COUNCIL OF
THE EUROPEAN UNION

Brussels, 6 July 2012

12132/12

Interinstitutional File:
2011/0156 (COD)

LIMITE

DENLEG 68
AGRI 476
SAN 169
CODEC 1827

NOTE

from :	General Secretariat of the Council
to :	Delegations
No. Cion prop. :	12099/11 DENLEG 98 AGRI 480 SAN 137 CODEC 1180
No. prev. doc. :	10186/12 DENLEG 48 AGRI 327 SAN 113 CODEC 1341
Subject :	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** *- Examination of the position of the European Parliament at first reading*

On 14 June 2012, the European Parliament (EP) adopted its position at first reading 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, voting 83 amendments[1].

On 7 June 2012[2], the Council agreed on the general approach.

In its general approach, the Council:

– added into the scope of the proposed Regulation **total diet replacement for weight control** (Amendments 1, 11, 12, 20, 22, 26, 36, 46, 71, 82);

[1] 11133/12.
[2] 10086/12.

– provided for the Commission to submit a report on the desirability of special provisions for food for **sportsmen**. The European Parliament also requires the Commission to evaluate the need for such rules (Amendment 6), the main difference being the deadline;

– based the **definitions** included in Article 2 on the definitions of the current specific measures (Amendment 12);

– has the same concerns as the European Parliament of reducing the use of **pesticides** to the lowest levels possible (Amendment 3, 15, 16, 17, 62, 63). However the Council considers that detailed rules should be dealt with by delegated acts;

– provided for the Commission to submit a report on the desirability of special provisions for **milk-based drinks**. The European Parliament also requires the Commission to clarify the status of those foods, the main difference being the deadline for the report (Amendments 21, 81);

– considers, as the European Parliament, that **lactose-free** products should be covered by Union law (Amendments 25, 80). The Council suggests to regulate lactose-free products within the context of Regulation (EU) No 1169/2011.

Furthermore, amendments 19, 39, 40, 48, 51, 52 are directly acceptable.

However, there are still some issues to clarify with the European Parliament:

– The European Parliament wishes to include **gluten-free food** within the scope of the proposed Regulation to protect coeliac people.
In the Council's view, adopting, in the context of Regulation (EU) No 1169/2011 on the provision of food information to consumers, the same rules now applicable for those gluten-free foods, would ensure to coeliac people the same level of protection as foreseen in Regulation (EC) No 41/2009. It would further allow to apply the rules also to non-prepacked foods.

For reasons of legislative coherence, this would allow to manage all information related to gluten (presence and absence) under the same legislation as Regulation (EU) No 1169/2011 already lays down rules on the mandatory information to consumers of the presence of gluten containing ingredients in foods.
Therefore, the Council can not accept Amendments 1 (related part), 11 (related part), 12 (related part), 20 (related part), 35, 44, 45, 70, 90.

– The European Parliament and the Council need to clarify the amendments related to the Union list of **substances** covered by the proposed Regulation (Amendments 22, 37, 87, 88, 89). Different proposals were suggested by the two institutions.

– The European Parliament intends to ease the access to the market of **small and medium-sized enterprises** (SME's) in the sector of the foods covered by the proposed Regulation. A general answer from the Council to Amendments 8, 30, 31, 91, 72 is therefore needed.

– For the European Parliament, formula intended for **low birth weight and pre-term infants** should be considered in all cases as foods for special medical purposes and should comply with Directive 2006/141/EC (Amendments 13, 34, 92 and 43). However, the Council believes that only a part of premature and low-birth infants would need adapted formula.

– The Council shares the views of the European Parliament (Amendments 24, 30, 31, 91) as regards the interest for **innovative products** to be placed rapidly on the market. Therefore, the Council reinforces the provisions of the proposal related to the adoption and update of the specific requirements by means of delegated acts applying to foods covered by the scope of the Regulation by giving special recognition to innovative products.

– The Council consider that provisions related to categories of food included in the scope, considering their level of detail and the possible need to be adapted to technical progress or international agreements, should not be included in the basic act but should be dealt with in **delegated acts**. It is the case of the provisions suggested in Amendments 71, 82.

– The Council prefers to **avoid** any **repetition of the legislation** already **existent,** as it is the case in Amendments 27, 58 (1st part) and in Article 6 of the Commission proposal.

Other specific remarks can be found in the table in the Annex.

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Delegations can find in the third column of the table in the Annex the text of the general approach agreed by the Council. The text of the Commission proposal that has been deleted disappeared. The text added to the Commission proposal is indicated by ***bold italics***.

Meanwhile, Lawyers-Linguists suggested some linguistic corrections to the text of the general approach. Those suggestions are now indicated by ***bold italics underlined*** (additions) or ~~strikethrough underlined~~ (deletions) and submitted to the delegations' agreement.

The agreed suggestions will be integrated in the text before it is submitted to the EP as part of the Council's position (no ***bold italics underlined*** and no ~~strikethrough underlined~~). The EP will only have the indication in the 4th column, under "Council remarks", that some text suggested by the Council correspond to simple legal-linguistic changes of the Commission proposal.

Delegations are invited to indicate any disagreement in relation to those corrections during the meeting.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Title **Amendment 1**			
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** (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on food intended for infants and young children, ***on food for special medical purposes, on food for people intolerant to gluten and on food intended for use in low and very low calory diets***	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on food intended for infants and young children**,** food for special medical purposes and ***total diet replacement for weight control.*** (Text with EEA relevance)	***Council's remarks:*** *1st part of the EP amendment not acceptable.* *Incompatible with the approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.* *2nd part covered by the Council's position.*
Visas			
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national Parliaments, Having regard to the opinion of the European Economic and Social Committee, Acting in accordance with the		THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION, Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, Having regard to the proposal from the European Commission, After transmission of the draft legislative act to the national ***p***arliaments, Having regard to the opinion of the European Economic and Social Committee, Acting in accordance with the	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
ordinary legislative procedure[1],		ordinary legislative procedure[2],	
Recital 1			
Whereas: (1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that measures having as their object the establishment and functioning of the internal market and which concern *inter alia* health, safety and consumer protection must take as a base a high level of protection taking account in particular of any new development based on scientific facts.		Whereas: (1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that ***for*** measures having as their object the establishment and functioning of the internal market and which concern *inter alia* health, safety and consumer protection the ***Commission will*** ~~must~~ take as a base a high level of protection taking account in particular of any new development based on scientific facts.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Recital 2 **Amendment 2**			
(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.***	(2) The ***safety*** of food***, especially when it is intended for vulnerable groups, such as infants, young children and persons with special diseases,*** is an essential ***prerequisite for the free movement of such persons and the proper functioning of the internal market.***		***Council's remarks:*** *EP amendment not acceptable. The proposed Regulation is not limited to the safety of food. For purposes of clarifying that this Regulation should be placed in the context of free movement of safe and wholesome food, the Commission proposal is more*

[1] Position of the European Parliament of … and position of the Council at first reading of ... Position of the European Parliament of ... and decision of the Council of ....

[2] Position of the European Parliament of … and the position of the Council at first reading of …

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
			appropriate.
Recital 2a **Amendment 3**			
	(2a) In this context, given that the relevant Union law has been drawn up to ensure that no food is placed on the market if it is dangerous, any substances that are liable to be harmful to the health of the groups of the population concerned should be excluded from the composition of categories of foods covered by this Regulation.		***Council's remarks:*** ***ACCEPTABLE*** *in principle, redrafting might be needed.* *Suggestion:* ***"Union law is drawn up to ensure that no food is placed on the market if it is unsafe. Therefore, any substances that are considered to be injurious to health of the groups of the population concerned or unfit for human consumption should be excluded from the composition of categories of foods covered by this Regulation."*** *Justification: alignment with the Regulation (EC) 178/2002 terminology. In fact, Article 14 of Regulation (EC) 178/2002 refers to 'unsafe' food not to 'dangerous'. Furthermore, Article 14(2) provides for 2 types of unsafe food: injurious to health and unfit for human consumption.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Recital 3 **Amendment 4**			
(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[3] lays down general rules on the composition and preparation of such foods that are specially designed to meet the particular nutritional requirements of the persons to whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and ***should therefore be reviewed.***	(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses lays down general rules on the composition and preparation of such foods that are specially designed to meet the particular nutritional requirements of the persons to whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and ***fail to address the difficulty experienced by consumers in making an informed choice between dietetic foods, fortified foods, foods bearing claims and foods for normal consumption. The interaction between that legislation and Union law adopted more recently, such as Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the***		***Council's remarks:*** *EP amendment acceptable in principle: the additional text proposed by the EP is already covered by recitals 9 to 13.*

[3] OJ L 124, 20.5.2009, p. 21.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	Member States relating to food supplements[4], Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[5], 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 other substances to food[6] and 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[7], is a further factor making it necessary to thoroughly overhaul Directive 2009/39/EC.		
Recital 4			
(4) Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses' and general labelling requirements, including that such foods should bear an indication of			

4 ***OJ L 83, 12.07.2002, p. 51.***
5 ***OJ L 404, 30.12.2066, p. 9.***
6 ***OJ L 404, 30.12.2066, p. 26.***
7 ***OJ L 304, 22.11.2011, p. 18.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
their suitability for the claimed nutritional purposes.			
Recital 5			
(5) The general composition and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, Commission Directive 2006/141/EC of 22 December 2006 lays down harmonised rules with respect to infant formulae and follow-on formulae[8], whereas Commission Directive 2006/125/EC of 5 December 2006 lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children[9]. Similarly, harmonised rules are also laid down by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[10], Commission Directive		(5) The general compositional and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, Commission Directive 2006/141/EC of 22 December 2006[13] lays down harmonised rules with respect to infant formulae and follow-on formulae, whereas Commission Directive 2006/125/EC of 5 December 2006[14] lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Similarly, harmonised rules are also laid down by Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[15], Commission Directive	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

[8] OJ L 401, 30.12.2006. p. 1.
[9] OJ L 339, 6.12.2006, p. 16.
[10] OJ L 55, 6.3.1996, p. 22.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[11] and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable people intolerant to gluten[12].		1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[16] and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable people intolerant to gluten[17].	
Recital 6			
(6) In addition, Council Directive 92/52/EEC of 18 June 1992 lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries[18].		(6) In addition, Council Directive 92/52/EEC of 18 June 1992[19] lays down harmonised rules with respect to infant formulae and follow-on formulae intended for export to third countries ***and Commission Regulation (EC) No 953/2009 of 13 October 2009***[20] ***lays down rules for substances that may be added for specific nutritional purposes in foods for***	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

13 OJ L 401, 30.12.2006. p. 1.
14 OJ L 339, 6.12.2006, p. 16.
15 OJ L 55, 6.3.1996, p. 22.
11 OJ L 91,7.4.1999, p. 29.
12 OJ L 16, 21.1.2009, p. 3.
16 OJ L 91,7.4.1999, p. 29.
17 OJ L 16, 21.1.2009, p. 3.
18 OJ L 179, 1.7.1992, p. 129.
19 OJ L 179, 1.7.1992, p. 129.
20 ***OJ L 269, 14.10.2009, p. 9.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		particular nutritional uses.	
Recital 6 **Amendment 5**			
	(6a) According to the Council Resolution of 18 June 1992[21] on the marketing of breast-milk substitutes in third countries by Community-based manufacturers.		**TO BE CONSIDERED** ***Comment:*** ***"The Council Resolution dates back to 1992. However, Regulation 178/2002, adopted 10 years later, contains a more recent and more specific position taken by the co-legislators in relation to the obligations of food business operators with regard to food imported into Union and to food exported or re-exported from the Union. Reference only to the Council Resolution is not complete and could be misleading. Should this reference be maintained, this recital should also recall Regulation (EC) No 178/2002. "***
Recital 7 **Amendment 6**			
(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	(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	(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	***Council's remarks*:** *To consider in the light of Recital 7b (for diabetes) and Article 10ab (for sports).* *The Council provides for a different*

[21] ***OJ L 172, 8.7.1992, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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[22] concludes that the scientific basis for setting specific compositional***	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 regards the development of specific provisions due to widely diverging views among Member States and stakeholders concerning the scope of the specific legislation. ***Nevertheless, the undertaking made by the Commission in Directive 2009/39/EC to recognise the nutritional requirements of sportspeople should still apply, as supported by EFSA scientific opinions on claims relevant to active individuals, and the report of the Scientific Committee on Food of 28 February 2001 on composition and specification of food intended to meet the***	uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report~~[23]~~ ***to the European Parliament and to the Council*** concludes that the scientific basis for setting specific compositional requirements is lacking. With regard to food intended to meet the expenditure of intense muscular effort**, *especially for sportsmen***, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among the 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	*deadline: 2 years after the entry into force.*

[22] COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes), Brussels, 26.6.2008.

