Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2011/0156(COD)
Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control Repealing Directive 2009/39/EC 2008/0003(COD) Subject 3.10.10 Foodstuffs, foodstuffs legislation 4.60.02 Consumer information, advertising, labelling 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	ALDE RIES Frédérique	30/08/2011
Former committee responsible		
ENVI Environment, Public Health and Food Safety	ALDE RIES Frédérique	30/08/2011
Former committee for opinion		
ITRE Industry, Research and Energy	ALDE TAKKULA Hannu	27/09/2011
IMCO Internal Market and Consumer Protection	PPE IVANOVA Iliana	01/12/2011

Council of the European Union

Council configuration	Meeting	Date
Agriculture and Fisheries	3234	22/04/2013
Transport, Telecommunications and Energy	3213	20/12/2012
Employment, Social Policy, Health and Consumer Affairs	3206	06/12/2012
Transport, Telecommunications and Energy	3171	07/06/2012

European Commission

Commission DG	Commissioner
Health and Food Safety	BORG Tonio

European Economic and Social Committee

Key events

20/06/2011	Legislative proposal published	COM(2011)0353	Summary
05/07/2011	Committee referral announced in		

	Parliament, 1st reading		
29/02/2012	Vote in committee, 1st reading		
26/04/2012	Committee report tabled for plenary, 1st reading	A7-0059/2012	
07/06/2012	Debate in Council	3171	Summary
14/06/2012	Results of vote in Parliament		
14/06/2012	Debate in Parliament		
14/06/2012	Decision by Parliament, 1st reading	T7-0255/2012	Summary
23/04/2013	Council position published	05394/1/2013	Summary
23/05/2013	Committee referral announced in Parliament, 2nd reading		
29/05/2013	Vote in committee, 2nd reading		
04/06/2013	Committee recommendation tabled for plenary, 2nd reading	A7-0191/2013	Summary
11/06/2013	Debate in Parliament		
11/06/2013	Decision by Parliament, 2nd reading	T7-0242/2013	Summary
12/06/2013	Final act signed		
12/06/2013	End of procedure in Parliament		
29/06/2013	Final act published in Official Journal		

Technical information

Procedure reference	2011/0156(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 2009/39/EC 2008/0003(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/7/12020

Documentation gateway

Legislative proposal		COM(2011)0353	20/06/2011	EC	Summary
Document attached to the procedure		SEC(2011)0762	20/06/2011	EC	
Document attached to the procedure		SEC(2011)0763	20/06/2011	EC	
Economic and Social Committee: opinion, report		CES1604/2011	26/10/2011	ESC	

Committee draft report		PE478.337	30/11/2011	EP	
Amendments tabled in committee		PE480.592	26/01/2012	EP	
Amendments tabled in committee		PE480.605	26/01/2012	EP	
Committee opinion	ITRE	PE475.941	10/02/2012	EP	
Committee opinion	IMCO	PE478.334	15/02/2012	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0059/2012	26/04/2012	EP	
Text adopted by Parliament, 1st reading/single reading		T7-0255/2012	14/06/2012	EP	Summary
Commission response to text adopted in plenary		SP(2012)540	12/07/2012	EC	
Council statement on its position		08351/2013	17/04/2013	CSL	
Council position		05394/1/2013	23/04/2013	CSL	Summary
Commission communication on Council's position		COM(2013)0241	23/04/2013	EC	Summary
Committee draft report		PE510.618	08/05/2013	EP	
Committee recommendation tabled for plenary, 2nd reading		A7-0191/2013	04/06/2013	EP	Summary
Text adopted by Parliament, 2nd reading		T7-0242/2013	11/06/2013	EP	Summary
Draft final act		00034/2013/LEX	12/06/2013	CSL	
Follow-up document		COM(2016)0169	31/03/2016	EC	Summary
Follow-up document		SWD(2016)0099	31/03/2016	EC	
Follow-up document		COM(2016)0402	15/06/2016	EC	Summary
Follow-up document		COM(2017)0438	22/08/2017	EC	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2013/609
OJ L 181 29.06.2013, p. 0035 Summary

Final legislative act with provisions for delegated acts

Delegated acts

2015/2862(DEA)	Examination of delegated act
2015/2863(DEA)	Examination of delegated act
2015/2861(DEA)	Examination of delegated act
2017/2717(DEA)	Examination of delegated act

2020/2578(DEA)	Examination of delegated act
2018/2556(DEA)	Examination of delegated act
2019/2662(DEA)	Examination of delegated act
2017/2661(DEA)	Examination of delegated act
2021/2634(DEA)	Examination of delegated act
2021/2520(DEA)	Examination of delegated act
2022/2511(DEA)	Examination of delegated act
2021/2635(DEA)	Examination of delegated act
2021/2521(DEA)	Examination of delegated act
2022/3025(DEA)	Examination of delegated act
2023/2507(DEA)	Examination of delegated act
2022/2814(DEA)	Examination of delegated act

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

PURPOSE: to ensure a high level of consumer protection in relation to foods intended for infants and young children and to foods for special medical purposes.

