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Committee on Industry, Research and Energy

2011/0156(COD)

10.2.2012

OPINION

of the Committee on Industry, Research and Energy

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

on the proposal for a regulation of the European Parliament and of the Council
on food intended for infants and young children and food for special medical
purposes
(COM(2011)0353 – C7-0169/2011 – 2011/0156(COD))

Rapporteur: Hannu Takkula

PA_Legam

SHORT JUSTIFICATION

The issue of food intended for those with particular nutritional needs (hereinafter 'Parnuts food') has been a focus area within the European Union's legislation, reflecting a clear market demand for a secure and healthy food supply. Once a niche market, the Parnuts food sector has grown significantly over the recent years, causing a lack of clarity when trying to distinguish between general foods and foods intended for specific groups of people. These developments are taken into account in the proposed legislative framework and therefore the draftsman strongly favours the objectives of this proposal.

General remarks

Despite some previous attempts at harmonisation, vast differences still exist between national laws relating to Parnuts food. These differences place obstacles in the way of the free movement of goods, create unnecessary regulatory burdens for companies operating within the food business sector and ultimately hinder the functioning of the internal market.

The draftsman believes that similar products must be treated the same way across the European Union, ensuring appropriate consumer information and allowing free movement and equal conditions of competition for goods. Rules which have become unnecessary, contradictory and potentially conflicting must be abolished, and the protection of the most vulnerable groups of the population and those with special nutritional needs must be guaranteed. A common legal system for Parnuts foods, as proposed by the Commission, must therefore be welcomed as a major step towards improved safety and clarity for consumers as well as producers.

The draftsman believes that it is of critical importance that all foods intended for infants and young children, as well as foods for special medical purposes be covered by a thorough and standardised prior authorisation process. In order to ensure safety and efficacy, this shall be undertaken by an independent body on the basis of up-to-date scientific information (and research).

This proposal concentrates the notification responsibilities and authorisation procedures of Parnuts foods onto the European Commission, which will remove several existing market barriers. In this context, the draftsman welcomes the introduction of the "Union list of permitted substances" (Article 11), which combines the currently existing (three separate) lists into a single one, thus creating greater clarity in this particular area. In order to guarantee a smooth transition process, the draftsman calls upon the Commission for a timely establishment and regular updating of this list, as well as for a streamlined process for entries to this list (as mentioned in Article 11(3)).

Several amendments tabled in the ITRE Committee highlighted the need to include in the text of the draft Regulation additional product groups, namely milk based drinks intended for young children and food for persons intolerant to gluten. The draftsman believes that the issue of the inclusion of other foods for special nutritional purposes should be carefully analysed within the ENVI Committee in the framework for the public health issues.

Research and innovation aspects

The draftsman believes that improved EU legislation in the field of special foods must be complemented by investments in research and innovation, as these will also lead to the development of new and enhanced practices, products and processes. In this context, the draftsman also draws attention to the fact that the health and safety aspects of foods are included in the Food Security chapter of the Union's Horizon 2020 Research and Innovation Programme and further efforts of interconnected research and innovation activities in the Parnuts food sector must also be strongly supported.

The legal modifications suggested in the Commission's proposal, such as the exclusion of diabetic food, low-gluten food and sports food, as well as the introduction of the Union's list, should not, in any case, hinder innovation. However, as our scientific knowledge in the Parnuts food sector continues to improve, flexible procedures must be maintained to foster further research and innovation in these areas.

Small and Medium-sized enterprises (SMEs)

The draftsman wishes to ensure that any changes to the legislative management of foods currently covered by the Parnuts food framework directive do not have a disproportional effect on SMEs, nor shall they diminish transparency and/or place unnecessary burdens on food business operators. Current data indicates that the Parnuts food sector is dominated by SMEs, and it has shown substantial growth over the past years. The draftsman is concerned with the existing large variation in the legislative burden between the Member States and believes that streamlined regulation combined with simplification measures will be advantageous for the entire market segment.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation

Recital 2

Text proposed by the Commission

(2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

Amendment

(2) In order to guarantee the health and well-being of citizens, the safety of food products represents an essential requirement to their free circulation in the internal market, which, in turn, benefits European competitiveness by allowing a larger home market for

companies.