~~[23] COM (2008) 392 Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes), Brussels, 26.6.2008~~.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
requirements is lacking.	***expenditure of intense muscular effort, especially for sportsmen. Therefore, the Commission should assess, not later than 1 July 2015, the need to review general food law in this regard.***	establishing compositional requirements and the potential impact on innovation in product development. ***Therefore, specific rules should not be developed at this stage. Meanwhile, based on the submission of requests by food business operators, relevant claims have been assessed to be included under the rules set out in Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods*** [24]***.***	
Recital 7a **Amendment 7**			
	(7a) The Commission report of 26 June 2008 on food for persons suffering from carbohydrate metabolism disorders (diabetes) concludes that the scientific basis for setting specific compositional requirements is lacking. This Regulation is therefore not the appropriate legal framework for that category of food. According to the Commission, it is more important, as regards persons with		**TO BE CONSIDERED** ***Comments:*** ***Redrafting is necessary.*** ***1st part is already in recital 7 of Council's position, which could be completed with the sentence "This Regulation is therefore not the appropriate legal framework for that category of food.".*** ***2nd part: not acceptable as "diabetes" is not covered by this proposal as a disease itself, only***

[24] ***OJ L 404, 30.12.2006, p. 9.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	diabetes, to consider the quantity and model of food absorbed. This conclusion is in no way contrary to the establishment of an Union-wide strategy comprehensively targeting diabetes (Type 1 and Type 2), which affects more than 32 million Union citizens. Those figures, which are expected to increase by 16% by 2030 as a result of the obesity epidemic and the ageing of the European population, therefore merit careful consideration at Union level, including in the area of research and development.		***foods intended for specific groups are. Therefore, such amendment is out of context.***
Recital 7b			
		(7a) However, different views exist on whether additional rules would be needed to ensure an adequate protection of the consumers of food intended for sportsmen, also called food intended to meet the expenditure of intense muscular effort. The Commission should, therefore, be invited, after consulting the Authority, to submit to the European Parliament and to the Council a report on the desirability of special provisions for food intended for sportsmen	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		with regard to composition, labelling and, if appropriate, other types of requirements. The consultation of the <u>European Food Safety Authority (' the Authority')</u> should take into account the report of the Scientific Committee on Food of 28 February 2001 on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether special provisions are needed to ensure the protection of vulnerable consumers, such as children and young people who use food intended for sportsmen in their diet.	
Recital 8			
(8) Directive 2009/39/EC also requires a general notification procedure at national level for food presented by food business operators as falling under the definition of 'foodstuffs for particular nutritional uses' and for which no specific provisions are laid down in Union law, prior to			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
their placing on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.			
Recital 9			
(9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure[25] showed that difficulties may arise from different interpretations of the definition of foodstuffs for particular nutritional uses which appeared to be open to different interpretations by the national authorities. It therefore concluded that a revision of the scope of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of the Union legislation.		(9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure[~~26~~] showed that difficulties may arise from different interpretations of the definition of foodstuffs for particular nutritional uses which appeared to be open to different interpretations by the national authorities. It therefore concluded that a revision ~~of the scope~~ of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of the Union legislation.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Recital 10			
(10) A study report[27] concerning the		(10) A study report[~~28~~] ***of 29 April***	***Council's remarks:***

[25] Report from the Commission to the European Parliament and the Council on the implementation of Article 9 of Council Directive 89/398/EEC on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, COM (2008)393, dated 27.6.2008.

[~~26~~] ~~Report from the Commission to the European Parliament and the Council on the implementation of Article 9 of Council Directive 89/398/EEC on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, COM (2008)393, dated 27.6.2008.~~

[27] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
revision of the legislation on foodstuffs for particular nutritional uses confirms the findings of the Commission report on the implementation of the notification procedure and indicates that an increasing number of foodstuffs are today marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in Directive 2009/39/EC. The study report also points out that the type of food regulated under that legislation differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption addressed to the population in general or to certain sub-groups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of		***2009 by Agra CEAS Consulting,*** dated concerning the revision of ***Directive 2009/39/EC*** ~~the legislation on foodstuffs for particular nutritional uses~~ confirms the findings of the Commission report on the implementation of the notification procedure and indicates that an increasing number of foodstuffs are today marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in ***that*** Directive ~~2009/39/EC~~. The study report also points out that the type of food regulated under that ***Directive*** ~~legislation~~ differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption***, including food supplements,*** addressed to the population in general or to certain sub-groups thereof such as pregnant women,	*The suggestion of the Council is of legal-linguistic nature only.*

– Study report Agra CEAS Consulting, dated 29.4.2009.

[28] An analysis of the European, social and environmental impact of the policy options for the revision of the Framework Directive on dietetic foods – Study report Agra CEAS Consulting, dated 29.4.2009.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out.		postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out.	
Recital 11			
(11) It appears that other Union acts recently adopted are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and the Council of 10 June on the approximation of the laws of the Member States relating to food supplements[29], Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on		(11) It appears that other Union acts recently adopted are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and the Council of 10 June on the approximation of the laws of the Member States relating to food supplements[32], Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

[29] OJ L 183, 12.7.2002, p. 51.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
nutrition and health claims made on foods[30] and Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to foods[31]. Furthermore, the provisions of these Union acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less administrative burden and more clarity as to the scope and objectives.		nutrition and health claims made on foods[33] and Regulation (EC) No 1925/2006 of the European Parliament and the Council of 20 December 2006 on the addition of vitamins and minerals and other substances to foods[34]. Furthermore, the provisions of ***those*** ~~these~~ Union acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less administrative burden and more clarity as to the scope and objectives.	
Recital 11a **Amendment 8**			
	(11a) There is therefore 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		**TO BE CONSIDERED** ***Comments:*** ***Repeats recitals 10 and 13.*** ***If kept, this recital should be placed before recital 13.*** ***To consider the special situation of SME's, ", including SME's," could be added in recital 10 after "food business operators".***

[32] OJ L 183, 12.7.2002, p. 51.
[30] OJ L 404, 30.12.2006, p. 9.
[31] OJ L 404, 30.12.2006, p. 26.
[33] OJ L 404, 30.12.2006, p. 9.
[34] OJ L 404, 30.12.2006, p. 26.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	the same way across the Union and would create a more level playing field for all operators across the internal market, especially SMEs.		
Recital 12			
(12) Moreover, experience shows that certain rules included in or adopted under Directive 2009/39/EC are no longer effective to ensure the functioning of the internal market.			
Recital 13			
(13) Therefore, the concept of "foodstuffs for particular nutritional uses" should be abolished and Directive 2009/39/EC should be replaced by the present act. To simplify its application and to ensure consistency throughout the Member States, the present act should take the form of a Regulation.		(13) Therefore, the concept of "foodstuffs for particular nutritional uses" should be abolished and Directive 2009/39/EC should be replaced by ***this*** ~~the present~~ act. To simplify its application and to ensure consistency throughout the Member States, ***this*** ~~the present~~ act should take the form of a Regulation.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Recital 14 **Amendment 9**			
(14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food	(14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food	(14) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food	**TO BE DEALT AT A LATER STAGE** ***Council's remarks on the EP amendment:*** ***To be acceptable, it should be***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Safety Authority and laying down procedures in matters of food safety[35] establishes common principles and definitions for Union food law in order to ensure a high level of ***health*** protection ***and*** the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (hereinafter referred to as 'the Authority'). Therefore, certain definitions laid down in that Regulation must also apply in the context of the present Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.	Safety Authority and laying down procedures in matters of food safety establishes common principles and definitions for Union food law in order to ensure a high level of protection ***of human health and consumers' interest, while ensuring*** the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food***, sets out that pursuant to the precautionary principle provisional risk management measures can be adopted,*** and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (hereinafter referred to as 'the Authority'). Therefore, certain definitions laid down in that Regulation must also apply in the context of the present Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.	Safety Authority and laying down procedures in matters of food safety[36] establishes common principles and definitions for Union food law in order to ensure a high level of health protection and the effective functioning of the internal market. It establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the ~~European Food Safety Authority (hereinafter referred to as 'the~~ Authority~~')~~. Therefore, certain definitions laid down in that Regulation ~~must~~ ***should*** also apply in the context of ~~the present~~ ***this*** Regulation. Moreover, for the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.	***compatible with Article 7 of Regulation (EC) No 178/2002 in relation to the precautionary principle.*** *Therefore, the Council supports the Commission proposal, the Council suggestion being of legal-linguistic nature only.*