PROPOSED ACT: Regulation of the European and of the Council.

BACKGROUND: the provisions of Directive 2009/39/EC were originally adopted in 1977. After several amendments, a recast version was adopted in 2009 to include the rules of the new Comitology procedure.

The main objective of the Framework Directive was to remove the differences between national laws relating to foodstuffs for particular nutritional uses, thus allowing their free movement and creating fair conditions of competitions.

Discussions with Member States and stakeholders have highlighted increasing difficulties for implementing the Framework Directive, in particular in relation to more recent pieces of Union legislation such as the legislation on food supplements, on the addition of vitamins and minerals and other substances to foods and nutrition and health claims.

This unclear situation has led also to distortions of trade in the internal market.

As foreseen in the Framework Directive, Member States were asked for their views and experience on the implementation of certain provisions of that Directive in order to prepare Commission reports on: (i) the implementation of the notification procedure of the Framework Directive on dietetic foods; (ii) the desirability of special provisions for foods for persons suffering from carbohydrate-metabolism disorders (diabetic foods).

As regards foods for diabetic people, the Commission's report concludes that there is no scientific basis on which to develop specific compositional requirements for this category of food and that diabetic people should eat as healthily as possible choosing a diet from a variety of food for normal consumption. Also, the report on the implementation of the notification procedure points out that the category of food regulated under that provision differs significantly between Member States creating as a result market distortions.

All abovementioned issues led to the need to consider an in-depth and global revision of the legislation on dietetic foods.

IMPACT ASSESSMENT: four options were assessed taking into account their economic, social and environmental impacts on the various stakeholders and authorities:

Option 1 ? Repeal all the legislation on dietetic foods (Framework Directive and all the specific Directives adopted under that Framework).

Option 2 ? Repeal the Framework Directive on dietetic foods but maintain certain of the specific rules adopted under that Framework.

Option 3 ? Revision of the Framework Directive establishing a positive list of dietetic foods with specific compositional and/or labelling rules.

Option 4 ? Amending the Framework Directive replacing the notification procedure with a centralised Union prior-authorisation procedure based on a scientific assessment.

The Commission proposal follows option 2 - Repeal the Framework Directive on dietetic foods but maintain certain of the specific rules adopted under that Framework.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU). This Article 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 takeas a base a high level of protection taking account in particular of any new development based on scientific facts.

CONTENT: the proposal revises the legislation on foodstuffs intended for particular nutritional uses covered by Directive 2009/39/EC the

so-called "Framework Directive on dietetic foods".

The proposal abolishes the concept of dietetic foods and provides for a new framework establishing general provisions only for a limited number of well-established and defined categories of food that are considered as essential for certain vulnerable groups of the population, i.e. food intended for infants and young children and food for patients under medical supervision.

The proposal provides the basis for the assurance of a high level of consumer protection in relation to foods intended for infants and young children and to foods for special medical purposes. It establishes also a single legal measure that regulates the list of substances that can be added to the foods covered by the proposal (Chapter I).

Chapters II and III provide for general principles and specific provisions that shall apply to infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children and foods for special medical purposes.

Chapter IV relates to the establishment of a Union list of substances that can be added to the foods covered by the proposal and provides for a procedure for updating the Union list.

Chapter V provides for a general confidentiality clause.

Chapter VI and VII concerns all the procedural provisions related to the implementation of the new proposal, the delegation of powers, the procedures, the necessary amendments and the measures that are to be repealed. It specifies also the transitional measures that would apply to the categories of foods currently regulated under Directive 2009/39/EC and the date of entry into force and application.

The proposal simplifies and clarifies legal requirements applying to certain categories of foods and establishes a single list of substances that may be added to the foods ('Union list') covered by this proposal. In particular, it:

- provides a new general Framework legislation applying to well-defined categories of foods that have been identified as essential for certain well-established groups of consumers with specific nutritional needs;
- establishes a clear and defined scope of application;
- maintains specific measures for categories of foods that are essential for certain groups of the population;
- lays down general rules as regards the composition and labelling applying to these categories of foods;
- removes differences in interpretation and difficulties for Member States and operators in applying different pieces of food legislation by simplifying the regulatory environment;
- removes the burdens associated with the notification procedure;
- ensures that similar products are treated in the same way across the Union;
- removes rules that have become unnecessary, contradictory and potentially conflicting.

BUDGETARY IMPLICATIONS: this proposal has no implications for the EU budget.

