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Committee on the Internal Market and Consumer Protection

2011/0156(COD)

15.2.2012

OPINION

of the Committee on the Internal Market and Consumer Protection

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 on food for special
medical purposes
(COM(2011)0353 – C7-0169/2011 – 2011/0156(COD))

Rapporteur: Iliana Ivanova

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SHORT JUSTIFICATION

Objectives of the proposal

The Commission proposal revises the rules on foodstuffs intended for particular nutritional uses, as laid down in Framework Directive 2009/39/EC and its implementing acts. After more than thirty years of application, the substantive provisions of the Directive do no longer respond to the needs of consumers and to the latest developments in the market. Furthermore, discussions with Member States and stakeholders have revealed difficulties in implementing the Framework Directive, in particular with regards to more recent pieces of EU legislation, such as Regulation (EC) No 1924/2006 on nutrition and health claims on foods (Claims Regulation) and Regulation (EU) No 1169/2011 on food information for consumers.

The Commission proposes to revise the Framework Directive by abolishing the general rules on dietetic foods, but to maintain some of the rules for specific foods adopted under the Framework.

General comments

The Rapporteur for opinion welcomes the proposal of the Commission and supports the general approach, maintaining the vertical Directives for infant formula, baby food and medical food under a new Framework Regulation, which provide a high level of protection to a group of vulnerable consumers, and abandoning the concept of dietetic food, which may mislead consumers and has led to market fragmentation.

The Rapporteur anticipates that the proposed simplification of the existing legal framework will reduce the administrative burden on companies, especially SMEs, and will further stimulate free movement of these goods. She expects that the reform will foster innovation in this segment of the food sector, which is one of the most competitive in the European industry.

Gluten

The Commission proposes to consider food for celiac people as normal food and proposes to withdraw Regulation (EC) No 41/2009. Instead, the Commission proposal suggests regulating this specific type of foods under the Nutrition and Health Claims Regulation. The Rapporteur realizes the importance of the topic and considers it more appropriate to regulate this category of foods under the new Regulation on food information for consumers, while maintaining the existing conditions as regards composition and labelling of the products, and hence the same standard of health protection as today.

Milk intended for young children

The so-called "growing milks" target young children in the age group of one to three years old and constitute a growing market in many Member States. No specific substantive rules are laid down for these products, which are today sometimes, but not always, notified to national

authorities under Framework Directive 2009/39/EC as "foods for particular nutritional uses". The Rapporteur supports the Commission in its proposal to have these milks regulated solely under the Nutrition and Health Claims Regulation, but invites the Commission to examine the desirability of special provisions regarding the composition and labelling of such milks.

Foods for sportspeople

Currently, no specific rules exist on composition or labelling for foods for sportspeople. Today, these foods are considered as "dietetic foods". The Commission acknowledges that a specific directive might hinder innovation in the sector, and proposes to include this category of foods in the Nutrition and Health Claims Regulation. The Rapporteur fully supports Commission's approach, since it will definitely bring more legal clarity and reinforce consumers' awareness and protection.

Slimming foods and very low calorie diets (VLCDs)

The Rapporteur shares the Commission's view that Directive 96/8/EC on slimming foods should be repealed, and that the same substantive rules should be maintained under the Nutrition and Health Claims Regulation.

In view of the health risks they entail, the Rapporteur is concerned that there are currently no specific rules at EU level on the composition, labeling and use of so-called very low calorie diets ("VLCDs"), which correspond to total diet replacements under 800 kcal. VLCDs should be made available under medical supervision only and should be regulated under Commission Directive 1999/21/EC on dietary foods for special medical purposes.

Delegated acts

The Commission should be empowered to lay down, by means of delegated acts, rules concerning specific composition and information requirements for food intended for infants and young children and medical food. However, the Rapporteur disagrees that the Commission should be empowered to amend the definitions of 'infant formula', 'baby food', 'food for special medical purposes', etc., since these concern essential elements of the basic legislative act and should therefore remain within the realm of the legislator.

Innovation

Taking into account relevant technical and scientific progress, the Commission should be empowered to speedily update the delegated acts adopted pursuant to this Regulation. This should foster innovation in the sector concerned.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection 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) The **guarantee** of safe and wholesome food **products** is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, **particularly of vulnerable consumer groups, such as infants and young children**, and to **the** social and economic interests **of citizens**. **A better harmonization of rules will stimulate the free movement of goods and thus contribute to releasing the true potential of the internal market.**

Amendment 2

Proposal for a regulation

Recital 7

Text proposed by the Commission

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

Amendment

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

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

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. ***With a view to improving the functioning of the internal market and enhancing consumer protection, while stimulating innovation, 'foods for sportspeople' should henceforth be regulated under general food law, such as Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods¹, Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods², Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers³, and Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements⁴ and comply with requirements therein.*** 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.