[35] OJ L 31, 1.2.2002, p. 1.
[36] OJ L 31, 1.2.2002, p. 1.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Recital 14a Amendment 10			
	(14a) Where a risk to life or health exists, whether immediate or in the long term, but scientific uncertainty persists, the precautionary principle should apply to ensure a high level of health protection, taking into account cumulative toxic effects and the particular health sensitivities of the particularly vulnerable groups of the population specified in this Regulation.		**TO BE CONSIDERED** ***Council's remarks:*** ***To be acceptable, it should be compatible with Article 7 of Regulation (EC) No 178/2002 in relation to the precautionary principle.***
Recital 15 Amendment 11			
(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	(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	(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 formula~~e~~ and follow-on formula~~e~~, processed cereal-based food and	***Council's remarks:*** *The drafting suggestion of the Council is of legal-linguistic nature only.* *See Council's suggestion for a new recital 15a.* *The inclusion of " food for people intolerant to gluten" under the scope of this regulation is incompatible with the Council's approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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.	baby food***,*** food for special medical purposes, ***food for people intolerant to gluten and food for use in low calorie diets (LCD) and very low calorie diets (VLCD)***. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. ***VLCD products are currently not covered by Commission Directive 96/8/EC but solely by Directive 2009/39/EC.*** It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children***,*** food for special medical purposes***, food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, ***while*** taking into account Commission Directive	baby food and food for special medical purposes. Experience has shown that the provisions laid down in ~~Commission~~ Directive***s*** 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 formula~~e~~, processed cereal-based food and baby food for infants and young children and to food for special medical purposes, taking into account ~~Commission~~ Directive***s*** 2006/141/EC, ~~Commission Directive~~ 2006/125/EC and ~~Commission Directive~~ 1999/21/EC.	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.		
Recital 15a			
		(15a) In addition, in view of the growing rates of people with overweight and obesity problems, an increasing number of food is placed on the market as total diet replacement for weight control, including food the energy content of which is very low, commonly named as very low calorie diet products. Given the nature of the food in question it would be appropriate to set certain specific provisions for it. Experience has shown that the relevant provisions laid down in ~~Commission~~ Directive 96/8/EC ensure the free movement of food presented as total daily diet replacement for weight control 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 food intended to replace the whole of the daily diet including food the energy content	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		of which is very low taking into account the relevant provisions of ~~Commission~~ Directive 96/8/EC.	
Recital 16 **Amendment 12**			
(16) To ensure legal certainty, definitions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC ***and*** Commission Directive 1999/21/EC should be transferred to this Regulation. However, the definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, ***and*** food for special medical purposes should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.	(16) To ensure legal certainty, definitions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, Commission Directive 1999/21/EC***, Commission Regulation (EC) No 41/2009 and Commission Directive 96/8*** should be transferred to this Regulation. However, the definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, food for special medical purposes, ***food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)*** should be regularly adapted taking into account technical and scientific progress and relevant developments at international level, as appropriate.	(16) ***This Regulation should establish, among others, definitions of infant formulae and follow-on formulae, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control, taking into account relevant provisions in ~~Commission~~ Directives 2006/141/EC, ~~Commission Directive~~ 2006/125/EC, ~~Commission Directive~~ 1999/21/EC and ~~Commission Directive~~ 1996/8/EC.***	
Recital 16a **Amendment 13**			
	(16a) According to the	***(16a) The nutritional requirements***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	recommendations of the World Health Organization, low-birth weight infants should be fed their mother's own milk. Nonetheless, low birth-weight infants and pre-term infants often have special nutritional requirements which cannot be met by the mother's own milk or standard infant formulae. Food for such infants should comply with rules applicable to food for special medical purposes, when this kind of food is chosen as the most appropriate formula, taking into account the specific medical situation of the infant. Formula intended for low birth weight or pre-term infants should in any event comply with the requirements of Directive 2006/141/EC.	***of low birth weight and/or preterm infants depend on the medical condition of the infant, in particular on his weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case by case basis whether the infant's condition requires the consumption under medical supervision of a formula adapted for the dietary management of his specific condition.***	
Recital 17 **Amendment 14**			
(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	(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		***Council' remarks:*** *Clarification would be needed from the EP as regards their objective with the addition of the word "independent". See also proposed position concerning EP amendments 57 in Article 9.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.	established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic ***and independent*** review of the available scientific data.		
Recital 17a **Amendment 15**			
	(17a) It is important that pesticides, maximum residue levels for which are authorised by Directive 2006/141/EC and Directive 2006/125/EC and which do not satisfy the safety conditions set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market[37]. be banned from the market and that they not be used in the production of food covered by this Regulation.	***(17a) The use of pesticides in food of plant and animal origin covered by this Regulation intended inter alia for infants and young children should be restricted as far as possible. A prohibition of their use in the production of such products would not necessarily guarantee that they are free from such pesticides, since some pesticides contaminate the environment and their residues may be found in the products concerned. Therefore, the maximum residues levels in the products concerned should be set at the lowest achievable level consistent with good agricultural practices for each pesticide with a view to protect those vulnerable groups of the population.***	
Recital 17b			

[37] ***OJ L 309, 24.11.2009, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	Amendment 16		
	(17b) Maximum residue levels of pesticides set out in relevant Union law, in particular Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin[38], should apply without prejudice to specific provisions set out in this Regulation and the delegated acts adopted in accordance with this Regulation.		***Council's remarks:*** *Unnecessary.*
	Recital 17c **Amendment 17**		
	(17c) However, given the vulnerable nature of infants and young children, severe limitations on pesticide residues are required in infant formula and follow-on formula and food for infants and young children. Specific maximum residue levels for such products are set in Commission Directive 2006/141/EC and Commission Directive 2006/125/EC. Particular attention should be paid to pesticides	***(17b) Limitations or bans of certain pesticides equivalent to those currently establised by the annexes to the Directives 2006/141/EC and 2006/125/EC should be taken into account in delegated acts. Those limitations or bans should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC)***	

[38] ***OJ L 70, 16.3.2005, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	containing substances classified as specifically hazardous to human health.	***No 1272/2008 as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, considered to have endocrine disrupting properties that may cause adverse effects in humans.***	
Recital 17d **Amendment 18**			
	(17d) At all stages of the food production chain, food businesses and food business operators, as defined in Regulation (EC) No 178/2002, should ensure that the food covered by this Regulation comply with the requirements of food law in general and of this Regulation in particular.		***Council's remarks:*** *Unnecessary.* *Article 17 in Regulation (EC) No 178/2002 deals with responsibility of food business operators.*
Recital 18 **Amendment 19**			
(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***[39]. Those	(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	(18) General labelling requirements are laid down in ***Regulation (EU) No 1169/2011*** of the European Parliament and of the Council of ***25 October 2011***[40]. Those general labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should	**ACCEPTABLE**

[39] OJ L 184, 17.7.1999, p. 23.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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.	from, the provisions of ***Regulation (EU) No 1169/2011***, where necessary, in order to meet the specific objectives of this Regulation.	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.	
Recital 18a			
		(18a) The labelling, presentation or advertising of foods falling under the scope of this Regulation should not attribute properties to such foods for the prevention, treatment or cure of human disease or imply such properties. Foods for special medical purposes, however, ~~are~~ is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take an ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical	

[40] OJ L 304, 22.11.2011, p.18.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		conditions for which the ~~product~~ food is intended should not be considered as attribution of a property for the prevention, treatment or cure of human disease.	
Recital 19 **Amendment 20**			
(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	(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes***, food for people intolerant to gluten and food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC. In order to lay down the specific compositional and information requirements with respect to the categories of food covered by this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of	(19) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes ***and total diet replacement for weight control***, taking into account ~~Commission~~ Directive***s*** 2006/141/EC, ~~Commission Directive~~ 2006/125/EC***,*** ~~Commission Directive~~ 1999/21/EC ***and ~~Commission Directive 96/8/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***	***Council's remarks:*** *This recital should be reviewed when Articles conferring the power to adopt delegated acts to the Commission are finalised.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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.	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.	***(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 ***TFEU*** should be delegated to the Commission. ***Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and thus to stimulate innovation, the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission for the purpose of a regular update of the requirements applying to infant formula and follow-on formula, processed cereal-based food and baby food for infants and young children, food for special medical purposes and total diet replacement for weight control, taking into account all relevant data, including data provided by interested parties.*** 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	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		drawing-up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and Council.	
Recital 19a **Amendment 21**			
	(19a) The Commission should, after consulting the Authority, clarify the status of milks intended for children between 12 and 36 months which are currently regulated by different legal acts of the Union, such as Regulation (EC) No 178/2002, Regulation (EC) No 1924/2006, Regulation (EC) No 1925/2006 and Directive 2009/39/EC, and submit a report to the European Parliament and the Council assessing whether further legislative action is required, at the latest 1 year after the date of the entry into force of this Regulation. If appropriate the report should be accompanied by a legislative proposal.	***(19a) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suited for young children ~~between one and three years~~. These products, which can be derived from protein of animal or vegetable origin such as, for example, cows' milk, goats' milk, soy or rice are often marketed as 'growing up milks' or 'toddlers' milks" or with similar terminology. These products are not covered by the specific existing measures applying to foods intended for infants and young children. Different views exist on whether these products respond to specific nutritional requirements of the population they target. The Commission should therefore, after consulting the Authority, present to the European***	**ACCEPTABLE in principle, subject to rewording as proposed by the Council.** *For the deadline,* **t***he Council suggests 2 years after the entry into force.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		Parliament and to the Council a report on the desirability of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of these milk-based drinks and similar products intended for young children. The Commission may accompany this report with a legislative proposal.	
Recital 19b			
		(19b) It is appropriate to establish and update a Union list of vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol that may be added to infant formula and follow-on formula, processed cereal-based food and baby food ~~for infants and young children~~, food for special medical purposes and total diet replacement for weight control subject to criteria laid down in this Regulation.	
Recital 19c			
		(19c) In order to take into account technical progress, scientific developments or consumers' health, the power to adopt acts in accordance with Article 290 TFEU should also be delegated to	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		the Commission in respect of extending the Union list to additional categories of substances that have a nutritional or physiological effect. 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.	
Recital 20 **Amendment 22**			
(20) It is appropriate to establish and update a Union list of vitamins, minerals***, amino acids*** and other substances that may be added to infant formula, follow-on formula, processed cereal-based food and baby food, ***and*** food for special medical purposes, subject to certain criteria laid down in this Regulation. Given the fact that the adoption of the list ***implies the*** application ***of criteria set out in***	(20) It is appropriate to establish and update a Union list of vitamins, minerals and other substances that may be added to infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes ***and food for use in low calorie diets (LCD) and very low calorie diets (VLCD)***, subject to certain criteria laid down in this Regulation. ***The list should be***	(20) ***In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether or not a given food falls within the scope of this Regulation and to which category of food under the scope it belongs, as well as to establish and to update, by applying the criteria laid down in this Regulation, a theUnion list of***	**Council's remarks:** *To be discussed in the context of the discussion on Article 11.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
this Regulation, implementing powers should be conferred on the Commission in that respect. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[41]**.** The Commission should adopt immediately applicable ***implementing*** acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require.	***adopted taking due account of the specific dietary habits of the groups of the population concerned and should take into account and replace the lists set out in Directives 2006/141/EC and 2006/125/EC, and Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses***[42]***, which does not apply to liquid or solid formula for infants and young children*** Given the fact that the adoption ***and updating*** of the list ***is a measure of general*** application ***to supplement or amend certain non-essential elements of this Regulation***, ***the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in that respect***.. The Commission should adopt immediately applicable ***delegated***	***vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[43] The Commission should adopt immediately applicable implementing acts ***relating to the updating of the Union list***, where, in duly justified cases relating to public health, imperative grounds of urgency so require.	

41 OJ L 55, 28.2.2011, p. 13.
42 ***OJ L 269, 14.10.2009, p.9.***
43 OJ L 55, 28.2.2011, p. 13.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	acts updating the Union list, where, in duly justified cases relating to public health, imperative grounds of urgency so require.		
Recital 21 **Amendment 23**			
(21) At present, pursuant to the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[44] on the risk assessment of products of nanotechnologies, dated 19 January 2009, there is inadequate information on the risks associated with engineered nanomaterials and existing test methods may not be sufficient to address all of the issues arising in relation to engineered nanomaterials. ***Therefore,*** engineered nanomaterials should not be included in the Union list for the categories of food covered by this Regulation, ***until an evaluation*** by the Authority ***is carried out.***	(21) At present, pursuant to the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the risk assessment of products of nanotechnologies, dated 19 January 2009, there is inadequate information on the risks associated with engineered nanomaterials and existing test methods may not be sufficient to address all of the issues arising in relation to engineered nanomaterials. ***Taking account of that scientific opinion and in view of the particular sensitivity of the vulnerable groups for whom foods covered by this Regulation are intended***, engineered nanomaterials should not be included in the Union	(21) ***The substances falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[45] should not be added to the foods covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) 258/97 in addition to the conditions set out in accordance with this Regulation. When, for a substance that has been used in accordance with this Regulation, there is a significant change in the production method or a change in particle size, for example through nanotechnology, this substance***	

[44] Scientific Committee established by Commission Decision of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (2008/721/EC), OJ L 241, 10.9.2008, p. 21.