DELEGATED ACTS: the proposal contains provisions giving the Commission the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union, as regards the specific compositional and information requirements.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The Committee on the Environment, Public Health and Food Safety adopted a report by Frédérique RIES (ALDE, BEL) 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. The committee recommends that the position of the European Parliament in first reading following the ordinary legislative procedure should be to amend the Commission proposal. The main amendments are as follows:

Title: the new title will be Regulation 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.

Subject matter: the committee takes the view that substitute meals replacing all or part of a person's daily food intake (meeting nutritional needs in terms of vitamins, minerals, protein, essential fatty acids, fibre, etc.) should continue to be the subject of specific legislation. This is the best way of retaining some control over the composition of the foods in question and of ensuring that there is no confusion with the aspects linked to the health claims made for foodstuffs (Regulation (EC) No 1924/2006).

The Regulation, complementing Union law on food, establishes compositional and information requirements for certain categories of food, including food for special medical purposes, including formula intended for low birth-weight and pre-term infants, food for people intolerant to gluten, and foods intended for use in low calorie diets (LCD) and very low calorie diets (VLCD). VLCD products contain between 400 and 800 kcal per day. LCD products contain between 800 and 1200 kcal per day.

With regard to gluten, the committee notes that some essential guarantees that are offered in the current dietetic Framework Directive (2009/39/EC), in particular those concerning food for people intolerant to gluten have been removed from the scope of the proposed revision to the detriment of those suffering from Coeliac disease.

Members add that the requirements laid down in the Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

Definitions: the report amended some definitions and added clarification on the meaning of foods for special medical purposes. The committee considers that definitions should not be updated through delegated acts as they are an essential part of the Regulation and should be changed by the ordinary legislative procedure..

Placing on the market: Members state that 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 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.

Innovation clause: the report adds a new clause whereby In order to enable food referred to in the Regulation and resulting from scientific and

technological progress to be placed on the market rapidly, the Commission may, after consulting the European Food Safety Authority, adopt delegated acts authorising, for a two-year period, the placing on the market of foodstuffs which do not comply with the rules on composition laid down by the Regulation.

Members note that there is such a clause in the current legislation providing for an accelerated procedure under EFSA supervision. Although it is used only rarely, such a procedure must be retained in the proposal.

Precautionary principle: a new clause states that 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 the text is intended.

Oversight: 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.

Food for normal consumption: a new clause states that 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 the Regulation.

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

General composition and information requirements: the composition of the food shall be such that it is appropriate to satisfy the nutritional needs of persons to whom it is intended, in accordance with generally accepted peer-reviewed and independently evaluated scientific data and medical opinion. The labelling, presentation and advertising of the food 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.

Members tightened the Commission text, stating that the dissemination of any useful information or recommendations with reference to certain categories of food may be made exclusively to persons having qualifications in medicine, nutrition or pharmacy. Additional information disseminated by healthcare professionals to the final consumer shall only be of a scientific and factual nature and shall not contain advertising.

Infant formula: the labelling of infant formula and follow-on formula 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.

Pesticides: the use of pesticides in agricultural products intended for the production of the food shall be restricted as far as possible, without prejudice to Directive 2006/125/EC and Directive 2006/141/EC.

Specific provisions relating to the food 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 on classification, labelling and packaging of substances and mixtures1 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 Regulation (EC) No 1107/2009.

Delegated acts: the Commission is empowered to adopt delegated acts with regard to specific composition and information requirements of certain foods. This list is expanded in the report.

Food for people intolerant to gluten: in addition to other requirements in the text, the committee added that 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. There are further provisions on labelling for gluten. The statement very low gluten content should be used only for products that contain less than 100 mg of gluten per kg, while foods with less than 20 mg of gluten per kg may be labelled gluten free.

Foods intended for use in low calorie diets and very low calorie diets: a new clause sets out labelling requirements. In addition, LCD and VLCD products must comply with the compositional requirements set out in a new Annex to the Regulation.

Access for SMEs to the internal market: the Commission shall adopt appropriate guidelines through delegated acts and provide technical guidance to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in the Regulation and assist them in the preparation and presentation of the application for scientific assessment.

Union list on vitamins: taking account of Directives 2006/141/EC and 2006/125/EC and Regulation (EC) No 953/2009, the Commission shall, no later than 2 years after the date of entry into force of the Regulation establish a Union list of vitamins, minerals and other substances which may be added to each category of food.

Food for people intolerant to lactose: at the latest 1 year after entry into force of the Regulation the Commission shall present a report, if appropriate accompanied by a legislative proposal, to clarify the status of labelling indications of 'lactose free' and 'very low lactose content' under general food law.