¹ OJ L 404, 30.12.2006, p. 9.

² OJ L 404, 30.12.2006, p. 26.

³ OJ L 304, 22.11.2011, p. 18.

⁴ OJ L 183, 12.7.2002, p. 51.

Justification

'Foods for sports people' are currently considered "foods for particular nutritional purposes". However, no specific compositional or labelling requirements are laid down for them at EU level, and the notification system results in a high administrative burden and unequal market conditions in the EU. To foster innovation and to contribute to a well-functioning internal market, 'foods for sports people' should be regulated under Regulation (EC) No 1924/2006 and other acts of general food law. Once a nutrition or health claim is authorized by EFSA, it can be used by other companies (particularly SMEs).

Amendment 3

Proposal for a regulation

Recital 11 a (new)

Text proposed by the Commission

Amendment

(11a) Hence there is a need to remove differences in interpretation and to tackle difficulties for Member States and operators in combining the different pieces of food legislation, by simplifying the regulatory environment. This would ensure that similar products are treated in the same way across the Union and would create a more level playing field for all operators across the internal market, especially SMEs.

Amendment 4

Proposal for a regulation

Recital 15

Text proposed by the Commission

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

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. Those categories of food

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

include infant formulae and follow-on formulae, processed cereal-based food and baby food and food for special medical purposes. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health **and consumers' interests**. 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. ***In this context, as for all food, any substances that are liable to be harmful to the health of the categories concerned should be excluded from the composition of categories of foods covered by this Regulation.***

Amendment 5

Proposal for a regulation Recital 16

Text proposed by the Commission

(16) To ensure legal certainty, definitions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC should be transferred to this Regulation. ***However, the definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, and food for special medical purposes should be regularly adapted taking into account technical and***

Amendment

(16) To ensure legal certainty, definitions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC should be transferred to this Regulation.

scientific progress and relevant developments at international level, as appropriate.

Justification

See amendment 18.

Amendment 6

Proposal for a regulation

Recital 18

Text proposed by the Commission

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

Amendment

(18) General labelling requirements are laid down in **Regulation (EU) No 1169/2011**. Those general labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, the provisions of **Regulation (EU) No 1169/2011**, where necessary, in order to meet the specific objectives of this Regulation.

Justification

Since the adoption of the Commission's proposal for a Regulation on food intended for infants and young children and on food for special medical purposes, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the law of the Member States relating to labelling, presentation and advertising of foodstuffs has been replaced by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.

Amendment 7

Proposal for a regulation Recital 19

Text proposed by the Commission

(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC. In order ***to adapt the definitions of infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes laid down in this Regulation taking into account technical and scientific progress and relevant developments at international level***, to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, including for additional labelling requirements to, or derogations from, the provisions of ***Directive 2000/13/EC*** and for the authorisation of nutrition and health claims, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.

Amendment

(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, and food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC. In order to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, including for additional labelling requirements to, or derogations from, the provisions of ***Regulation (EU) No 1169/2011*** 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 ***to the*** Council.

Justification

Subsequent to Article 290 of the TFEU, "a legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain

non-essential elements of the legislative act". The adaptation of the definitions, however, concerns an essential element of the legislative act and should not be the subject of a delegation to the Commission. See also Amendment 18.

Amendment 8

Proposal for a regulation Recital 19 a (new)

Text proposed by the Commission

Amendment

(19a) Taking into account relevant technical and scientific progress, the Commission should be empowered to update the delegated acts adopted pursuant to this Regulation. This should foster innovation in the sector of food intended for infants and young children and food for special medical purposes, which must not occur at the expense of food safety.

Justification

The Rapporteur for opinion supports the Commission's proposal to introduce a more simplified innovation procedure, which allows for updating the relevant delegated acts in case technical or scientific progress is demonstrated by a market operator.

Amendment 9

Proposal for a regulation Recital 26

Text proposed by the Commission

Amendment

(26) Currently, the statements 'gluten-free' and 'very low gluten' may be used for food intended for particular nutritional uses and for food for normal consumption under the rules specified in Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. ***Such statements could be construed as nutrition claims, as defined in Regulation (EC) No 1924/2006. For the sake of***

(26) Currently, the statements 'gluten-free' and 'very low gluten' may be used for food intended for particular nutritional uses and for food for normal consumption under the rules specified in Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. ***Regulation (EU) No 1169/2011 provides for the adoption by the Commission of implementing acts regulating voluntary***

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.

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, the Commission should be granted a mandate under Regulation (EU) No 1169/2011 to also adopt implementing acts regulating voluntary information on the absence or reduced presence in food of substances causing intolerances, such as gluten and lactose, and to withdraw Regulation (EC) No 41/2009. It is necessary that Regulation (EU) No 1169/2011 is amended to that effect and that the required implementing acts be adopted by the Commission prior to the entry into application of this Regulation. The implementing act concerned should maintain the statements 'gluten-free' and 'very low gluten' on food and their associated conditions of use as currently regulated under Regulation (EC) No 41/2009, and hence provide for the same level of consumer protection.