Amendment 2

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) This Regulation aims at ensuring the safety of food products placed on the market and addressed to vulnerable groups of the population such as infants, young children and people affected by particular illnesses. To ensure that the health of these people receives a high level of protection it is vital that a certain number of potentially dangerous substances or substances recognised as dangerous are not included in the composition of these products or in the composition of their container.

Amendment 3

Proposal for a regulation

Recital 7

Text proposed by the Commission

Amendment

(7) Directive 2009/39/EC foresees that specific provisions could be adopted regarding the two following specific categories of food falling within the definition of foodstuffs for particular nutritional uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. With regard to food intended to meet the expenditure of intense muscular effort, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among Member States and stakeholders

(7) Directive 2009/39/EC foresees that specific provisions could be adopted regarding the two following specific categories of food falling within the definition of foodstuffs for particular nutritional uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. With regard to food intended to meet the expenditure of intense muscular effort, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among Member States and stakeholders

concerning the scope of the specific legislation, the number of sub-categories of the food to be included, the criteria for establishing composition requirements and the potential impact on innovation in product development. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report concludes that the scientific basis for setting specific compositional requirements is lacking.

concerning the scope of the specific legislation, the number of sub-categories of the food to be included, the criteria for establishing composition requirements and the potential impact on innovation in product development. ***With a view to the proper functioning of the internal market this category of food should be governed by Regulation (EC) No 1924/2006 and should meet the requirements laid down in that Regulation.*** As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report concludes that the scientific basis for setting specific compositional requirements is lacking.

Justification

An appropriate regulatory framework for food for sportsmen enhances legal certainty and avoids there being a large number of national laws, which may disrupt the proper functioning of the internal market.

Amendment 4

Proposal for a regulation

Recital 15

Text proposed by the Commission

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. Those categories of food include infant formulae and follow-on formulae, processed cereal-based food and baby food **and** food for special medical purposes. Experience has shown that the provisions laid down in *Commission Directive 2006/141/EC*, *Commission Directive 2006/125/EC*, **as well as**

Amendment

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. Those categories of food include infant formulae and follow-on formulae, processed cereal-based food and baby food, ***milk-based drinks intended for young children***, food for special medical purposes. Experience has shown that the provisions laid down in *Directive 2006/141/EC*, *Directive 2006/125/EC*,

*Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children **and to** food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC **and** Commission Directive 1999/21/EC.*

*Directive 1999/21/EC, **Regulation (EC) No 41/2009, as well as Directive 96/8/EC** ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children, **milk-based drinks intended for young children**, food for special medical purposes, taking into account Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC, **Directive 96/8/EC and Regulation (EC) No 41/2009. In addition, the concept of ‘specialised nutrition’ should be maintained and strictly limited to products that demonstrate their unique ability to fulfil the specific nutritional needs of vulnerable groups of the population, which otherwise could not be placed on the market using current Union acts.***

Justification

It is necessary to re-introduce the concept of food intended for specialised nutrition. This inclusion will establish criteria to protect young children with respect to nutritional and food safety requirements specific to the age group, for example limits for the addition of nutrients, microbiological hazards and contaminants. Failure to include these products will result in these products being regulated as general foods and subject to the nutritional and purity criteria laid down for the adult population which are not always appropriate for children aged 12-36 months.

Amendment 5

Proposal for a regulation Recital 17

Text proposed by the Commission

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom

Amendment

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom

they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic **and independent** review of the available scientific data.

Justification

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

Amendment 6

Proposal for a regulation Recital 17 a (new)

Text proposed by the Commission

Amendment

(17a) To update the list of banned substances, the Authority and the national authorities competent in the matter are to perform a regular assessment on the basis notably of new data and scientific and statutory developments in the Member States or internationally.