Milks intended for young children: one year after the date of the entry into force of the Regulation, the Commission shall submit a report 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 either decide that there is no need for special provisions regarding the composition and labelling of milks intended for young children, or submit any appropriate legislative proposal in accordance with the ordinary legislative procedure and on the basis of Article 114 of the TFEU.

Prior to the preparation of the 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.

Compositional requirements for LCD and VLCD products: the amended text sets out requirements for energy, protein, fat, dietary fibre and vitamins and minerals.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The European Parliament adopted by 603 votes to 8 with 8 abstentions a legislative resolution 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. Parliament adopted its position in first reading following the ordinary legislative procedure. The main amendments are as follows:

Title: the new title will be a Regulation 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 calorie diets

Scope: Parliament clarifies that the Regulation, complementing Union law on food, establishes compositional and information requirements for certain categories of food, including food for special medical purposes, including formula intended for low birth-weight and pre-term infants, food for people intolerant to gluten, and foods intended for use in low calorie diets (LCD) and very low calorie diets (VLCD).

VLCD products contain between 400 and 800 kcal per day. LCD products contain between 800 and 1200 kcal per day.

Subject matter: the 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 above for a specific nutritional purpose. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

Definitions: Parliament amended some definitions and added clarification on the meaning of ?foods for special medical purposes.? Parliament deleted the Commission?s proposal on empowering the latter to amend certain definitions through delegated acts.

Placing on the market: Members state that 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 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.

Innovation clause: Parliament adds a new clause whereby In order to enable food referred to in the Regulation and resulting from scientific and technological progress to be placed on the market rapidly, the Commission may, after consulting the Authority, adopt delegated acts authorising, for a two-year period, the placing on the market of food which does not comply with the rules on composition laid down by the Regulation and by the delegated acts adopted pursuant to the Regulation for food referred to in the text.

Precautionary principle: a new clause states that 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 the text is intended.

Oversight: Parliament adds this clause stating that 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.

Food for normal consumption: a new clause states that 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 the Regulation.

General composition and information requirements: the composition of the food shall be such that it is appropriate to satisfy the nutritional needs of persons to whom it is intended, in accordance with generally accepted peer-reviewed and independently evaluated scientific data and medical opinion. The labelling, presentation and advertising of the food 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.

Members tightened the Commission text, stating that the dissemination of any useful information or recommendations with reference to certain categories of food may be made exclusively to persons having qualifications in medicine, nutrition or pharmacy. Additional information disseminated by healthcare professionals to the final consumer shall only be of a scientific and factual nature and shall not contain advertising.

Parliament adds that in order to ensure efficient official monitoring, food business operators shall notify the competent authority of each Member State in which they place food on the market, by forwarding it a model of the product's label.

Infant formula: the labelling of infant formula and follow-on formula 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.

Pesticides: the use of pesticides in agricultural products intended for the production of the food shall be restricted as far as possible, without prejudice to Directive 2006/125/EC and Directive 2006/141/EC.

Specific provisions relating to the food 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 on classification, labelling and packaging of substances and mixtures1 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 Regulation (EC) No 1107/2009.

Delegated acts: the Commission is empowered to adopt delegated acts with regard to specific composition and information requirements of certain foods. This list is expanded in the resolution.

Food for people intolerant to gluten: in addition to other requirements in the text, the committee added that 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. There are further provisions on labelling for gluten. The statement ?very low gluten content? should be used only for products that contain less than 100 mg of gluten per kg, while foods with less than 20 mg of gluten per kg may be labelled ?gluten free?.

Food intended for people intolerant to gluten shall also comply with the following criteria: (i) they shall provide roughly the same amount of vitamins and mineral salts as the foodstuffs they are replacing; (ii) they shall be prepared with special care, in compliance with good manufacturing practice (GMP), to avoid gluten contamination; (iii) 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.

Foods intended for use in low calorie diets and very low calorie diets: a new clause sets out labelling requirements. In addition, LCD and VLCD products must comply with the compositional requirements set out in a new Annex to the Regulation.

Access for SMEs to the internal market: the Commission shall adopt appropriate guidelines through delegated acts and provide technical guidance to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in the Regulation and assist them in the preparation and presentation of the application for scientific assessment. It shall be empowered to adopt delegated acts in order to adopt those guidelines.

Union list on vitamins: 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 the Regulation, delegated, in order to insert in Annex I a list of vitamins, minerals and other substances which may be added to each category of food.

Parliament expanded the conditions which must be met in order for vitamins, minerals, amino acids and other substances may be added to food, including the condition that they must have, on the basis of generally accepted scientific evidence, a nutritional or physiological effect.

For substances that are engineered nanomaterials, certain additional conditions will apply.

Updating of the list of permitted substances: the applicant shall submit an application to the Commission which shall acknowledge receipt in writing within 14 days of its receipt.