Justification

The Commission proposes to consider food for celiac people as normal food, to withdraw Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten and to regulate the statements concerned under the Claims Regulation. The Rapporteur for opinion, however, prefers regulating the statements 'gluten-free' and 'very low gluten' 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 10

Proposal for a regulation Recital 27 a (new)

Text proposed by the Commission

Amendment

(27a) There are currently no specific rules at Union level harmonising the composition, labelling and use of 'milks intended for young children', i.e. milks

promoted as being particularly suited for children between one and three years old. Some of these milks are currently being notified by market players as 'foods for particular nutritional purposes' under Directive 2009/39/EC, whereas others are not. Moreover, while several of these milks are being marketed as 'growing milks', sound scientific evidence demonstrating the added health or nutritional value of these milks over normal milk is lacking. This situation causes obstacles to the functioning of the internal market and entails unequal levels of consumer protection across the Union. In order to remedy this situation, 'milks intended for young children' should be regulated under general food law, such as Regulation (EC) No 1924/2006, Regulation (EC) No 1925/2006, Regulation (EU) No 1169/2011 and Directive 2002/46/EC and comply with requirements therein. Furthermore, the Commission should, 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 milks intended for young children, and propose measures accordingly.

Amendment 11

Proposal for a regulation Recital 27 b (new)

Text proposed by the Commission

Amendment

(27b) There are currently no specific rules at Union level on the composition, labelling and use of so-called "Very Low Calorie Diets" (VLCDs), which correspond to total diet replacements under 800 kcal. In view of the health risks they entail, VLCDs should be made available under medical supervision only

***and should be regulated under
Commission Directive 1999/21/EC.***

Justification

Other than for meal replacements of 200-400 kcal and total diet replacements (low calorie diets or “LCDs”) of 800-1200 kcal, there are currently no specific rules at EU level on the composition, labelling and use of VLCDs. Whereas the previous categories should henceforth be regulated under the Nutrition and Health Claims Regulation, VLCDs should be regulated under Commission Directive 1999/21/EC on dietary foods for special medical purposes, for reasons of the health risks they entail.

Amendment 12

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

Text proposed by the Commission

Amendment

***(27c) Pursuant to Regulation (EC)
No 882/2004 of the European Parliament
and of the Council of 29 April 2004 on
official controls performed to ensure the
verification of compliance with feed and
food law, animal health and animal
welfare rules¹, Member States should
conduct inspections on the compliance of
undertakings with this Regulation and the
delegated acts adopted pursuant thereto,
following a risk-based approach.***

¹ OJ L 165, 30.4.2004, p. 1.

Amendment 13

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

Text proposed by the Commission

Amendment

***(29a) To ease access of small and
medium-sized enterprises (SMEs) to the
market which in some sectors, for
example baby food and medical food,***

appear to be dominated by few large companies, the Commission should, in close cooperation with concerned stakeholders, adopt guidelines to help undertakings, in particular SMEs, to comply with the requirements laid down in this Regulation and thus facilitate competitiveness and innovation,

Amendment 14

Proposal for a regulation

Article 1 – paragraph 1 – point a

Text proposed by the Commission

(a) infant formula and follow-on formula;

Amendment

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

Amendment 15

Proposal for a regulation

Article 1 – paragraph 1 – point b

Text proposed by the Commission

(b) processed cereal-based food and baby food for infants and young children;

Amendment

(b) processed cereal-based food and baby food for infants and young children *in good health*;

Amendment 16

Proposal for a regulation

Article 2 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) the definitions of *'prepacked food' and 'labelling'* in points (e) and (j) of Article 2(2) of *Regulation (EU) No 1169/2011*;

Justification

Alignment to the recently adopted Regulation (EU) No 1169/2011 on food information to consumers, which replaces Directive 2000/13/EC.

Amendment 17

Proposal for a regulation Article 2 – paragraph 2 – point h

Text proposed by the Commission

(h) ‘food for special medical purposes’ means food intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet.

Amendment

(h) ‘food for special medical purposes’ means food intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet. ***Food for special medical purposes also includes Very Low Calorie Diets (VLCDs), which correspond to a total diet replacement under 800 kcal.***

Amendment 18

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

deleted

Justification

Subsequent to Article 290 of the Treaty on the functioning of the European Union, "a legislative act may delegate to the Commission the power to adopt non-legislative acts of

general application to supplement or amend certain non-essential elements of the legislative act". The adaptation of the definitions, however, concerns an essential element of the legislative act and should not be the subject of a delegation to the Commission.