[45] ***OJ L 43, 14.2.1997, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	list for the categories of food covered by this Regulation ***as long as their safety***, ***based on adequate and sufficient test methods, their nutritional value and their suitability for the persons for whom the food is intended have not been demonstrated*** by the Authority.	***should be considered different from the one that has been used in accordance with this Regulation and should be re-evaluated under Regulation (EC) No 258/97.***	
Recital 22 **Amendment 24**			
(22) In the interests of ***efficiency and*** legislative simplification, there should be a medium-term examination of the question whether to extend the scope of the Union list to other categories of food governed by other specific Union legislation.	(22) In the interests of legislative simplification ***and a clear desire to support innovation***, there should be a medium-term examination of the question whether to extend the scope of the Union list to other categories of food governed by other specific Union legislation. ***Such an extension should be decided by the European Parliament and the Council in accordance with the ordinary legislative procedure, on the basis of an evaluation by the Authority.***	*Deleted*	
Recital 23			
(23) It is necessary to establish procedures for the adoption of emergency measures in situations where food covered by this Regulation constitutes a serious		*Deleted*	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
risk to human health. In order to ensure uniform conditions for the implementation of emergency measures, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011. The Commission should adopt immediately applicable implementing acts relating to emergency measures, where, in duly justified cases relating to public health, imperative grounds of urgency so require.			
Recital 24			
(24) Council Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the European Union have to comply with Union law unless otherwise required by the importing country. This principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.		(24) ~~Council~~ Directive 92/52/EEC states that infant formulae and follow-on formulae exported or re-exported from the ~~European~~ Union have to comply with Union law unless otherwise required by the importing country. This principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Recital 25			
(25) Regulation (EC) No			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods[46] establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or non-legislative acts adopted pursuant to this Regulation.			
Recital 26 **Amendment 90**			
(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.***	(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***.	(26) Currently, ***the rules on the use of*** the statements 'gluten-free' and 'very low gluten' ***are*** specified in ~~Commission~~ Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten[47]. ***That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in foods and sets specific rules for***	***Council's remarks:*** *EP amendment not acceptable. Incompatible with the approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.*

[46] OJ L 404, 30.12.2006, p. 9.
[47] OJ L 14, 20.1.2009, p. 5.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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***.	Regulation (EC) No 41/2009 ***should therefore be repealed***.	***foods that ~~are~~ is specially processed, prepared or manufactured to reduce the gluten content of one or more gluten containing ingredients and other foods that ~~are~~ is made exclusively from ingredients naturally free of gluten. Regulation (EU) No 1169/2011 ~~on the provision of food information to consumers~~ sets out rules on information to provide on the presence in all foods, including non-prepacked foods, of ingredients, such as gluten containing ingredients, with a scientifically proven allergenic or intolerant effect to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should also be regulated under Regulation (EU) No 1169/2011. It is necessary that the acts pursuant to Regulation (EU) No 1169/2011, transferring the rules on the use of***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		the statements 'gluten-free' and 'very low gluten' as regulated under Regulation (EU) No 41/2009 be completed prior to the application of this Regulation.	
Recital 26a Amendment 25			
	(26a) Labelling indicating 'lactose free' and 'very low lactose content' is currently not covered by Union law. Those indications are, however, important for people who are intolerant to lactose. The Commission should therefore clarify their status under general food law.	***(26a) Labelling and compositional rules indicating the absence or reduced presence of lactose in food are currently not harmonised at Union level. Those indications are, however, important for people who are intolerant to lactose. As mentioned above, Regulation (EU) No 1169/2011 sets out rules on information to provide on substances with a scientifically proven allergenic or intolerant effect, to enable consumers, such as lactose intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the establishment of rules on the use of the statements indicating the absence or reduced presence of lactose in food should be regulated under Regulation (EU) No 1169/2011.***	***Council's remarks:*** *The concerns of both the EP and the Council are the same. The Council suggests an immediate solution.(Reg. 1169/2011 is all that is needed for dealing with lactose intolerance)*
Recital 27			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Amendment 26			
(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are considered as food for particular nutritional uses and are governed by specific rules adopted under Directive 96/8/EC. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. In order to eliminate any potential confusion between food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'total diet replacement for weight control' and as 'meal replacement for weight control' and associated conditions of use as regulated under Directive	(27) 'Meal replacement for weight control' and 'total diet replacement for weight control' are ***currently*** considered as food for particular nutritional uses and are governed by specific rules adopted under Directive 96/8/EC***, while foods intended for very low calorie diets (VLCD) are governed by Directive 2009/39/EC only***. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. ***Against the background of the growing number of food products containing generic claims and the risk of disorders in dietary habits arising from certain unsupervised diets, the Authority regularly carries out scientific assessments of health claim applications relating to meal replacement. The assessment carried out by the Authority does not cover the safety of compositional criteria put forward by the operator applying for the use of a claim or certain labelling methods. Specific***	(27) 'Meal replacement for weight control' ***intended to replace part of the daily diet is*** considered as food for particular nutritional uses and ***is currently*** governed by specific rules adopted under Directive 96/8/EC. However, more and more food intended for the general population has appeared on the market carrying similar declarations which are presented as health claims for weight control. In order to eliminate any potential confusion ***within this group*** of food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, such statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'meal replacement for weight control' and associated conditions of use as regulated by Directive 96/8/EC be completed prior to the entry into	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
96/8/EC be completed prior to the entry into application of this Regulation.	***provisions are therefore needed in this Regulation on food intended for use in low calorie diets (LCD) and very low calorie diets (VLCD). Such provisions are an important nutrition and health safety tool for people seeking to lose weight.*** In order to eliminate any potential confusion between food marketed for weight control and in the interests of legal certainty and coherence of Union legislation, ***while protecting the most vulnerable,*** such statements ***on food intended for the general population*** should be regulated by Regulation (EC) No 1924/2006 and comply with requirements therein**,** ***with the exception of foods intended for use in low calorie diets (LCD) and very low calorie diets (VLCD), which should comply with this Regulation***. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the health claims referring to the body weight control for food presented as 'total diet replacement for weight control' and as 'meal replacement for weight control' and associated	application of this Regulation.	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	conditions of use as regulated under Directive 96/8/EC be completed prior to the entry into application of this Regulation.		
Recital 27a Amendment 27			
	(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.		***Council's remarks:*** *Unnecessary as a repetition of Regulation (EC) No 882/2004.*
Recital 27b Amendment 28			
	(27b) 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 rules[48], Member States should conduct inspections on the compliance of undertakings with this Regulation and the delegated acts adopted pursuant thereto, following a risk-		***Council's remarks:*** *Unnecessary.*