The Commission shall be empowered to adopt delegated acts in order to update Annex I.

Confidentiality of information: any scientific data gathered from animal testing for the assessment of the safety of the substance will not be regarded as confidential.

General transparency and confidentiality clause: Parliament adds that the Commission, the Authority and 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.

Food for people intolerant to lactose: at the latest 1 year after entry into force of the Regulation the Commission shall present a report, if appropriate accompanied by a legislative proposal, to clarify the status of labelling indications of 'lactose free' and 'very low lactose content' under general food law.

Milks intended for young children: one year after the date of the entry into force of the Regulation, the Commission shall submit a report 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 either decide that there is no need for special provisions regarding the composition and labelling of milks intended for young children, or submit any appropriate legislative proposal in accordance with the ordinary legislative procedure and on the basis of Article 114 of the TFEU.

Prior to the preparation of the 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) No1924/2006.

Compositional requirements for LCD and VLCD products: the amended text sets out requirements for energy, protein, fat, dietary fibre and vitamins and minerals. It also sets out the amino acid requirement pattern.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The Council adopted its position at first reading by qualified majority with regard to the adoption of the Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes and total diet replacement for weight control. The United Kingdom delegation abstained and the German delegation voted against.

The Council's position introduces several changes to the Commission's proposal and it takes into account almost all of the substantive amendments proposed by the European Parliament in first reading.

As regards the scope of the proposed Regulation, the Council retains:

- the inclusion of the category of total diet replacement for weight control foods ;
- the principle that people who are intolerant to gluten should be given at least the same level of protection as they receive under the current legal framework;

- the importance of clarifying the legal status of "lactose-free" statements;
- the need for Commission reports to assess the necessity of provisions regarding : (i) food for sportsmen; (ii) milk-based drinks and similar products intended for young children;
- the inclusion of 'low birth weight and pre-term infants foods'.

The Council position also takes into account:

- the fact that substances injurious to health should be excluded from the composition of categories of food referred in the proposed Regulation;
- the need for the Commission's technical guidance to facilitate compliance of food business operators, in particular small and medium size enterprises (SMEs), with the proposed Regulation;
- the application of the precautionary principle, as referred to in Regulation (EC) No 178/2002 of the European Parliament and of the Council;
- the need to restrict, as far as possible, pesticide residues in the foods covered by the proposed Regulation;
- the establishment of the Union list of substances, as set out in the Annex to the proposed Regulation, that may be added to one or more categories of food and its possible update by means of delegated acts;
- the submission of substances which are engineered nanomaterials to adequate test methods;
- the exclusion from the powers to be conferred on the Commission of adaptations to the definitions (concerning essential elements of the proposed Regulation to be modified only through the ordinary legislative procedure);
- the fact that the labelling, presentation and advertising of food should not attribute properties to food for the prevention, treatment or cure of human diseases;
- the importance of 'breast-feeding' and extending the prohibition of pictures of infants in the labelling, presentation and advertising of infant formula to the labelling of follow-on formula;
- the information to be provided to health care professionals concerning foods and information to be provided on recommendations for appropriate use of the food.

The Council's position further permits the Commission to adopt implementing acts to decide whether or not a given food falls within the scope of the proposed Regulation and regardless of the category of food.

The amendments made by Parliament that are not reflected in the Council position concern particularly:

- a special emphasis on the safety of the food referred in Article 1 of the proposed Regulation;
- the Union's contribution to the application of appropriate practices for the marketing of breast-milk substitutes in third countries by Community-based manufacturers;
- the food to be absorbed by persons suffering from carbohydrate metabolism disorder ("diabetes");
- providing a temporary authorisation through the same (rapid) procedure as indefinite authorisation;
- the categories of foods for special medical purposes, the elements to be notified for monitoring purposes and the definitions of low calorie food and very low calorie food;
- wording on labelling of food on "normal consumption", which is prohibited.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The Commission supports the position of the Council at first reading adopted on 22 April 2013 with a view to the adoption of 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.

Taking into account the developments in the informal discussions between the Council and the European Parliament following the European Parliament first reading, the Commission did not prepare an amended proposal but expressed its views on the Parliament amendments in the Commission Communication on action taken on legislative opinions and non-legislative resolutions adopted by Parliament at its June part-session (document SP (2012)540) sent to the European Parliament on 12 July 2012. The Commission indicated that it could accept in full, in part, in principle or subject to rewriting 53 of the 83 amendments, as it considered that these amendments could clarify or improve the Commission's proposal.

The Commission considers that the common position adopted by the Council reflects the original goals of the Commission's proposal and takes into account many concerns of the European Parliament.

Although on certain elements, the common position differs from the Commission's original proposal, the Commission considers that it represents a carefully balanced compromise.

