulation shall be conferred for an indeterminate period of time from the (*) [(*) Date of entry into force of the basic legislative act or from any other date set by the legislator.]

Amendment

2. The delegation of power referred to in **Articles 10 and 11** of this Regulation shall be conferred for an indeterminate period of time from the (*) [(*) Date of entry into force of the basic legislative act or from any other date set by the legislator.]

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 requirements laid down in Article 11(1) are very open. Therefore delegated acts should be applied.

Amendment 264
Kartika Tamara Liotard

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission

3. The delegation of powers referred to in **Articles 2(3) and 10** of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of powers referred to in **Article 10** of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. en

Amendment 265

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 3

Text proposed by the Commission

3. The delegation of powers referred to in *Articles 2(3)* and *10* of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment

3. The delegation of powers referred to in *Articles 10* and *11* of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Or. 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 requirements laid down in Article 11(1) are very open. Therefore delegated acts should be applied.

Amendment 266

Kartika Tamara Liotard

Proposal for a regulation

Article 15 – paragraph 5

Text proposed by the Commission

5. A delegated act adopted pursuant to *Articles 2(3)* and *10* of this Regulation shall enter into force only if no objection

Amendment

5. A delegated act adopted pursuant to *Article 10* of this Regulation shall enter into force only if no objection has been

has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Or. en

Amendment 267

Carl Schlyter

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 5

Text proposed by the Commission

5. A delegated act adopted pursuant to **Articles 2(3)** and **10** of this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

Amendment

5. A delegated act adopted pursuant to **Articles 10** and **11** of this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.

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 requirements laid down in Article 11(1) are very open.

Therefore delegated acts should be applied.

Amendment 268

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 17 – paragraph 2**

Text proposed by the Commission

Amendment

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

Or. en

Justification

Regulation (EC) 41/2009 should not be repealed. This Regulation establishes rules about the composition and labelling of foodstuffs for particular nutritional uses which are specially produced, prepared and/or processed to meet the special dietary needs of people intolerant to gluten and of foodstuffs for normal consumption suitable for people intolerant to gluten.

**Amendment 269
Oreste Rossi**

**Proposal for a regulation
Article 17 – paragraph 2**

Text proposed by the Commission

Amendment

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

Or. en

Amendment 270
Anja Weisgerber, Renate Sommer

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. de

Amendment 271
Esther de Lange

Proposal for a regulation
Article 17 a (new)

Text proposed by the Commission

Amendment

Article 17 a

At the latest one year before the repeal of Directive 2009/39/EC the Commission shall present a report, and if necessary legislative proposals, to clarify the status of so-called 'growing-up milks' (GUMs) under general food legislation.

Or. en

Amendment 272
Esther de Lange

Proposal for a regulation
Article 17 b (new)
Commission Directive 96/8/EC
Article 1 – paragraph 2

Text proposed by the Commission

Amendment

Article 17 b

Article 1(2) of Directive 96/8/EC is replaced by:

" foods intended for very low calorie diets (VLCD) are specifically formulated foods which, when used as instructed by the manufacturer, replace [...] the total daily diet and contain between 400 and 800 kcal per day."

Or. en

Amendment 273
Esther de Lange

Proposal for a regulation
Article 17 c (new)
Commission Directive 96/8/EC
Article 4

Text proposed by the Commission

Amendment

Article 17 c

Article 4 of Directive 96/8/EC is replaced by:

"All individual components making up the products referred to [...] Article 1(2), as sold, shall be contained in the same package."

Or. en

Amendment 274
Esther de Lange

Proposal for a regulation
Article 17 d (new)

Commission Directive 96/8/EC
Article 5 – paragraph 1

Text proposed by the Commission

Amendment

Article 17 d

Article 5(1) of Directive 96/8/EC is replaced by:

"1. The name under which the product is sold shall be: 'Total diet replacement for use in very low calorie diets'."