[48] ***OJ L 165, 30.4.2004, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	based approach.		
Recital 28			
(28) Since the objectives of the actions to be taken cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.			
Recital 28a			
		(28a) Directives 2009/39/EC, 92/52/EC, 96/8/EC, 2006/141/EC, 2006/125/EC, 1999/21/Ec and Regulations (EC) No 41/2009 and (EC) No 953/2009 should be repealed.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Recital 29 **Amendment 29**			
(29) Adequate ***transitional*** measures ***are necessary*** to enable ***food business operators*** to adapt to the requirements of this Regulation. HAVE ADOPTED THIS	(29) ***The Commission should take*** adequate measures ***to ensure legal certainty between entry into force and application of this Regulation and provide the assistance and up-to-date information necessary to***		***Council' remarks:*** *To be clarified.* *What is the Commission required to do to ensure "legal certainty between entry into force and application of this Regulation"?*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
REGULATION:	***the food business operators*** to enable ***them*** to adapt to the requirements of this Regulation.		*What kind of measures the Commission is supposed to take? Transitional measures are established by the legislator in Article 18 with no additional delegation of powers to the Commission.*
Recital 29a Amendment 30			
	(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 a 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.		***Council's remarks:*** *To be discussed with the EP in general.*
Recital 29b Amendement 31			
	(29b) In order to facilitate market access for operators – especially SMEs – wishing to sell foods resulting from scientific and technological innovations, the Commission, in close cooperation		***Council's remarks:*** *To be discussed with the EP in general.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	with the relevant stakeholders, should adopt guidelines on the procedure for placing such food on the market on a temporary basis.		
	Recital 29c Amendment 91		
	(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. HAVE ADOPTED THIS REGULATION:		***Council's remarks:*** *To be discussed with the EP in general (see art. 10 (3) of Council's position).* *There is no reason for placing certain innovative foods on the market on a temporary basis through delegated acts when, using the same (rapid) procedure, it is possible to provide for an authorisation for an indefinite period. Unnecessary administrative burden.* *The obligation to consult EFSA is already provided for in Article 8.*
	Article 1(1)(a) Amendment 33		
CHAPTER I SUBJECT MATTER AND DEFINITIONS	**CHAPTER I SUBJECT MATTER AND DEFINITIONS**		***Council's remarks:*** *Unclear. Need to clarify the intention.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 1 ***Subject matter*** 1. This Regulation establishes compositional and information requirements for the following categories of food:	*Article 1* ***Subject matter*** 1. This Regulation***, complementing Union law on food,*** establishes compositional and information requirements for the following categories of food:		
Article 1(1)(a)			
(a) infant formula and follow-on formula;			
Article 1(1)(b)			
(b) processed cereal-based food and baby food for infants and young children;		(b) processed cereal-based food and baby food ~~for infants and young children~~;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 1(1)(c) **Amendment 34**			
(c) food for special medical purposes.	(c) food for special medical purposes, ***including formula intended for low birth-weight and pre-term infants.***	(c) food for special medical purposes***;***	***Councils remarks:*** *See Council's position for Recital 16a.*
Article 1(1)(ca) **Amendment 35**			
	(ca) food for people intolerant to gluten.		***Council's remarks:*** *Not acceptable.* *Incompatible with the approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.* *(see also rec. 26 of Council's position)*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 1(1)(cb) **Amendment 36**			
	(cb) foods intended for use in low calorie diets (LCD) and very low calorie diets (VLCD).	***(d) total diet replacement for weight control.***	***Council's remarks:*** *Covered by the Council's position.*
Article 1(2) **Amendment 37**			
2. This Regulation provides the rules for the establishment and ***update*** of a Union list of. vitamins, minerals and other substances that can be added to the categories of food referred to in paragraph 1.	2. This Regulation provides the rules for the establishment and ***updating*** of a ***clearly defined*** Union list of vitamins, minerals and other substances that can be added to the categories of food referred to in paragraph 1 ***for a specific nutritional purpose***.	2. This Regulation provides the rules for the establishment and update of a Union list of vitamins, minerals, ***amino acids, carnitine, taurine, nucleotides, choline and inositol*** that ***may*** be added to the categories of food referred to in paragraph 1 ~~***("Union list")***~~.	***Council's remarks:*** *To be discussed in the context of Article 11.*
Article 1(2a) **Amendment 38**			
	2a. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.		***Council's remarks:*** ***ACCEPTABLE in principle*** *(has been moved from Article 7(2)). The better place for this provision deserves further reflection.*
Article 2(1)			
Article 2 ***Definitions*** 1. For the purposes of this Regulation, the following definitions shall apply:			
Article 2(1)(a) **Amendment 39**			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
(a) the definitions of 'food' and 'placing on the market' set out in Articles 2 and 3(8) of Regulation (EC) No 178/2002;	(a) the definitions of 'food', ***'retail'*** and 'placing on the market' set out in Articles 2 and ***3(7) and*** 3(8) of Regulation (EC) No 178/2002;	(a) the definitions of 'food'**,** ***'retail'*** and 'placing on the market' set out ***respectively*** in Articles 2 and ***Article*** 3***(7) and*** (8) of Regulation (EC) No 178/2002;	**ACCEPTABLE**
Article 2(1)(b) **Amendment 40**			
(b) the definitions of 'labelling' ***and 'pre-packaged foodstuff'*** in points ***(a)*** and ***(b)*** of Article ***1(3)*** of ***Directive 2000/13/EC***;	(b) the definitions of ***'prepacked food' and*** 'labelling' ***set out*** in points ***(e)*** and ***(j)*** of Article ***2(2)*** of ***Regulation (EU) No 1169/2011***;	(b) the definitions of 'labelling' and ***'prepacked food' set out respectively*** in points ***(e)*** and ***(j) of*** Article ***2(2) of Regulation (EU) No 1169/2011***; ***and***	**ACCEPTABLE**
Article 2(1)(c)			
(c) the definitions of 'nutrition claim' and 'health claim' set out in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006; and,		(c) the definitions of 'nutrition claim' and 'health claim' set out ***respectively*** in points (4) and (5) of Article 2(2) of Regulation (EC) No 1924/2006.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 2(1)(d)			
(d) the definition of 'other substance' set out in Article 2(2) of Regulation (EC) No 1925/2006.		*Deleted*	
Article 2(1)(da) **Amendment 41**			
	(da) the definition of 'engineered nanomaterial' set out in point (t) of Article 2(2) of Regulation (EU) No 1169/2011.		**TO BE CONSIDERED** **Linked with amendments 23 and 87 (Art. 11 (2a)).**
Article 2(2)(a)			
2. The following definitions shall			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
also apply: (a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;			
Article 2(2)(b)			
(b) 'infants' means children under the age of 12 months;		(b) 'infant~~s~~' means ***a*** child~~ren~~ under the age of 12 months;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 2(2)(c)			
(c) 'young children' means children between one and three years;		(c) 'young child~~ren~~' means ***a*** child~~ren~~ between one and three years;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 2(2)(d)			
(d) 'infant formula' means food used by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;			
Article 2(2)(e)			
(e) 'follow-on formula' means food used by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;			
Article 2(2)(f)			
(f) 'processed cereal-based food'		(f) 'processed cereal-based food'	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
means food (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food and (ii) pertaining to the following four categories: – simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids; – cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid; – pastas which are to be used after cooking in boiling water or other appropriate liquids; – rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;		means food (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food and (ii) pertaining to ***one of*** the following four categories: – simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids; – cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid; – pastas which are to be used after cooking in boiling water or other appropriate liquids; – rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids;	
Article 2(2)(g)			
(g) 'baby food' means food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
supplement to their diet and/or for their progressive adaptation to ordinary food, excluding: (i) processed cereal-based food and (ii) milk intended for young children;			
Article 2(2)(h) Amendment 92			
(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.***	(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.	***Council's remarks:*** *First part of the EP amendment:* ***ACCEPTABLE.*** *Last part of the EP amendment covered and better explained by Council's position (see recital 16a).*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	Article 2(2)(ha) Amendment 43		
	(ha) 'Formula intended for low birth weight and pre-term infants' means a food specifically developed to meet the medically-determined nutrient requirements of infants who are born prematurely or at a low birth weight.		***Council's remarks:*** *To be covered in the recitals (see Council's position for recital 16a). For the Council, the definition of food for medicinal purposes is inclusive enough to cover 'formula intended for low birth weight and pre-term infants'.*
	Article 2(2)(hb) Amendment 44		
	(hb) 'food for people intolerant to gluten' means foodstuffs for particular nutritional uses which are specially produced, prepared or processed to meet the special dietary needs of people intolerant to gluten;		***Council's remarks:*** *Not acceptable. Incompatible with the approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.*
	Article 2(2)(hc) Amendment 45		
	(hc) 'gluten' means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives thereof and which is insoluble in water and 0.5 M sodium chloride solution;		***Council's remarks:*** *Not acceptable. Incompatible with the approach of regulating gluten free products in the context of Regulation (EU) No 1169/2011.*
	Article 2(2)(hd) Amendment 46		
	(hd) 'food intended for use in low	***(i) 'total diet replacement for***	***Council's remarks:***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	calorie diets (LCD)' and 'food intended for use in very low calorie diets (VLCD)' means specifically formulated food which, when used as instructed by the manufacturer, replaces the total daily diet. ***VLCD products contain between 400 and 800 kcal per day.*** ***LCD products contain between 800 and 1200 kcal per day.***	***weight control' means food specially formulated for use in energy-restricted diets for weight reduction which, when used as instructed by the food business operator, replace the whole total daily diet.***	*1st part: covered by Council's position.* *2nd part: to be inserted in the delegated acts adopted in accordance to Article 10(2)(a).*
Article 2(2)(1a) **Amendment 47**			
	Foods for special medical purposes within the meaning of point (h) of the first subparagraph fall into one of the following three categories: ***(i) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;*** ***(ii) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with***		***Council's remarks:*** *The description of foods for special medical purposes should not be in the basic act.* *Definition in point (h) of Article 2(2) is detailed enough.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended; ***(iii) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.***		
Article 2(3) **Amendment 48**			
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.	***deleted***	*Deleted*	**ACCEPTABLE**
Article 2a			
		Article 2a ***Interpretation decisions*** ***In order to ensure the uniform implementation of this Regulation, the Commission may adopt***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		implementing acts to decide: ***– whether or not a given food falls within the scope of this Regulation;*** ***– to which specific category referred to in Article 1(1) a given food belongs.*** ***Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).***	
Article 3(1) **Amendment 49**			
CHAPTER II **PLACING ON THE MARKET** *Article 3* ***Placing on the market*** Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation.	**CHAPTER II** **PLACING ON THE MARKET** *Article 3* ***Placing on the market*** **1**. Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation ***and Union law applicable to food.***	**CHAPTER II** **PLACING ON THE MARKET** *Article 3* ***Placing on the market*** ***1.*** Food referred to in Article 1(1) may be placed on the market only if it complies with the provisions of this Regulation.	***Council's remarks:*** *Repeats Article 7(1).*
Article 3(2) **Amendment 49**			
	2. Food imported into the Union for the purpose of being placed on the market shall comply with the applicable provisions of Union food law. Food exported or re-exported from the Union for the purpose of being placed on the		***Council's remarks:*** *Covered by Article 11 and 12 of Regulation (EC) No 178/2002.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	market in a third country shall comply with the applicable provisions of Union food law, save if specific circumstances in the importing country, linked, for example, to climate or topography, justify a different composition and a different market preparation.		
Article 3(3) **Amendment 49**			
	3. Food referred to in Article 1(1) may only be placed on the market in the form of pre-packed food.	***2.*** Food referred to in Article 1(1) shall only be allowed on the retail market in the form of ***prepacked*** food**.**	**ACCEPTABLE, with different drafting.** *Moved from Article 4*
Article 3(4) **Amendment 49**			
	4. Member States may not restrict or forbid the placing on the market of food which complies with this Regulation, for reasons related to their composition, manufacturing, presentation or labelling.	***3.*** Member States may not restrict or forbid the placing on the market of food which complies with this Regulation for reasons related to ***its*** composition, manufacturing, presentation or labelling.	**ACCEPTABLE, with legal-linguistic correction.** *Moved from Article 5*
Article 3(1a) **Amendment 50**			
	1a. In order to enable food referred to in Article 1(1) and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting		***Council's remarks:*** *Unnecessary given the possibility to amend delegated acts (Article 10(3)).* *See also Council's position for Recital 29b.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	the Authority, adopt delegated acts in accordance with Article 15 authorising, for a two-year period, the placing on the market of food referred to in Article 1(1), which does not comply with the rules on composition laid down by this Regulation and by the delegated regulations adopted pursuant to this Regulation for food referred to in Article 1(1).		
Article 4 **Amendment 51**			
Article 4 ***Pre-packaged food*** Food referred to in Article 1(1) shall only be allowed on the retail market in the form of pre-packaged food.	***deleted***	*Moved to Article 3(2)*	
Article 5 **Amendment 52**			
Article 5 ***Free movement of goods*** Member States may not, for reasons related to their composition, manufacturing, presentation or labelling, restrict or forbid the placing on the market of food which complies with this Regulation.	***deleted***	*Moved to Article 3(3)*	
Article 6(1)			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 6 ***Emergency measures*** 1. Where it is evident that a food referred to in Article 1(1) is likely to constitute a serious risk to human health and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission on its own initiative or at the request of a Member State, shall without delay take any appropriate interim emergency measures, including measures restricting or prohibiting the placing on the market of the food concerned, depending on the gravity of the situation. Those measures shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 14(2).		*Deleted*	***Council's remarks:*** *Article 6 repeats Articles 53 and 54 of Regulation (EC) No 178/2002.*
Article 6(2)			
2. On duly justified imperative grounds of extreme urgency to contain and/or address a serious risk to human health, the Commission shall adopt immediately applicable implementing acts in accordance		*Deleted*	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
with the procedure referred to in Article 14(3).			
Article 6(3)			
3. Where a Member State officially informs the Commission of the need to take emergency measures and the Commission has not acted in accordance with paragraph 1, the Member State concerned may adopt any appropriate interim emergency measures, restricting or prohibiting the placing on the market of the food concerned, depending on the gravity of the situation, within its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. The Commission shall adopt implementing acts aiming at extending, amending or abrogating the national interim emergency measures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2). The Member State may maintain its national interim emergency measures until the implementing acts mentioned in this paragraph have been adopted.		*Deleted*	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 6a **Amendment 53**			
	Article 6a. ***Precautionary principle*** ***Where, following an assessment of available scientific information, there are reasonable grounds for concern for the possibility of adverse effects but scientific uncertainty persists, provisional risk management measures may be adopted that are necessary to ensure a high level of protection of the vulnerable groups of the population for whom the food referred to in Article 1(1) is intended.***		***Council's remarks:*** *Covered by Article 7(1) of Regulation (EC) No 178/2002.*
Article 6b **Amendment 54**			
	Article 6b ***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.***		***Council's remarks:*** *Unnecessary. Established by Regulation (EC) No 882/2004.*
Article 7(1)			
CHAPTER III **REQUIREMENTS**			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Section 1 **Introductory provisions** *Article 7* ***Introductory provisions*** 1. Food referred to in Article 1(1) shall comply with any requirement of Union law applicable to food.			
Article 7(2) **Amendment 55**			
2. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.	***deleted***	*Moved to Article 1(2a))*	***Council's remarks:*** *See Council's remarks for Article 1(2a).*
Article 8			
Article 8 ***Opinions of the Authority*** The European Food Safety Authority shall provide scientific opinions in accordance with Articles 22 and 23 of Regulation (EC) No 178/2002 for the purpose of application of the present Regulation.		*Article 8* ***Opinions of the Authority*** The Authority shall provide scientific opinions in accordance with Articles 22 and 23 of Regulation (EC) No 178/2002 for the purpose of application of ***this*** Regulation. ***These opinions ~~will~~ shall serve as the scientific basis for any Union measure adopted pursuant to this Regulation which is likely to have an effect on public health.***	
Article 8a **Amendment 56**			
	Article 8a ***Food for normal consumption***		**TO BE CONSIDERED** ***Council's remarks*:**