The main amendments of the European Parliament accepted by the Commission and incorporated in full or in part in the Council's position include:

- the inclusion in the scope of the Regulation of total diet replacement products for weight control, including Very Low Calorie Diet products (VLCDs), which also replace the totality of the daily diet but have a lower energy content. An unambiguous description of products for low-calorie diets is given in the recitals;
- the obligation of the Commission to prepare a report on milk-based drinks and similar products intended for young children in the two years following the entry into force;
- the introduction of provisions on the use of pesticides, including foods for infants and young children;

- the use of pictures in labelling of follow-on formula;
- the adoption by the Commission of technical guidance to facilitate compliance of food business operators, in particular SMEs, with the requirements of the Regulation;
- the introduction of a cross-reference to the relevant provisions of Regulation (EC) No 178/2002, regarding the application of the precautionary principle.

The European Parliament's amendments rejected by the Commission and incorporated in full, in part, in the Council's position include:

- the inclusion, as an Annex to the Regulation, of the Union list of authorised substances;
- the establishment of specific criteria for the evaluation of nanomaterials and their inclusion in the Union list of authorised substances, including with regard to the test methods for evaluating their safety;
- the inability to change the definitions by means of delegated acts, as they are essential elements of Regulation;
- the possibility for the Commission to adopt delegated acts for a period of five years tacitly extended in the absence of opposition.

Certain amendments accepted by the Parliament and rejected by the Commission have not been included in the first reading Council position. These amendments sought to:

- clarify that foods for special medical purposes could fall under three different categories;
- include foods for people intolerant to gluten in the scope of the Regulation;
- include formula for low birth weight and pre-term infants in the scope of the regulation as a sub-category of foods for special medical purposes;
- provide a temporary authorisation procedure for innovative products;
- ask the Commission to draft a report, accompanied, if necessary, by a legislative proposal to clarify the legal status of indications of " Lactose free" and "very low lactose".

The Commission accepts the new provisions introduced by the Council as regards:

- the drafting of a report by the Commission on the necessity, if any, of specific rules for foods intended for sportsmen with the possibility to accompany this report with a legislative proposal;
- the adoption by the Commission of implementing measures to decide whether a food falls within the scope of the Regulation and under what category;
- the introduction of a transition period of three years plus exhaustion of stocks,
- the deletion of rules on emergency measures.

The Commission states that it will pay particular attention to pesticides containing active substances, safeners or synergists classified in accordance with Regulation (EC) No 1272/2008 as mutagen category, carcinogen category, toxic for reproduction category, or considered to have endocrine disrupting properties that may cause adverse effects in humans, or which are very toxic, or which cause critical effects such as developmental neurotoxic or immunotoxic effects, with the objective to ultimately avoid their use.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The Committee on the Environment, Public Health and Food Safety adopted the recommendation for second reading contained in the report by Frédérique RIES (ADLE, BE) on the Council position at first reading with a view to the adoption of 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 and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

The committee recommends that the European Parliament approves, unamended, the Council position at first reading.

A statement by the Commission on pesticides is annexed to the draft legislative resolution.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

PURPOSE: to draw up new rules for food intended for vulnerable population groups, such as infants and young children.

LEGISLATIVE ACT: Regulation (EU) No 609/2013 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 and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

CONTENT: the Regulation replaces Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, as well as a certain number of Commission acts implementing that Directive. It establishes compositional and information requirements for the following categories of food:

- infant formula and follow-on formula;
- processed cereal-based food and baby food;
- food for special medical purposes;
- total diet replacement for weight control.

The Commission may decide, by means of implementing acts, whether a given food falls within the scope of this Regulation and, if so, to which specific category of food a given food belongs.

In order to ensure a high level of health protection in relation to the persons for whom the food is intended, the precautionary principle as set

out in Regulation (EC) No 178/2002 shall apply.

The Regulation also establishes a single Union list of categories of substances (such as vitamins, minerals, amino-acids or others) that are permitted to be added to the categories of food covered by this Regulation.

General and specific requirements: the Regulation stipulates the general compositional and information requirements for categories of food covered by the Regulation. Food referred shall not contain any substance in such quantity as to endanger the health of the persons for whom it is intended.

For substances which are engineered nanomaterials, compliance with the requirements shall be demonstrated on the basis of adequate test methods, where appropriate.

The labelling, presentation and advertising of foods shall provide information for the appropriate use of such foods, and shall not mislead, or attribute to such foods the property of preventing, treating or curing a human disease, or imply such properties.

The Commission is empowered to adopt, by 20 July 2015, delegated acts laying down the specific compositional or information requirements for each category of food. The specific requirements concern, among other things, the use of pesticides on products as well as pesticide residues in these foodstuffs.