Or. en

Amendment 275
Esther de Lange

Proposal for a regulation

Article 17 e (new)

Commission Directive 96/8/EC
Article 5 – paragraph 2

Text proposed by the Commission

Amendment

Article 17 e

Article 5(2) of Directive 96/8/EC is replaced by:

"2. The labelling of the products concerned shall bear, in addition to those provided for in Article 3 of Council Directive 79/112/EEC, the following mandatory particulars:

- (a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;**
- (b) the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of Annex 1, expressed in numerical form, per specified quantity**

of the product ready for use as proposed for consumption. [...]

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

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

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

[...]

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

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

[...]

Or. en

Amendment 276
Oreste Rossi

Proposal for a regulation
Article 18

Text proposed by the Commission

Food not complying with this Regulation but complying with Directives 2009/39/EC and 96/8/EC, Regulations (EC) No 41/2009 and (EC) No 953/2009, and labelled prior to [2 years after the date of the *entry into force* of this Regulation] may continue to be marketed after that date until stocks are exhausted.

Amendment

Food not complying with this Regulation but complying with Directives 2009/39/EC and 96/8/EC, Regulations (EC) No 41/2009 and (EC) No 953/2009, and labelled prior to [2 years after the date of the *application* of this Regulation] may continue to be marketed after that date until stocks are exhausted.

Or. en

Amendment 277

Oreste Rossi

Proposal for a regulation

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Regulation (EC) No 1169/2011 shall apply to food referred to in Article 1(1) 3 years after the date of the entry into force of the delegated regulations referred to in Article 10(2) of this Regulation.

Or. en

Amendment 278

Sophie Auconie

Proposal for a regulation

Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. No later than ...*, the Commission shall submit to the European Parliament and the Council a report – accompanied, where appropriate, by a legislative proposal – on the need to control the marketing of low-calorie diets.

**** OJ: please insert date: three years after the entry into force of this Regulation.***

Or. fr

Amendment 279

Kartika Tamara Liotard

Proposal for a regulation
Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18 a

Follow-on formula and growing-up milk

The Commission shall no later than [Two years after the entry into force of this Regulation], after having reviewed the scientific opinion of the Authority on this matter, present a report to the European Parliament and Council, where appropriate followed by a legislative proposal, on the benefits of follow-on formula and growing-up milk and whether or not follow-on formula and growing-up milk should continue to be considered as a food for a specific nutritional purpose and consequently whether or not follow-on formula and growing-up milk fall under the scope of this Regulation.

Or. en

Justification

The Commission should, after having studied the scientific opinion of the Authority, review whether follow-on formula and growing-up milk still need to be considered as food with a specific nutritional purpose and therefore fall under this Regulation, or whether it should be considered as normal food.

Amendment 280
Julie Girling

Proposal for a regulation
Article 18 a (new)
Regulation (EU) No 1169/2011
Article 36 – paragraph 3 – point (a a) (new)

Text proposed by the Commission

Amendment

Article 18a

*Amendment of Regulation (EU) No
1169/2011*

*In Article 36(3) of Regulation (EU) No
1169/2011, the following point is inserted:*

*"(aa) information on the possible absence
or reduced presence in foods of
substances that can cause intolerance,
such as gluten and lactose;"*

Or. en

Justification

*The statements 'gluten/lactose free' and 'very low gluten' should be considered under the
Regulation on Food information for consumers, which already provides for the adoption of
specific rules to indicate the presence of substances that cause allergy or intolerance.*

Amendment 281
Françoise Grossetête

Proposal for a regulation

Article 18 a (new)

Regulation (EU) n° 1169/2011

Article 36 – paragraph 3 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

Article 18a

*Amendment to Regulation (EU)
No 1169/2011*

*In Article 36(3), first subparagraph of
Regulation (EC) No 1169/2011, the
following point shall be added:*

*'(ca) the absence or reduced presence in
foods of substances that can cause
intolerance, such as gluten.'*

Or. fr

Justification

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

Amendment 282

Françoise Grossetête, Christine De Veyrac, Esther de Lange

Proposal for a regulation

Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18a

Food intended to meet the expenditure of intense muscular effort

No later than 1 July 2015, the Commission shall submit a report to the European Parliament and the Council to assess the need to harmonise the rules on the composition and labelling of food intended to meet the expenditure of intense muscular effort. The Commission may accompany this report with proposals to modify the relevant Union provisions.

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.