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	In the labelling, presentation and advertising of food 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 such food;*** ***(b) all other markings or any presentation likely to give the impression that the food belongs to one of the categories referred to in Article 1(1).***		**1) Referring to 'food for normal consumption', such an Article should find its place in Regulation (EU) No 1169/2011. Anyway, it is not appropriate to refer to "specialised nutrition" as the expression has no signification** **2) Point (b) is already covered by Article 7 of Regulation (EU) No 1169/2011.**
Article 9(1) **Amendment 57**			
Section 2 **General requirements** *Article 9* ***General composition and information requirements*** 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.	**Section 2** **General requirements** *Article 9* ***General composition and information requirements*** 1. The composition of food referred to in Article 1(1) shall be such that it is appropriate to satisfy the nutritional needs of, and it is suitable for the persons to whom it is intended, in accordance with generally accepted ***peer-reviewed and independently evaluated*** scientific data ***and medical opinion***.	~~**Section 2**~~ ~~**General requirements**~~ *Article 9* ***General compositional and information requirements***	***Council's remarks:*** *A "peer review" would limit the possibility for EFSA to assess safety and suitability issues.* *The other parts of the amendment are not necessary.*
Article 9(2)			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons to whom they are intended.		2. Food referred to in Article 1(1) shall not contain any substance in such quantity as to endanger the health of the persons to whom ~~they are~~ ***it is*** intended.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 9(2a)			
		2a. Without prejudice to Article 3, food referred to in Article 1(1) may contain substances covered by Article 1 of Regulation (EC) No 258/97 ~~concerning novel foods and novel food ingredients~~, provided that those substances fulfil the conditions for placing on the market under Regulation (EC) No 258/97.	
Article 9(3) **Amendment 58**			
3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ***provide adequate consumer information*** and must not be misleading.	3. The labelling, presentation and advertising of food referred to in Article 1(1) shall ***be accurate, clear and easy to understand for consumers*** and must not be misleading. ***It shall not attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.***	3. The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information ***for the appropriate use of the food,*** and ***shall*** not be misleading, ***nor attribute properties to such products for the prevention, treatment or cure of human disease, or imply such properties.***	***Council's remarks:*** *The 1st part of the EP amendment repeats Article 7(2) of Regulation (EU) No 1169/2011.* *The 2nd part is* **ACCEPTABLE.**
Article 9(3a) **Amendment 59**			
	3a. The labelling of infant		***Council's remarks:***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	formulae and follow-on formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. Graphic representations for easy identification of the product and for illustrating methods of preparation shall, however, be permitted. Directive 2006/141/EC shall be amended accordingly.		*To be considered in the context of delegated acts.*
Article 9(4) **Amendment 60**			
4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in Article 1 (1) may be made exclusively by persons having qualifications in medicine, nutrition, pharmacy ***or other*** professionals ***responsible for maternal and child health care***.	4. The dissemination of any useful information or recommendations with reference to the categories of food referred to in ***points (a), (b) (c) and (ca) of*** Article 1 (1) may be made exclusively ***to*** persons having qualifications in medicine, nutrition ***or*** pharmacy***. Additional information disseminated by health care*** professionals ***to the final consumer shall only be of a scientific and factual nature and shall not constitute advertising.***	4. ***Paragraph 3 shall not prevent*** the dissemination of any useful information or recommendations ***exclusively intended for*** persons having qualifications in medicine, nutrition, pharmacy or other ***health care*** professionals responsible for maternal and child care.	
Article 9(4a) **Amendment 61**			
	4a. In order to ensure efficient official monitoring, food business operators shall notify the		***Council's remarks:*** *For reasons of flexibility, the issues of notification should be tackled by*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	competent authority of each Member State in which they place on the market food referred to in Article 1(1), by forwarding it a model of the product's label.		*delegated acts – cf. Art. 10(2)(d) – or at national level, and not provided as a general obligation for all products covered by the scope of the proposed regulation, with the risk of creating an unnecessary huge administrative burden.*
Article 9(4a) Amendment 62			
	4b. The use of pesticides in agricultural products intended for the production of food referred to in Article 1(1) shall be restricted as far as possible, without prejudice to Directive 2006/125/EC and Directive 2006/141/EC.		**TO BE CONSIDERED *Commment:* The use of pesticides should be tackled by delegated acts (see art. 10(2)(b), recitals 17a, 17b)**
Article 9(4a) Amendment 63			
	4c. Specific provisions relating to food referred to in Article 1(1)that lay down limitations on the use of or that ban certain pesticides shall be updated regularly, with particular attention being paid to pesticides containing active substances, safeners or synergists classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on		***Council's remarks:*** *See Council's position for Recitals 17a and 17c.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	classification, labelling and packaging of substances and mixtures[49] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, considered to have endocrine-disrupting properties that may cause adverse effects in humans, or pesticides approved as 'candidate for substitution' pursuant to Article 24 of Regulation (EC) No 1107/2009.		
Article 10(1)			
Section 3 **Specific requirements** *Article 10* ***Specific composition and information requirements*** 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.		**Section 2** **Specific requirements** *Article 10* ***Specific compositional and information requirements*** 1. *Deleted*	***Council's remarks:*** *Article 10(1) is superfluous as it repeats what is already stated in Article 7 and 9.*
Article 10(2) **Amendment 64**			
2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive	2. Subject to the general requirements of Articles 7 and 9***, and to the specific requirements of Articles 10a and 10b,*** and taking	2. Subject to the general requirements of Articles 7 and 9 and taking into account ~~any~~ ***relevant*** technical and scientific	

[49] ***OJ L 353, 31.12.2008, p. 1.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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:	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 as referred to in Article 6(a),*** the Commission shall be empowered to adopt delegated ***acts for foods referred to in Article 1(1)*** no later than [2 years after the date of the entry into force of this Regulation], in accordance with Article 15, with respect to the following:	progress, the Commission shall be empowered to adopt delegated ***acts*** in accordance with Article 15, with respect to the following:	
Article 10(2)(a)			
(a) the specific compositional requirements of food referred to in Article 1(1);		(a) the specific compositional requirements of food referred to in Article 1(1), ***with the exception of requirements as set out in accordance with Article 11;***	
Article 10(2)(b)			
(b) the specific requirements on the use of pesticides in agricultural products intended for the production of such food and on pesticides residues in such food;		(b) the specific requirements on the use of pesticides in ***products of plant and animal origin*** intended for the production of food ***referred to in Article 1(1)*** and on pesticides residues in such food;	
Article 10(2)(c) **Amendment 66**			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1), including the authorisation of nutrition and health claims thereof;	(c) the specific requirements on labelling, presentation and advertising of food referred to in Article 1(1); ***those requirements shall include the specific related rules already in force for food referred to in Article 1(1);***		***Council's remarks:*** *Should be specified in a recital rather than in an Article. Anyway, not all the requirements of the rules in force could be transferred to delegated acts due to the change in the legislative approach.*
Article 10(2)(ca) Amendment 67			
	(ca) the requirements for information to be provided on recommendations for appropriate use of food referred to in Article 1(1).		***Council's remarks:*** *Covered by Article 9(3).*
Article 10(2)(d)			
(d) the notification procedure for the placing on the market of a food referred to in Article 1(1) in order to facilitate the efficient official monitoring of such food on the basis of which food operators shall notify the competent authority of the Member State(s) where the product is being marketed;		(d) the notification for the placing on the market of ~~a~~ food referred to in Article 1(1) in order to facilitate the efficient official monitoring of such food on the basis of which food ***business*** operators shall notify the competent authority of the Member State(s) where the product is being marketed;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 10(2)(e)			
(e) the requirements on promotional and commercial practices relating to infant formulae; and,		(e) the requirements on promotional and commercial practices relating to infant formula~~e~~; and	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 10(2)(f)			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
(f) the requirements on information to be provided on infant and young child feeding in order to ensure adequate information on appropriate feeding practices.			
Article 10(2)(fa) Amendment 68			
	(fa) a requirement for post-market monitoring in order to verify whether the specific requirements are being complied with.		***Council's remarks:*** *Repetition of a general obligation provided for in Regulation (EC) No 882/2004.*
Article 10(2) last sub-paragraph			
		Those delegated acts shall be adopted no later than[50] […].	
Article 10(3) subparagraph 1 Amendment 69			
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 ***general*** requirements of Articles 7 and 9***, and to the specific requirements of Articles 10a and 10b,*** and taking into account relevant technical and scientific progress, ***in particular the results of new risk assessments and the precautionary principle as referred to in Article 6a),*** the Commission shall update the delegated ***acts*** mentioned in paragraph 2 *of this Article* in accordance with Article 15.	3. Subject to the ***general*** requirements of Articles 7 and 9 and taking into account relevant technical and scientific progress, ***including data provided by interested parties in relation to innovative products,*** the Commission ***shall be empowered to adopt delegated acts aimed at updating the delegated acts*** mentioned in paragraph 2 ***of this Article*** in accordance with Article 15.	

[50] ***2 years after the date of the entry into force of this Regulation.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 10(3) subparagraph 2			
Where in the case of emerging health risks, imperative grounds of urgency so require, the procedure provided in Article 16 shall apply to delegated acts adopted pursuant to this paragraph.		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.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 10a **Amendment 70**			
	Article 10a ***Food for people intolerant to gluten*** ***In addition to the requirements of Article 9, food intended for people intolerant to gluten consisting of or containing one or more ingredients made from wheat, rye, barley, oats or their crossbred varieties which have been especially processed to reduce gluten, shall contain a level of gluten not exceeding 100 mg/kg in the food as sold to the final consumer.*** ***Food intended for people intolerant to gluten sold to the final consumer which contain a level of gluten not exceeding 100***		***Council's remarks:*** *Not acceptable.* *To be covered in the implementing acts to be adopted in the context of Regulation (EU) No 1169/2011.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	mg/kg may be labelled 'very low gluten content'. ***Food intended for people intolerant to gluten sold to the final consumer which contain a level of gluten not exceeding 20 mg/kg may be labelled 'gluten free'.*** ***Food intended for people intolerant to gluten shall also comply with the following criteria:*** ***– they shall provide roughly the same amount of vitamins and mineral salts as the foodstuffs they are replacing,*** ***– they shall be prepared with special care, in compliance with good manufacturing practice (GMP), to avoid gluten contamination,*** ***– where the terms 'very low gluten content' or 'gluten free' are used, they shall appear in proximity to the name under which the product is marketed.***		
Article 10aa			
		Article 10aa ***Milk-based drinks and similar products intended for young***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		children ***By[51] […], the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the desirability of special provisions for milk-based drinks and similar products intended for young children with regard to composition, labelling and , if appropriate, other types of requirements. The Commission may accompany this report with a legislative proposal.***	
Article 10ab			
		Article 10ab ***Foods intended for sportsmen*** ***By[52] […], the Commission shall, after consulting the Authority, present to the European Parliament and to the Council a report on the desirability of special provisions for food intended for sportsmen with regard to composition, labelling and, if appropriate, other types of requirements. In its report, the Commission shall, in particular,***	

[51] ***2 years after the date of the entry into force of this Regulation.***
[52] ***2 years after the entry into force of this Regulation.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		evaluate whether specific provisions are needed to ensure the protection of vulnerable consumers, such as children and young people who use food intended for sportsmen in their diet. The Commission may accompany this report with a legislative proposal.	
Article 10b **Amendment 71**			
	Article 10b ***Foods intended for use in low calorie diets and very low calorie diets*** ***1. LCD and VLCD products shall comply with the compositional requirements set out in the Annex to this Regulation.*** ***2. All individual components making up LCD and VLCD products, as sold, shall be contained in a single package.*** ***3. The name under which LCD and VLCD products are sold shall be:*** ***(a) for VLCD products, 'Total diet replacement for use in very low calorie diets';*** ***(b) for LCD products, 'Total diet replacement for use in***		***Council's remarks:*** *To be considered in the context of delegated acts.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	low calorie diets' ***4. The labelling of LCD and VLCD products shall bear, in addition to those provided for in Chapter IV of Regulation (EU)No 1169/2011, the following mandatory particulars:*** ***(a) the available energy value expressed in kJ and kcal, and the content of proteins, carbohydrates and fat, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;*** ***(b) the average quantity of each mineral and each vitamin for which mandatory requirements are stipulated in paragraph 5 of the Annex to this Regulation, expressed in numerical form, per specified quantity of the product ready for use as proposed for consumption;*** ***(c) instructions for appropriate preparation, when necessary and a statement as to the importance of following those instructions;*** ***(d) if a product, when used as instructed by the manufacturer, provides a daily intake of polyols in excess of 20 g per day, there***		

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	shall be a statement to the effect that the food may have a laxative effect; ***(e) a statement on the importance of maintaining an adequate daily fluid intake;*** ***(f) a statement that the product provides adequate amounts of all essential nutrients for the day;*** ***(g) a statement that the product should not be used for more than three weeks without medical advice;*** ***5. The labelling, advertising and presentation of LCD and VLCD products concerned shall not make any reference to the rate or amount of weight loss which may result from their use.***		
Article 10c **Amendment 72**			
	Article 10 c ***Access for SMEs to internal market*** ***The Commission shall, in close cooperation with all stakeholders and the Authority, adopt appropriate guidelines and provide technical guidance to enable undertakings, in particular small and medium-sized enterprises, to***		***Council's remarks:*** *To be discussed with the EP in general.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	comply with the requirements laid down in this Regulation and assist them in the preparation and presentation of the application for scientific assessment. The Commission shall be empowered to adopt delegated acts in accordance with Article 15 in order to adopt those guidelines.		
Article 11(1) **Amendment 87**			
CHAPTER IV **UNION LIST OF PERMITTED SUBSTANCES** *Article 11* ***Union list of permitted substances***	**CHAPTER IV** **UNION LIST OF PERMITTED SUBSTANCES** *Article 11* ***Establishment of a*** list of permitted substances 1. ***Taking account of Directives 2006/141/EC and 2006/125/EC and Regulation (EC) No 953/2009, the Commission shall be empowered to adopt, no later than ... [2 years after the date of entry into force of this Regulation], delegated acts in accordance with Article 15, in order to insert in Annex -1 a list of vitamins, minerals and other substances which may be added to each category of food referred to in Article 1(1).***	**CHAPTER IV** **UNION LIST ~~OF PERMITTED SUBSTANCES~~** *Article 11* ***Union list ~~of permitted substances~~***	***Council remarks*:** **1) The reasons why the Council suggests to establish the Union list and to subsequently update it by means of implementing acts are the following:** • **The Union list is to be established and updated on the basis of the criteria provided for in the Regulation.** • **As such, the Union list does not amend, nor supplements non-essential elements of the Regulation (i.e. it does not establish a new substantial requirement/rule/principle), as it is required by Article 290**