Infant formulae and follow-on formulae: the Regulation stipulates that the labelling, presentation and advertising of infant formula and follow-on formula shall be designed so as not to discourage breast-feeding. Nor should they include pictures of infants, or other pictures or text which may idealise the use of such formulae.

Milk-based drinks for young children, foods for sportspeople: these are excluded from the scope of the new rules. However, the Commission, after consulting the European Food Safety Authority, shall present, before 20 July 2015, a report on the necessity, if any, of provisions for food intended for sportspeople.

Gluten-free or very low gluten or lactose: the current rules on the use of gluten-free and very low gluten shall be governed by the provisions of Regulation (EU) No 1169/2011on food information to consumers. The same applies in regard to the rules governing the absence or reduced presence of lactose in food.

Technical guidelines: the Commission may adopt technical guidelines to facilitate compliance by food business operators, in particular SMEs, with this Regulation.

ENTRY INTO FORCE: 19/07/2013.

DELEGATED ACTS: the Commission is empowered to adopt delegated acts in order to take into account technical progress, scientific developments or consumers health. The power to adopt such acts is conferred on the Commission for a period of five years starting on 19 July 2013. 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. Should the European Parliament or the Council object to it, the delegated act does not enter into force.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The European Parliament approved, at second reading of the ordinary legislative procedure, the Council position at first reading with a view to the adoption of 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 and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

Parliament takes note of the Commission statement annexed to this resolution.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

This report meets the obligation set for the Commission by Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control "FSG Regulation").

The report examines the necessity, if any, of special provisions in terms of composition and labelling for milk-based drinks and similar products intended for young children. It is based on two scientific opinions by the European Food Safety Authority (EFSA), a market study carried out for EFSA and extensive consultation with national competent authorities and interested parties.

The market for young child formulae in the EU: young-child formulae are not defined in EU legislation. They can be described as specifically processed/formulated protein-based drinks intended to satisfy the nutritional requirements of young children aged 1-3 years.

The market in young-child formulae experienced growth in almost all the countries reviewed in the period 2008-2012. In 2012, retail market size can be estimated to more than 42 000 tonnes and retail market value to more than EUR 500 million. While the number of manufacturers is small, EU manufacturers are leaders in the global scene.

The report arrives at the following conclusions:

EFSAs advice: the European Food Safety Authority issued scientific advice on young child formulae in 2013, stating that young-child formulae are one of the means to increase n-3 polyunsaturated fatty acids, iron and vitamin D intakes of infants and young children (these were identified by EFSA as nutrients, together with iodine, at risk of inadequacy for some infants and young children in the EU).

According to EFSA, however, no unique role of young-child formulae can be identified, so they cannot be considered as necessary to satisfy

the nutritional requirements of young children when compared with other foods that may be included in their normal diet.

In its opinion of 26 June 201429, EFSA noted, in addition, that formulae consumed during the first year of life can continue to be used by young children and therefore, it did not consider it necessary to propose specific compositional criteria for young child formulae.

No safety issues: the report notes that the composition of young-child formulae is varied. However, the content of different nutrients in these products is generally within the ranges of permitted concentrations in follow-on formulae. There is no reported safety issue with respect to these products. However, some young-child formulae may contain substances (e.g. sugars, flavours) in amounts that are generally not recommended for young children. Others may lack the nutrients identified by EFSA as being at risk of inadequate intake for young children.

The Commission considers that the correct and complete application of the general framework of EU food law seems sufficient to adequately regulate the composition of young-child formulae (e.g. food additives, addition of vitamins and minerals or use of novel substances) and the communication on the characteristics of the products (e.g. food information, nutrition and health claims).

Forecast for post-2016: after 20 July 2016, the situation will evolve in those Member States that today classify young-child formulae as dietetic foods as a consequence of the repeal of Directive 2009/39/EC, which provides that, as a general requirement, the nature or composition of the products shall be such that the products are appropriate for the particular nutritional use intended.

As of this date, all young-child formulae in the market in the EU will be classified in the same way (normal foods fortified in certain nutrients) and will have to comply with the relevant existing horizontal rules of EU food law.

The Commission feels that it is not possible to foresee many developments after 2016, given that no concrete information exists on how operators or consumers will adapt to the new legal framework or on how Member States will react at national level to their inability to apply Directive 2009/39/EC. In any event, all draft national rules will be assessed by the Commission in order to verify compliance with EU law.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

This report is intended to meet the obligation set for the Commission by Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ('FSG Regulation').

The report relates to the necessity, if any, of specific provisions for food intended for sportspeople ('sports food'). The request for the report is linked to the repeal by the FSG Regulation of the framework on foodstuffs intended for particular nutritional uses, as of 20 July 2016. This framework was established by a Council Directive in 1989 and completed by the recast Directive 2009/39/EC.

