Amendment 88
Frédérique Ries
on behalf of the ALDE Group
Esther de Lange
on behalf of the PPE Group
Carl Schlyter
on behalf of the Verts/ALE Group
Julie Girling
on behalf of the ECR Group
Kartika Tamara Liotard
on behalf of the GUE/NGL Group

Report **A7-0059/2012**
Frédérique Ries
Food intended for infants and young children and food for special medical purposes
COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)

Proposal for a regulation
Article 11 - paragraphs 3, 4 and 5

Text proposed by the Commission	*Amendment*
	Article 11a
	Updating of the list of permitted substances
3. The entry of a substance ***in the Union list referred to in paragraph 2*** may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may also represent several interested parties (***hereinafter referred to as*** the applicant). ***Applications shall be sent to the Commission, in accordance with paragraph 4.***	***1.*** The entry of a ***new*** substance ***into Annex -1*** may be initiated either on the initiative of the Commission or following an application. Applications may be made by a Member State or by an interested party, who may also represent several interested parties (the 'applicant').
	1a. The applicant shall submit an application to the Commission in accordance with paragraph 2. The Commission shall acknowledge receipt in writing within 14 days of its receipt.
4. The application shall include:	***2.*** The application shall include:

(a) the name and the address of the applicant;	(a) the name and the address of the applicant;
(b) the name and a clear description of the substance; (c) the composition of the substance; (d) the proposed use of the substance and conditions thereof, (e) a systematic review of the scientific data and appropriate studies performed following generally accepted expert guidance on the design and conduct of such studies;	(b) the name and a clear description of the substance; (c) the composition of the substance; (d) the proposed use of the substance and conditions thereof; (e) a systematic review of the scientific data and appropriate ***peer-reviewed*** studies performed following generally accepted expert guidance on the design and conduct of such studies;
(f) scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it is intended and its suitability for the intended uses;	(f) scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it is intended and its suitability for the intended uses;
(g) scientific evidence demonstrating that the substance is available for use by the human body;	(g) scientific evidence demonstrating that the substance is available for use by the human body ***and has a nutritional or physiological effect***;
(h) a summary of the content of the application.	(h) a summary of the content of the application.
5. When a substance is already included in ***the Union list*** and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods shall be considered as different substance ***and*** the ***Union list*** shall ***be modified accordingly before it can be placed on the Union market***.	***3.*** When a substance is already included in ***Annex -1*** 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 *a* different substance ***which is not included in Annex - 1 and which*** shall ***require a separate application***.
	4. If a substance that is in Annex -1 no longer meets the conditions referred to in Article 11(2) and (2a), the Commission shall decide to remove that substance from Annex -1.
	5. The entry for a substance into Annex -1 shall include:
	- a specification of the substance
	- where appropriate, a specification of the conditions of use, and

- where appropriate, a specification of the applicable purity criteria.

6. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to update Annex -1. Where, in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided for in Article 16 shall apply to delegated acts adopted pursuant to this paragraph.

Or. en

Justification

Since the Regulation will only apply after 2 years after the entry into force it seems that the Commission first shall establish a list (Article 11) which then could be updated on the initiative of the Commission or following an application (Article 11a). Concerning this updated list, it is good sense to set up provisions not only for addition of substances but also for deletion of certain substances in the specific foodstuff.

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.

Amendment 89
Frédérique Ries
on behalf of the ALDE Group
Esther de Lange
on behalf of the PPE Group
Carl Schlyter
on behalf of the Verts/ALE Group
Julie Girling
on behalf of the ECR Group
Kartika Tamara Liotard
on behalf of the GUE/NGL Group

Report **A7-0059/2012**
Frédérique Ries
Food intended for infants and young children and food for special medical purposes
COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)

Proposal for a regulation
Annex -1 (new)

Text proposed by the Commission	*Amendment*
	Annex -1
	List of permitted substances

Or. en

Amendment 90
Frédérique Ries
on behalf of the ALDE Group
Esther de Lange
on behalf of the PPE Group

Report **A7-0059/2012**
Frédérique Ries
Food intended for infants and young children and food for special medical purposes
COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)

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 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***.	(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. ***Those*** statements should be regulated solely by ***this Regulation*** and comply with requirements ***herein***. Regulation (EC) No 41/2009 ***should therefore be repealed***.

Or. en

Amendment 91
Frédérique Ries
on behalf of the ALDE Group
Esther de Lange
on behalf of the PPE Group
Julie Girling
on behalf of the ECR Group

Report **A7-0059/2012**
Frédérique Ries
Food intended for infants and young children and food for special medical purposes
COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)

Proposal for a regulation
Recital 29 c (new)

Text proposed by the Commission	*Amendment*
	(29c) The Commission should be empowered to authorise, by means of delegated acts, food resulting from scientific and technological progress 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 delegated act for the specific food category concerned. However, in the interests of consumer health protection, a marketing authorisation may be granted only after the European Food Safety Authority has been consulted.

Or. en

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 92
Frédérique Ries
on behalf of the ALDE Group
Kartika Tamara Liotard
on behalf of the GUE/NGL Group

Report **A7-0059/2012**
Frédérique Ries
Food intended for infants and young children and food for special medical purposes
COM(2011)0353 – C7-0169/2011 – 2011/0156(COD)

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

Text proposed by the Commission	*Amendment*
(h) 'food for special medical purposes' means food intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet.	h) 'food for special medical purposes' means food ***specially processed or formulated and*** intended for the dietary management of patients to be used under medical supervision. It is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein ***or metabolites***, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet. ***Foods for special medical purposes also include formula intended for low birth-weight and pre-term infants, which also have to comply with Directive 2006/141/EC.***

Or. en