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
1. Vitamins, minerals, amino acids and other substances may be added to food referred to in Article 1(1), provided that such substances meet the following conditions:	***2.*** Vitamins, minerals, amino acids and other substances may be added to food referred to in Article 1(1), provided that such substances meet the following conditions:	1. Vitamins, minerals, amino acids**,** ***carnitine, taurine, nucleotides, choline and inositol*** may be added to food referred to in Article 1(1), provided that ***they are included in the Union list.*** **1a**. ***Substances belonging to the categories listed in paragraph 1 shall be included in the Union list***, provided that, ***on the basis of generally accepted scientific data***, they meet ***each*** of the following ***criteria***:	**TFEU.** • **It rather gives effect to the rules (criteria) already laid down in the Regulation. It actually brings into life that legislation without changing its content.** • **Therefore, the conditions for delegated acts under Article 290 TFEU are not met.** **2) Repealed Directives should not be mentioned in the enacting part of the Regulation.**
Article 11(1)(a) **Amendment 87**			
(a) they do not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer; and,	a) they do not, on the basis of the ***generally accepted and peer-reviewed*** scientific evidence available, pose a safety concern to the health of the consumer;	a) they do not pose a safety concern to the health of the consumer;	
Article 11(1)(b)			
(b) they are available for use by the human body.		b) they are ***bio***-available for use by human body;	
Article 11(1)(ba) **Amendment 87**			
	(ba) they are suitable for the nutritional use for which they are	***d) they are suitable for the persons to whom the category (categories)***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	intended;	***of food referred to in Article 1(1) are intended for.***	
Article 11(1)(bb) Amendment 87			
	(bb) they have, on the basis of generally accepted scientific evidence, a nutritional or physiological effect.	***c) they do have a nutritional or physiological effect;***	
Article 11(2a) Amendment 87			
	2a. For substances referred to in paragraph 2 that are engineered nanomaterials, the following additional conditions shall apply:		
Article 11(2a)(a) Amendment 87			
	(a) the condition in point (a) of paragraph 2 has been demonstrated on the basis of adequate test methods; and		
Article 11(2a)(b) Amendment 87			
	(b) their nutritional value and the suitability for the persons for whom they are intended has been shown.		
Article 11(1x)			
		1x. For the purposes of taking into account technical progress, scientific developments or	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		consumers' health, the Commission shall be empowered to adopt delegated acts in accordance with Article 15 to provide for additional categories of substances that have a nutritional or physiological effect to the categories referred to in paragraph 1 of this Article.	
Article 11(1y)			
		1y. Substances belonging to categories not listed in paragraph 1 of this Article may ~~still~~ be added to food referred to in Article 1(1), provided that they satisfy the criteria set out in paragraph 1a of this Article, the requirements set out in Articles 7 and 9 and, where applicable, the requirements established in accordance with Article 10.	
Article 11(1z)			
		1z. The entry of a substance into the Union list shall include: ***– the name, the description of the substance and, where appropriate, the specification of its form;*** ***– where appropriate, the conditions of use;***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		– ***the purity criteria.***	
Article 11(2)			
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).		2. ~~No later than~~ ***By***[53] […], the Commission shall ~~establish~~, by means of implementing ***acts, establish the Union list referred to in paragraph 1 of this Article.*** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2). ~~***The Commission shall, pursuant to paragraphs 2a to 4c, update the Union list.***~~	
Article 11a			
		Article 11a	***Council's remarks:***

[53] ***2 years after the date of the entry into force of this Regulation.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		Updating the Union list ***~~2a.~~ 1. ~~"Updating the~~ The Union list~~" means~~ may be updated in order to:*** ***(a) add~~ing~~ a substance to the Union list;*** ***(b) remove~~ing~~ a substance from the Union list;*** ***(c) add~~ing~~, remove~~ing~~ or amend~~ing~~ the specifications, conditions of use, or the applicable purity criteria associated with the presence of a substance on the Union list.***	*Separation on a new Article suggested by the Lawyers-Linguists.*
Article 11a(1) **Amendment 88**			
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.***	***Article 11a*** ***Updating of the list of permitted substances*** ***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').	***~~3.~~ 2. The updating of the Union list*** 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 ***submitted*** to the Commission. ***Where the Commission starts the procedure to update the Union list on its own initiative, the Commission shall inform the***	***Council's remarks*:** *Article 11a should be consistent with the option adopted for Article 11.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		Member States.	
Article 11a(1a) Amendment 88			
	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.		
Article 11a(2)(a) Amendment 88			
4. The application shall include: (a) the name and the address of the applicant;	***2.*** The application shall include: (a) the name and the address of the applicant;	~~4.~~ ***3.*** The application shall include: (a) the name and the address of the applicant;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 11a(2)(b) Amendment 88			
(b) the name and a clear description of the substance;			
Article 11a(2)(c) Amendment 88			
(c) the composition of the substance;			
Article 11a(2)(d) Amendment 88			
(d) the proposed use of the substance and conditions thereof;			
Article 11a(2)(e) Amendment 88			
(e) a systematic review of the scientific data and appropriate	(e) a systematic review of the scientific data and appropriate		

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
studies performed following generally accepted expert guidance on the design and conduct of such studies;	***peer-reviewed*** studies performed following generally accepted expert guidance on the design and conduct of such studies;		
Article 11a(2)(f)			
(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;			
Article 11a(2)(g) **Amendment 88**			
(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***;	g) scientific evidence demonstrating that the substance is ***bio***-available for use by the human body ***and has a nutritional or a physiological effect;***	
Article 11(4)(h)			
(h) a summary of the content of the application.			
Article 11(4)(i)			
		i) the production method;	
Article 11(4)(j)			
		j) where applicable, the analysis method;	
Article 11(4)(k)			
		k) the purity criteria.	
Article 11(4a)			
		4a. ~~4.~~ Within 2 months of	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		receiving an application to update the Union list, the Commission shall send to the applicant a written acknowledgement, stating the date of receipt, and informing him whether the submitted application contains all the elements provided for in paragraph 4 in order to be admissible. Where one or more of the elements provided for in paragraph 4 are missing, the Commission shall inform the applicant, setting a period for their submission. Where at the end of that period, the applicant has not submitted the missing elements, the application is considered inadmissible.	
Article 11(4b)			
		4b. ~~5.~~ Where an application does not meet the conditions of this Article, the Commission shall decide not to proceed with the update of the Union list and shall inform the applicant and the Member States accordingly indicating the reasons for its decision.	
Article 11(4c)			
		4c. ~~6.~~ Where an application or	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		initiative of the Commission to update the Union list meets the conditions of this Article, the Commission shall, by means of implementing acts, update the Union list. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2). ***On duly justified imperative grounds of extreme urgency relating to emerging health risks, the Commission shall adopt immediately applicable implementing acts updating the Union list in accordance with the procedure referred to in Article 14(3).***	
Article 11a(3) **Amendment 88**			
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***	***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	*Deleted*	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
list shall ***be modified accordingly before it can be placed on the Union market***.	substance ***which is not included in Annex - 1 and which*** shall ***require a separate application***.		
Article 11a(4) Amendment 88			
	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.		
Article 11a(5) Amendment 88			
	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.		
Article 11a(6) Amendment 88			
	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		

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	provided for in Article 16 shall apply to delegated acts adopted pursuant to this paragraph.		
Article 12(1)			
Article 12 ***Confidential information relating to applications*** 1. Among the information provided in the application referred to in Article 11, confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of the applicant.			
Article 12(2)			
2. Information relating to the following shall not, in any circumstances, be regarded as confidential:			
Article 12(2)(i)			
(i) the name and address of the applicant;		(~~i~~ ***a***) the name and address of the applicant;	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*
Article 12(2)(ii)			
(ii) the name and description of the substance;		(~~ii~~ ***b***) the name and description of the substance;	
Article 12(2)(iii)			
(iii) the justification for the use of the substance in or on specific food;		(~~iii~~ ***c***) the justification for the use of the substance in or on specific food;	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 12(2)(iv)			
(iv) information that is relevant to the assessment of the safety of the substance;		(~~iv~~ ***d***) information that is relevant to the assessment of the safety of the substance;	
Article 12(2)(v)			
(v) where applicable, the analysis method(s) used by the applicant.		(v ***e***) where applicable, the analysis method(s) used by the applicant.	
Article 12(2)(va) **Amendment 75**			
	(va) any scientific data gathered from animal testing for the assessment of the safety of the substance.		***Council's remarks****:* *Covered by Article 12 (2)(iv)*
Article 12(3)			
3. Applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.		3. Applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification ***shall*** be given in such cases.	
Article 12(4)			
4. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.		4. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants**,** the Member States ***and the Authority*** accordingly.	
Article 12(5)			
5. After being made aware of the Commission's position, applicants shall have three weeks in which to			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.			
Article 12(6)			
		6. The Commission, the Member States and the Authority shall keep confidential all the information identified as confidential under ~~the previous paragraphs~~ paragraph 3, subject to the conditions set out in paragraph 5, and the information identified as confidential under paragraph 4. ***Notwithstanding the ~~previous~~ first subparagraph, the Commission shall make public such information where this is appropriate in order to protect human health, animal health or the environment.***	
Article 13 **Amendment 76**			
CHAPTER V **CONFIDENTIALITY** *Article 13* ***General confidentiality clause*** The Commission, the Authority and the Member States shall, in	**CHAPTER V** **CONFIDENTIALITY** *Article 13* General ***transparency and*** confidentiality clause The Commission, the Authority and	**CHAPTER V** **CONFIDENTIALITY** *Article 13* ***Access to documents*** ***The Commission shall apply Regulation (EC) No 1049/2001 to***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.	the Member States shall, in accordance with Regulation (EC) No 1049/2001, ***guarantee the broadest possible access to documents and, in particular, shall assist members of the public with, and inform them about, the procedures for submitting applications for access to documents***. ***They shall also*** take the necessary measures to ensure appropriate confidentiality of the information received by them under this Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.	***applications for access to any document covered by this ~~the present~~ Regulation.***	
Article 14(1)			
CHAPTER VI **PROCEDURAL PROVISIONS** *Article 14* ***Committee*** 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		**CHAPTER VI** **PROCEDURAL PROVISIONS** *Article 14* ***Committee procedure*** 1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health ***established by Regulation (EC) No 178/2002***. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Article 14(2)			
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.			
Article 14(3)			
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.			
Article 15(1)			
Article 15 ***Exercise of the delegation*** 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.			
Article 15(2) **Amendment 77**			
2. The ***delegation of*** power referred to in Articles ***2(3) and 10*** of this Regulation shall be conferred for	2. The power ***to adopt delegated acts*** referred to in Articles ***3(1a), 10(2) and (3), 10c, 11(3)*** and	2. The power ***to adopt delegated acts*** referred to in Articles 10 ***and 11(1b)*** shall be conferred ***on the***	