Amendment 7

Proposal for a regulation Recital 19

Text proposed by the Commission

Amendment

(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes, taking into account *Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC*. In order to adapt the definitions of infant formula, follow-on

(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, ***milk-based drinks intended for young children*** and food for special medical purposes, taking into account *Directive 2006/141/EC, Directive 2006/125/EC, Directive 1999/21/EC, Directive 96/8/EC and Regulation (EC)*

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

No 41/2009. In order to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, ***milk-based drinks intended for young children***, and food for special medical purposes laid down in this Regulation taking into account technical and scientific progress and relevant developments at international level, to lay down the specific compositional and information requirements ***and the process for placing on the market of food resulting from scientific and technological innovations*** with respect to the categories of food covered by this Regulation, including for additional labelling requirements to, or derogations from, the provisions of Directive 2000/13/EC and for the authorisation of nutrition and health claims, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council. ***A clear and time-efficient procedure with due regard for consumer health protection should also be ensured to enable the foodstuff resulting from scientific and technological innovations to be placed on the market rapidly.***

Justification

It is necessary to re-introduce the concept of food intended for specialised nutrition. This would ensure that the strictest safety specifications with regard to nutrition, microbiological hazards, pesticides and contaminants, colourings and sweetening agents govern these products. Failure to include these products within the scope will result in these products being regulated as general foods and subject to the nutritional and purity criteria laid down for the adult population which are not appropriate for children aged 12-36 months.

Amendment 8

Proposal for a regulation Recital 26

Text proposed by the Commission

(26) Currently, the statements 'gluten-free' and 'very low gluten' may be used for food ***intended for particular nutritional uses and for food for normal consumption*** under the rules specified in Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. ***Such statements could be construed as nutrition claims, as defined in Regulation (EC) No 1924/2006. For the sake of simplification, those statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the nutrition claims 'gluten-free' and 'very low gluten' and their associated conditions of use as regulated under Regulation (EC) No 41/2009 be completed prior to the entry into application of this Regulation.***

Amendment

(26) Currently, the statements 'gluten-free' and 'very low gluten' may be used for food ***for specialised nutrition intended for people intolerant to gluten*** under the rules specified in ***Article 3 of Regulation (EC) No 41/2009 . Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers¹ provides for the adoption by the Commission of implementing acts regulating voluntary information on the possible and unintentional presence in food of a substance causing allergies or intolerances. For reasons of coherence and simplification of the legal framework, implementing powers should be conferred on the Commission under Regulation (EU) No 1169/2011 to adopt implementing acts regulating voluntary information on the absence or reduced presence in food of substances causing intolerances, such as gluten and lactose, repealing Regulation (EC) No 41/2009. It is necessary that Regulation (EU) No 1169/2011 is amended to that effect and that the required implementing provisions be adopted by the Commission prior to the entry into application of this Regulation. The implementing act concerned should maintain on the foods in question the statements 'gluten-free' and 'very low gluten' and their associated conditions of use as specified in Article 4 of Regulation (EC) No 41/2009, which does not allow the use of the statement "very low gluten" for these foods, as well as an indication of the persons for whom the foods are***

intended, as currently regulated under Regulation (EC) No 41/2009, and hence provide for the same level of consumer protection. Such foodstuff for specialised nutrition intended for people intolerant to gluten should be maintained in this Regulation, as providing such safe food intended for people intolerant to gluten and informing coeliacs about the absence of gluten is vital to the management of the disease. This is in line with the international standard for food for special dietary use for persons intolerant to gluten (CODEX STAN 118-1979 revised in 2008)

¹ OJ L 304, 22.11.2011, p. 18.

Justification

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

Amendment 9

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

Amendment

(27a) In order to ensure a high level of consumer protection, adequate procedures for oversight, in respect of both hygiene and composition, both before and after foods are placed on the market, should be established at Member State level.

Amendment 10

Proposal for a regulation Recital 29

Text proposed by the Commission

Amendment

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

(29) *The Commission should take adequate measures to ensure legal certainty during the transition to the*

this Regulation.

implementation of this Regulation and provide the assistance and up-to-date information to the food business operators necessary to enable them to adapt to the requirements of this Regulation.