The FSG Regulation does not include sports food within its scope. Thus, since a categorisation as foodstuff intended for particular nutritional uses will no longer be available to sports food, this type of food will be exclusively governed by horizontal rules of food law as from 20 July 2016.

This report reflects on potential consequences of the change of status for sports food.

Sports food market: taking into account the classifications developed over the years and the current market, three categories of sports food are established: (1) sports drinks; (2) (protein-based) muscle strengthening, building and post exercise recovery products, and (3) energy and performance boosting products and products for on-going supplementation of sportspeople.

The EU wide market for sports nutrition and drinks was worth EUR 3.07 billion (retail value) in 2014. The market for sports food at EU level has grown by 11.2% between 2009 and 2014, equivalent to a compound annual growth rate of 2.2%. This growth has mainly been driven by protein-based products, which grew by 68% over the period.

Issues relating to sports food after 20 July 2016: the report analyses how sports food currently classified as food intended for particular nutritional uses would be affected under the horizontal rules of food law in the absence of specific legislation after 20 July 2016 (when Directive 2009/39/EC is repealed). It examines aspects related to food safety, consumer information, composition, and notification required by national competent authorities.

The report also examines the need for legislation for the products concerned. No change would occur for sports food currently considered as food for normal consumption governed by relevant horizontal rules of food law.

National competent authorities and interested parties positions: the report notes that the majority of national competent authorities believe that the existing horizontal rules of food law are either quite suitable or very suitable for regulating sports food. Six national competent authorities have recognised the need for specific rules for sports food.

Operators are clearly divided on the question whether specific legislation is necessary for sports food or whether sports food should be governed by horizontal rules of food law. In general, food industry groups consider that the legislation, whether horizontal in nature or specific, should adequately allow the provision of relevant information for sports food with particular attention to the nutritional characteristics and the intended use.

Conclusions: the report concludes that people carrying out sports activity can hardly be characterised as a specific vulnerable group of consumers but rather as a target group of the general population who is protected at an appropriate level by horizontal legislation.

The Commission considers that the growing completion of the horizontal rules of food law which took place in the last few years, has put in place an appropriate legislative framework to ensure that sports food classified nowadays as food intended for particular nutritional uses can remain on the market and can operate. Furthermore, the horizontal rules of food law provide the necessary safeguards for these products in terms of food safety, food composition, consumer information and legal certainty.

As a result, not only will all sports food products be subject to the same legal requirements but they will also have the same level of harmonisation as other foods falling under the horizontal rules of food law.

Accordingly, the report concludes that there is no necessity for specific provisions for food intended for sports people. The Commission will ensure proper application of horizontal legislation and monitor the developments after 20 July 2016, since sports food may include some

element of specificity, which may have to be taken into account by the Commission in the application and implementation of the horizontal rules.

Food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

The Commission presented a report on the exercise of the delegation conferred on the Commission pursuant to Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control (FSG Regulation).

As a reminder, the FSG Regulation empowers the Commission to adopt delegated acts for a period of five years from 19 July 2013 (which may be extended for periods of identical duration).

With this report the Commission fulfills the obligation to draw up a report on the exercise of delegation no later than nine months before the end of the five-year period.

Exercise of the delegation: the FSG regulation has been in force for less than one year and is not yet fully applicable. Since the entry into force of the FSG Regulation, the Commission has adopted four delegated acts accordingly:

1) Commission Delegated Regulation (EU) 2016/127 supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. This legal act was adopted on 25 September 2015 with the objective to update the requirements for formulae intended for infants based on the latest scientific evidence.

2) Commission Delegated Regulation supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for processed cereal-based food and baby food.

In a resolution adopted on 20 January 2016, Parliament objected to the Delegated Regulation. It expressed concerns on the compositional requirements for processed cereal-based food and baby food (in particular with respect to the sugar levels in the products) and the labelling and marketing requirements for these products (with respect to the provision of information on the introduction of complementary feeding before six months of age).

3) Commission Delegation Regulation (EU) 2016/128 supplementing the FSG Regulation as regards the specific compositional and information requirements for food for special medical purposes.

The Delegated Regulation extended, inter alia, the rules on pesticides that apply to infant formula, follow-on formula, processed cereal-based food and baby food to food for special medical purposes for infants and young children. The Regulation will apply from 22 February 2019.

4) Commission Delegated Regulation supplementing the Food for Specific Groups Regulation as regards the specific compositional and information requirements for total diet replacement for weight control. This Delegated Regulation was adopted by the Commission on 2 June 2017 and was submitted to the European Parliament and the Council for scrutiny.

Lastly, the delegated act amending the Annex to Regulation (EU) No 609/2013 as regards the list of substances that may be added to processed cereal-based food and baby food and to food for special medical purposes was adopted by the Commission on 10 April 2017.