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
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.]***	***11a(6)*** shall be conferred for ***a*** period ***of 5 years from ... [date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegation of power not later than nine 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.***	***Commission*** for **a** period of time ***of 5 years from [...][54]. The Commission shall draw up a report in respect of the delegation of power not later than nine 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.***	
Article 15(3) **Amendment 78**			
3. ***The delegation of powers*** referred to in Articles ***2(3) and*** 10 of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified	3. The ***power to adopt delegated acts*** referred to in Articles ***3(1a), 10(2) and (3), 10c, 11(3) and 11a(6)*** of this Regulation may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of	3. The delegation of powers referred to in Articles 10 ***and 11(1b)*** may be revoked at any time by the European Parliament or by the Council. A decision ***to revoke*** shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not	

[54] ***Date of the entry into force of this Regulation.***

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
therein. It shall not affect the validity of any delegated acts already in force.	the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	affect the validity of any delegated acts already in force.	
Article 15(4)			
4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.			
Article 15(5) **Amendment 79**			
5. A delegated act adopted pursuant to ***Articles 2(3)*** and ***10*** of this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.	5. A delegated act adopted pursuant to ***Articles 3(1a), 10(2) and (3), 10c, 11(3) and 11a(6)*** of this Regulation shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or the Council.	5. A delegated act adopted pursuant to Articles 10 ***and 11(1b)*** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of ***two*** months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by ***two*** months at the initiative of the European Parliament or ***of*** the Council.	
Article 16(1)			
Article 16			

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Urgency procedure 1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.			
Article 16(2)			
2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 15. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.		2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 15. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or ***by*** the Council.	***Council's remarks***: *The suggestion of the Council is of legal-linguistic nature only.*
Article 16a **Amendment 80**			
	Article 16a ***Food for people intolerant to lactose*** ***By ... [1 year after entry into force of this Regulation], the Commission shall present a report, if appropriate accompanied by a legislative proposal, to the European Parliament and to the***		***Council's remarks***: *See Council's position for Recital 26a.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	Council, in order to clarify the status of labelling indications of 'lactose free' and 'very low lactose content' under general food law.		
Article 16b **Amendment 81**			
	Article 16b ***Milks intended for young children*** ***By ... [1 year after the date of the entry into force of this Regulation], the Commission shall, after consulting the Authority, submit a report to the European Parliament and to the Council assessing the need for special provisions regarding the composition and labelling of milks intended for young children between one and three years. This report shall consider the nutritional needs, the pattern of consumption, the nutritional intake and the levels of exposure to contaminants and pesticides of these young children. The report shall also consider whether these milks have any nutritional benefits when compared to a normal diet for a child who is being weaned. In the light of the conclusions of that report, the Commission shall***		***Council's remarks***: *See Council's position for Article 10aa.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
	either: ***(a) decide that there is no need for special provisions regarding the composition and labelling of milks intended for young children; or*** ***(b) submit, if appropriate, in accordance with the ordinary legislative procedure and on the basis of Article 114 of the TFEU, any appropriate legislative proposal.*** ***Prior to the preparation of the above Commission report the milks intended for young children between one and three years shall continue to fall within the scope of the relevant Union legislation such as Regulation (EC) No 178/2002, Regulation (EC) No 1925/2006 and Regulation (EC) No 1924/2006;***		
Article 17(1)			
CHAPTER VII **FINAL PROVISIONS** *Article 17* ***Repeal*** 1. Directive 92/52/EEC and Directive 2009/39/EC are repealed from *[the first day of the month 2*		**CHAPTER VII** **FINAL PROVISIONS** *Article 17* ***Repeal*** 1. Directive 2009/39/EC ***is*** repealed ***with effect*** from[55]. References to the repealed acts shall be construed	***Council's remarks:*** *The suggestion of the Council is of legal-linguistic nature only.*

[55] ***3*** *years after the date of the entry into force of this Regulation.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
years after the date of the entry into force of this Regulation]. References to the repealed acts shall be construed as references to this Regulation.		as references to this Regulation.	
Article 17(1a)			
		1a. Directive 92/52/EEC and Regulation (EC) No 41/2009 are repealed with effect from[56] […].	
Article 17(1b)			
		1b. Without prejudice to the first subparagraph of paragraph 2, Directive 96/8/EC shall not apply to foods presented as replacement for one or more meals of the daily diet from[57] […].	
Article 17(2)			
2. Directive 96/8/EC and Regulation (EC) No 41/2009 are repealed from *[the first day of the month 2 years after the date of the entry into force of this Regulation].*		2. ***Directive***s 96/8/EC, ***2006/141/EC, 2006/125/EC, 1999/21/EC*** and Regulation (EC) ***No 953/2009*** are repealed from ***the date of application of the delegated acts referred to in Article 10(2) and of the implementing acts referred to in ~~the first subparagraph of~~ Article 11(2). ~~The delegated acts referred to in Article 10(2) and the~~***	

[56] ***3*** *years after the date of the entry into force of this Regulation.*
[57] ***3*** *years after the date of the entry into force of this Regulation.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		~~implementing acts referred to in the first subparagraph of Article 11(2) shall apply from the same date.~~ ***In case of conflict between Directives 96/8/EC, 2006/141/EC, 2006/125/EC, 1999/21/EC, Regulation (EC) No 953/2009 and this Regulation, provisions of this Regulation shall prevail.***	
Article 18			
Article 18 ***Transitional measures*** Food not complying with this Regulation but complying with Directives 2009/39/EC and 96/8/EC, Regulations (EC) No 41/2009 and (EC) No 953/2009, and labelled prior *to [2 years after the date of the entry into force of this Regulation]* may continue to be marketed after that date until stocks are exhausted.		*Article 18* ***Transitional measures*** 1. Food ***covered by Article 1(1) which does*** not comply with this Regulation but ***complies*** with Directives 2009/39/EC**,** 96/8/EC, ***2006/141/EC, 2006/125/EC, 1999/21/EC and*** Regulation (EC) No 953/2009, ***which is placed on the market or*** labelled before[58] […] may continue to be marketed after that date until stocks ***of such food*** are exhausted. ***Where the date of application of the delegated and implementing acts referred to in Article 17(2) is after[59] […], food covered by***	

[58] ***3*** *years after the date of the entry into force of this Regulation.*
[59] ***3*** *years after the date of the entry into force of this Regulation.*

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
		Article 1(1) which complies with this Regulation, Regulation (EC) No 953/2009, Directives 96/8/EC, 2006/141/EC, 2006/125/EC and 1999/21/EC but does not comply with the delegated and implementing acts referred to in Article 17(2), and which is placed on the market or labelled before the date of application of those delegated and implementing acts, may continue to be marketed after that date until stocks of such food are exhausted.	
Article 18(2)			
		2. Food which is not covered by Article 1(1) of this Regulation but which is placed on the market or labelled in accordance with Directives 2009/39/EC, 96/8/EC, Regulations (EC) 41/2009 and (EC) 953/2009 before[60] […] may continue to be marketed after that date until stocks of such food are exhausted.	
Article 19			
Article 19 ***Entry into force*** This Regulation shall enter into		*Article 19* ***Entry into force*** This Regulation shall enter into	

[60] ***3 years after the date of the entry into force of this Regulation***.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from [*the first day of the month 2 years after the entry into force*], This Regulation shall be binding in its entirety and directly applicable in all Member States.		force on the twentieth day following that of its publication in the *Official Journal of the European Union*. It shall apply from[61] […], ***with the exception of Articles 14 to 16, as well as the power conferred on the Commission in Articles 10(2), 10(3), 11(1b), 11(2) and 11(4c) which shall apply from the date of entry into force.*** ***For the purposes of Article 17(2), the delegated acts referred to in Article 10(2) and the implementing acts referred to in the first subparagraph of Article 11(2) shall apply from one and the same date, but not earlier than …[62].*** This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Done at Brussels, *For the European Parliament* *The President* *For the Council The President*		Done at …, *For the European Parliament* *The President* *For the Council The President*	

[61] ***3*** *years after the entry into force of this Regulation.*

[62] ***3 years after the entry into force of this Regulation***.

Commission's Proposal	EP's Position	Council's Position	Possible compromises/Remarks
Amendment 89 **Annex -1**			
	Annex -1 ***List of permitted substances***		***Council's remarks***: *Incompatible with the Council's position for Article 11.*
Annex **Amendment 82**			
	Compositional requirements for LCD and VLCD products ***These specifications refer to LCD and VLCD products ready for use, marketed as such or reconstituted as instructed by the manufacturer.*** ***1. Energy*** ***1.1. The energy provided by a VLCD product shall not be less than 1680 kJ (400 kcal) and shall not exceed 3360 kJ (800 kcal) for the total daily ration.*** ***1.2. The energy provided by a LCD product shall not be less than 3360 kJ (800 kcal) and shall not exceed 5040 kJ (1200 kcal) for the total daily ration.*** ***2. Protein*** ***2.1. The protein contained in LCD and VLCD products shall provide not less than 25 % and not more than 50 % of the total energy of the product. In any event the***		***Council's remarks:*** *See text under Council's proposal regarding Article 10(2)(b) (Amendment 71).*

	amount of protein of these products shall not exceed 125 g. ***2.2. Point 2.1 refers to a protein the chemical index of which is equal to that of the FAO/WHO (1985) reference protein set out in table 2. If the chemical index is lower than 100 % of the reference protein, the minimum protein levels shall be correspondingly increased. In any event the chemical index of the protein shall at least be equal to 80 % of that of the reference protein.*** ***2.3. The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein in and the quantity of each corresponding amino acid of the reference protein.*** ***2.4. In every event, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.*** ***3. Fat*** ***3.1. The energy derived from fat shall not exceed 30 % of the total available energy of the product.*** ***3.2. The linoleic acid (in the form***		

	of glycerides) shall not be less than 4,5 g. ***4. Dietary fibre*** ***The dietary fibre content of LCD and VLCD products shall not be less than 10 g and shall not exceed 30 g for the daily ration.*** ***5. Vitamins and minerals*** ***The LCD and VLCD products shall provide for the whole of the daily diet at least: 100 % of the amounts of vitamins and minerals specified in Table 1.***				
	Table 1				
	Vitamin A	***(µ RE)***	***700***		
	Vitamin D	***(µ)***	***5***		
	Vitamin E	***(mg-TE)***	***10***		
	Vitamin C	***(mg)***	***45***		
	Thiamin	***(mg)***	***1,1***		
	Riboflavin	***(mg)***	***1,6***		
	Niacin	***(mg-NE)***	***18***		
	Vitamin B_6	***(mg)***	***1,5***		
	Folate	***(µ)***	***200***		
	Vitamin B12	***(µ)***	***1,4***		
	Biotin	***(µ)***	***15***		
	Panthotenic acid	***(mg)***	***3***		
	Calcium	***(mg)***	***700***		
	Phophorus	***(mg)***	***550***		
	Potassium	***(mg)***	***3100***		
	Iron	***(mg)***	***16***		
	Zinc	***(mg)***	***9,5***		

	Copper	***(mg)***	***1,1***		
	Iodine	***(µ)***	***130***		
	Selenium	***(µ)***	***55***		
	Sodium	***(mg)***	***575***		
	Magnesium	***(mg)***	***150***		
	Manganese	***(mg)***	***1***		
	Table 2 AMINO ACID REQUIREMENT PATTERN[63]				
		g/100g protein			
	Cystine + methionine	***1,7***			
	Histidine	***1,6***			
	Isoleucine	***1,3***			
	Leucine	***1,9***			
	Lysine	***1,6***			
	Phenylalanine + tyrosine	***1,9***			
	Threonine	***0,9***			
	Thryptophan	***0,5***			
	Valine	***1,3***			

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[63] ***World Health Organisation. Energy and protein requirements. Report of a Joint FAO/WHO/UNU Meeting. Geneva: World Health Organisation, 1985. (WHO Technical Report Series, 724).***