Justification

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

Amendment 11

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

Text proposed by the Commission

Amendment

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

Justification

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

Amendment 12

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

Text proposed by the Commission

Amendment

(29b) In order to facilitate market access

for operators – especially small and medium-sized enterprises – wishing to sell foods resulting from scientific and technological innovations, the Commission, in close cooperation with the relevant stakeholders, should adopt guidelines on the procedure for placing such foods on the market on a temporary basis.

Amendment 13

Proposal for a regulation

Article 2 – paragraph 2 – point g – point ii

Text proposed by the Commission

Amendment

(ii) milk intended for young children;

deleted

Justification

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

Amendment 14

Proposal for a regulation

Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6a

Oversight

The national competent authorities shall ensure that an adequate system of oversight is put in place to ensure that market operators comply with this Regulation and with the relevant health requirements.

Amendment 15

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 ***and independently evaluated*** scientific data ***and medical opinion***.

Justification

See justification for AM 1.

Amendment 16

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) must not be misleading ***and shall:***

(a) provide clear and adequate consumer information; and,

(b) be based on the advice of independent persons with qualifications in medicine, nutrition or pharmacy, taking into account the specific needs of the persons for whom the food is intended, using scientific data validated by the Authority.

Amendment 17

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

Text proposed by the Commission

Amendment

3a. 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 (2) is involved.

Justification

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. A clear distinction must be made between foods for labelling nutrition and foodstuffs for normal consumption. Only normal foodstuffs with approved nutrition or health claims should be able to communicate on their suitability for specific conditions.

Amendment 18

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. **Responsibility for disseminating** any useful information or recommendations with reference to the categories of food referred to in Article 1(1) **shall lie** exclusively **with** persons having qualifications in medicine, nutrition, pharmacy or other professionals responsible for maternal and child health care **and shall be based on scientific data that can be independently verified.**

Justification

Any information on these categories of food disseminated by passive means (e.g. via the internet) must be drawn up by qualified professionals and be based on verifiable scientific data.

Amendment 19

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, ***in particular the results of risk evaluations and the precautionary principle***, the Commission shall be empowered to adopt delegated Regulations ***for foods covered under Article 1(1)*** no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:

Amendment 20

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ba) the specific compositional limitations of the packaging of the food referred to in Article 1(1);

Justification

The Commission should be given the power to control or ban substances in the packaging of infant and children foods which might have an effect on a product before it is consumed, e.g. the use of BPA in the tin can lining of infant formula containers which could leak into the product.

Amendment 21

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(ca) the derogations from the minimum font size due to the additional specific requirements on mandatory information to be provided on labels of certain foods referred to in Article 1(1) and other legibility requirements, established in Article 13(2) of Regulation (EU) No 1169/2011;

Justification

The specific labelling provisions applying to these groups of products will be reviewed and recast in the form of delegated acts. It is appropriate at that point in time to consider the specific consumer information needs and legibility requirements applicable to these products, which may necessitate derogation from minimum font size and certain other legibility criteria set for general foods.

Amendment 22

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(da) the process for the placing on the market of foods 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;

Justification

Foods falling within the scope of this regulation are required to provide substantial additional information to that required by general food labelling provisions in order to ensure their safe use. The specific labelling provisions applying to these groups of products will be reviewed and recast in the form of delegated acts. It is appropriate at that point in time to consider the specific consumer information needs and legibility requirements applicable to these products, which may necessitate derogation from minimum font size and certain other legibility criteria set for general foods.

Amendment 23

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).

Justification

Foods falling within the scope of this regulation are required to provide substantial additional information to that required by general food labelling provisions in order to ensure their safe use.

Amendment 24

Proposal for a regulation

Article 10 – paragraph 3 – subparagraph 1

Text proposed by the Commission

Amendment

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

3. Subject to the requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, ***the results of new risk assessments and the precautionary principle***, the Commission shall update the delegated Regulations mentioned in paragraph 2 *of this Article* in accordance with Article 15.