Amendment 19

Proposal for a regulation

Article 3 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

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

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

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

Justification

The aim here is to include a clause that appears in Directive 2009/39/EC to prevent giving the impression that a food that meets only one requirement can be used for the people or diets covered by this regulation.

Amendment 20

Proposal for a regulation

Article 4 – title

Text proposed by the Commission

Amendment

Pre-packaged food

Prepacked food

Justification

Alignment to the recently adopted Regulation (EU) No 1169/2011.

Amendment 21

Proposal for a regulation Article 4

Text proposed by the Commission

Food referred to in Article 1(1) shall only be allowed on the retail market in the form of **prepackaged** food.

Amendment

Food referred to in Article 1(1) shall only be allowed on the retail market in the form of **prepacked** food.

Justification

Alignment to the recently adopted Regulation (EU) No 1169/2011.

Amendment 22

Proposal for a regulation Article 9 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide adequate consumer information, must not be misleading, **shall not attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties, and must be based on scientific data validated by the European Food Safety Authority.**

Amendment 23

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

Amendment

4. The **drawing up and** 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,

professionals responsible for maternal and child health care.

nutrition, pharmacy or other professionals responsible for maternal and child health care **and must be based on scientific data that can be independently verified.**

Amendment 24

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.

deleted

Justification

Unnecessary repetition of Articles 7 and 9.

Amendment 25

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

Text proposed by the Commission

Amendment

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:

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 **acts**, 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:

Justification

'Delegated acts' is the agreed standard wording to be used in provisions of this kind

Amendment 26

Proposal for a regulation

Article 10 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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.

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 **acts** mentioned in paragraph 2 in accordance with Article 15.

Justification

'Delegated acts' is the agreed standard wording to be used in provisions of this kind

Amendment 27

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

Milks intended for young children

By ...^{}, the Commission shall, after consulting the European Food Safety Authority which should notably carry out an exhaustive and independent review of existing scientific literature, present to the European Parliament and to the Council a report on the desirability of special provisions regarding the composition and labelling of milks 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 milks intended for young children;

(b) present, in accordance with the procedure laid down in Article 114 TFEU, any appropriate legislative proposals.

**OJ: please insert the date: 2 years after entry into force of this Regulation.*

Justification

Several national health authorities seem to doubt the added value of so-called 'growing milks' or 'toddler milks', and/or consider them to be too rich in sugar, flavours or minerals, whereas a small number of associations of health professionals have supported the intake of such milks as part of the daily diet of toddlers. It would therefore be useful to have EFSA's scientific opinion on the desirability to include specific compositional and labelling requirements for these milks in the Commission's delegated acts on follow-on formulae or baby food.

Amendment 28

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

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 implementing **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 implementing **acts** 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

updating the Union list in accordance with Article 14(3).

Union list in accordance with Article 14(3).

Amendment 29

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 to Regulation (EU) No 1169/2011

In Article 36, paragraph 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;”.

Justification

The Commission proposes to consider food for celiac people as normal food, to withdraw Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten and to regulate the statements concerned under the Claims Regulation. The Rapporteur for opinion prefers regulating the statements 'gluten-free' and 'very low gluten' 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 30

Proposal for a regulation

Article 18 b (new)

Text proposed by the Commission

Amendment

Article 18b

Technical guidance for SMEs

The Commission, in close cooperation with all stakeholders and the European

Food Safety Authority, shall make available appropriate technical guidance and tools to assist food business operators, in particular SMEs, in the preparation and presentation of an application for scientific assessment to the European Food Safety Authority, and, more generally, to comply with the requirements laid down in this Regulation.

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	IMCO 5.7.2011
Discussed in committee	20.12.2011
Date adopted	6.2.2012
Result of final vote	+: 35 –: 1 0: 4
Members present for the final vote	Pablo Arias Echeverría, Adam Bielan, Jürgen Creutzmann, Cornelis de Jong, Christian Engström, Vicente Miguel Garcés Ramón, Evelyne Gebhardt, Mikael Gustafsson, Małgorzata Handzlik, Iliana Ivanova, Philippe Juvin, Edvard Kožušník, Kurt Lechner, Toine Manders, Hans-Peter Mayer, Franz Obermayr, Phil Prendergast, Mitro Repo, Heide Rühle, Matteo Salvini, Andreas Schwab, Peter Skinner, Emilie Turunen, Michael Theurer, Róza Gräfin von Thun und Hohenstein, Gino Trematerra, Bernadette Vergnaud
Substitute(s) present for the final vote	Raffaele Baldassarre, Frank Engel, Marielle Gallo, Ildikó Gáll-Pelcz, Liem Hoang Ngoc, María Irigoyen Pérez, Constance Le Grip, Emma McClarkin, Antonyia Parvanova, Olga Sehnalová, Laurence J.A.J. Stassen, Marc Tarabella, Wim van de Camp