Amendment 25

Proposal for a regulation

Article 10 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

In order to enable foodstuffs intended for particular nutritional uses and resulting from scientific and technological progress

to be placed on the market rapidly, the Commission may, after consulting the Authority, adopt delegated acts in accordance with Article 15 authorising for a two-year period the placing on the market of foodstuffs which do not comply with the rules as to composition laid down by this Regulation and by the delegated regulations for groups of foodstuffs referred to in Article 1(1).

Justification

The innovation clause provided for in Directive 2009/39 on foodstuffs intended for particular nutritional uses must be reinserted. This procedure, which is rarely used at present, should be facilitated to ensure that consumers can benefit as soon as possible from suitable products.

Amendment 26

Proposal for a regulation Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

Milk intended for young children

By the end of the transition period defined in Article 18(1), the Commission shall, after consulting the Authority, submit a report to the European Parliament and to the Council 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;

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

Justification

Milk Based Drinks Intended for Young Children are currently present on the European market as per the provisions laid down in Framework Directive 2009/39/EC. However, there is a lack of consensus across EU members states on how such products should be regulated. 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 27

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 **6 months** 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 28

Proposal for a regulation Article 15 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The power to *adopt delegated acts* referred to in Articles 2(3) and 10 shall be conferred *on the Commission* for a period of ***five years starting*** from the ***date of entry into force of this Regulation.*** ***The Commission shall submit a report on the delegation of power no later than six months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

Amendment 29

Proposal for a regulation Article 18 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Ia. 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 foodstuffs shall apply to milk-based drinks intended for young children currently on the market during the transition period laid down in paragraph 1.

¹ OJ L 364, 20.12.2006, p. 5.

² OJ L 338, 22.12.2005, p. 1.

Amendment 30

Proposal for a regulation Article 18 a (new)

Text proposed by the Commission

Amendment

Article 18a

Amendment to 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;”***

Justification

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

Amendment 31

Proposal for a regulation Article 18 b (new)

Text proposed by the Commission

Amendment

Article 18b

***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
assessing the need to harmonise 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 legislation.***

Justification

The Commission should submit a report on the need to harmonise provisions on the

composition and labelling of food intended to meet the expenditure of intense muscular effort, with due regard for requirements relating to consumer protection and the operation of the internal market.

PROCEDURE

Title	Food intended for infants and young children and food for special medical purposes
References	COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)
Committee responsible Date announced in plenary	ENVI 5.7.2011
Committee(s) asked for opinion(s) Date announced in plenary	ITRE 5.7.2011
Previous rapporteur(s)	Corinne Lepage
Discussed in committee	12.1.2012
Date adopted	6.2.2012
Result of final vote	+: 42 –: 11 0: 1
Members present for the final vote	Gabriele Albertini, Amelia Andersdotter, Josefa Andrés Barea, Jean-Pierre Audy, Ivo Belet, Maria Da Graça Carvalho, Giles Chichester, Pilar del Castillo Vera, Dimitrios Droutsas, Christian Ehler, Vicky Ford, Norbert Glante, Robert Goebbels, András Gyürk, Jacky Hélin, Kent Johansson, Romana Jordan, Krišjānis Kariņš, Béla Kovács, Philippe Lamberts, Marisa Matias, Judith A. Merkies, Jaroslav Paška, Vittorio Prodi, Herbert Reul, Michèle Rivasi, Jens Rohde, Paul Rübig, Amalia Sartori, Salvador Sedó i Alabart, Britta Thomsen, Patrizia Toia, Evžen Tošenovský, Ioannis A. Tsoukalas, Claude Turmes, Marita Ulvskog, Kathleen Van Brempt, Alejo Vidal-Quadras
Substitute(s) present for the final vote	Antonio Cancian, António Fernando Correia De Campos, Françoise Grossetête, Cristina Gutiérrez-Cortines, Jolanta Emilia Hibner, Yannick Jadot, Seán Kelly, Bernd Lange, Werner Langen, Marian-Jean Marinescu, Zofija Mazej Kukovič, Morten Messerschmidt, Vladko Todorov Panayotov, Mario Pirillo, Silvia-Adriana Țicău
Substitute(s) under Rule 187(2) present for the final vote	Michael Theurer