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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

(presented by the Commission pursuant to Article 114 of the Treaty on the Functioning of the European Union)

(Text with EEA relevance)

{SEC(2011) 762 final}
{SEC(2011) 763 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

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 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.

Foodstuffs for particular nutritional uses are foods that are different from foods for normal consumption and are, as currently regulated, specially manufactured products intended to satisfy the particular nutritional requirements of specific categories of the population. The designation under which a dietetic food is sold is accompanied by a suitability statement for the particular nutritional use and the specific group of the population to whom the food is intended, e.g.: *gluten-free food for celiac people, processed cereal-based food for young children, infant formulae for infants from birth* etc.

After more than 30 years of application, the evolution of both the food market and food legislation makes an overall revision necessary. Indeed, the application of the broad concept of "foodstuffs for particular nutritional uses" on which the Framework Directive is based in the evolved market and legal context has led to considerable problems for stakeholders and controlling authorities. The classification of many foods as 'dietetic' foods and the need for such a category of foods has been seriously questioned, although the desirability of maintaining rules on certain specific categories of foods actually addressing nutritional benefits for certain sub-groups of the population is being recognised.

Consequently, in pursuing the objectives of better regulation and simplification, the proposal aims to rectify this situation by simplifying and clarifying the rules that apply to products hitherto regulated as 'dietetic' foods, taking into account the evolution of the regulatory measures in relevant areas.

Given the above, 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.

Further to these objectives, the proposal also aims at creating a single legal measure that regulates lists of substances such as vitamins, minerals and other substances that may be added to the categories of food covered by this proposal. The currently existing three different lists of substances included in three different legal measures would be combined into a single one. Clarity for

stakeholders and Member States and better Union administration would be the outcome of the establishment of such a merged measure.

The revision of the legislation is accompanied by an impact assessment giving an overview of the application of Directive 2009/39/EC.

- **General context**

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 (Directive 2002/46/EC), on the addition of vitamins and minerals and other substances to foods (Regulation (EC) No 1925/2006) and nutrition and health claims (Regulation (EC) No 1924/2006). In effect, as the food market evolved, so did the Union legislation governing it in order to ensure the functioning of the internal market and guarantee the same level of protection to citizens across Europe.

This unclear situation has led also to distortions of trade in the internal market due to different interpretation and enforcement of Directive 2009/39/EC across Member States and in particular regarding its scope of application. Furthermore, it appears that these more recently adopted Union legislations mentioned above would adequately cover all products addressing nutritional benefits for the general population and certain sub-groups thereof with less administrative burden and more clarity as to their scope.

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 1) the implementation of the notification procedure of the Framework Directive on dietetic foods and 2) 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. On top, a company is requested to notify to the competent authorities each product they want to market as a 'dietetic' product and has to repeat that procedure in all the Member States where they wish to place the product on the national market. The resulting administrative burden is significant for both the Member States and the company while the added value in terms of public health and consumer information is questionable.

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

- **Existing provisions in the area of the proposal**

The following pieces of legislation cover the area of foods for particular nutritional uses:

– *Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, "the Framework Directive on dietetic foods"*. The Directive lays down a common definition on foods for particular nutritional uses as well as general provisions (e.g. a general notification procedure for categories for foods not covered by specific Commission legislation) and common labelling rules.

According to the definition, foods for particular nutritional uses are foods that are different from foods for normal consumption and are specially manufactured products intended to satisfy the particular nutritional requirements of specific categories of the population.

Specific measures adopted for certain categories of foods under that framework legislation are:

– *Commission Directive 2006/141/EC on infant formulae and follow-on formulae.*

This Directive was adopted originally in 1991 and revised globally in 2006. It establishes detailed and complete compositional and labelling rules for products intended to infants from birth up to 12 months of age. Infant formulae are suitable as the sole source of nourishment during first months of life if infants are not breastfed while follow-on formulae may constitute the principal liquid element in a progressively diversified diet.

* *Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries* established the rules for infant formulae and follow-on formulae exported or re-exported from the European Union to third countries.

– *Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children.*

Directive 2006/125/EC was adopted originally in 1996 and was codified in 2006. This Directive covers foods that are intended to be part of a diversified diet of infants and young children. It lays down general compositional and labelling rules for a large diversity of products. No major changes have been introduced since its first date of adoption.

– *Commission Directive 1999/21/EC on dietary foods for special medical purposes.*

Dietary foods for special medical purposes are intended for the exclusive or partial feeding of patients with disturbed capacity to take ordinary

food and whose dietary management cannot be achieved by modification of the normal diet or by other dietetic foods. It establishes general compositional criteria and quite detailed labelling rules. These foods are to be used under medical supervision. No updates have been made since 1999.

– *Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction.*

This Directive covers two categories of products intended for weight control: products presented as a replacement for the whole daily diet and products presented as a replacement for one or more meals of the daily diet.

It sets general compositional and compulsory labelling rules for these products.

– *Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.*

This Regulation was adopted in 2009. A transitional period applies until 1 January 2012. It fixes gluten thresholds and associated labelling rules for the voluntary indication of the absence of gluten in products for people suffering from a permanent intolerance to gluten (coeliac people). The Regulation foresees that the statement 'gluten-free' can be used on foods for normal consumption as well.

– *Commission Regulation (EC) No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.*

This Regulation adopted in 2009 updates and replaces Directive 2001/15/EC and established a consolidated list of substances such as vitamins, minerals, and other substances that may be used in dietetic foods except those that can be used in infant formulae and follow-on formulae and in cereal-based foods and other baby foods which are included in the relevant specific Directives. The addition of new substances to that list is subjected to the scientific assessment of the European Food Safety Authority (EFSA).

- **Consistency with the other policies and objectives of the Union**

The proposal is in line with the Commission's Better Regulation Policy, the Lisbon Strategy and the EU's Sustainable Development strategy. The emphasis is on simplifying the regulatory process, thus reducing the administrative burden and improving the competitiveness of the European food industry, while ensuring the safety of food, maintaining high level of public health protection and taking global aspects into consideration.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods, main sectors targeted and general profile of respondents

There was a broad consultation of all interested parties seeking their views on the provisions and application of existing legislation and the need for change. The respondents were the competent authorities of the Member States, industry association representatives and consumer organisations.

Summary of responses and how they have been taken into account

– Consumer organisations main concern is that certain foods are unduly covered by special designation/status under the current Framework Directive which could put them out of the scope of other important provisions – e.g. Regulation on Nutrition and Health Claims. These stakeholders have highlighted that where there are no compositional or labelling requirements justified by specific nutritional needs and consumer protection there is no need to grant a special status to foods. This is especially the case when this status allows the food to bear a suitability statement that could be confused with a nutrition or health claim or make the food appear more appropriate than a similar normal food.

– The specialised 'dietetic food' industry believes that clear and transparent legislation governing the composition of products for the dietetic food sector is essential to maintain the protection of vulnerable groups of the population and those with special nutritional needs from a public health and food safety perspective. In that context, they suggest to strengthen the current legislation and to include in a positive list at least the following groups of products: 'Foods for infants and young children up to the age of three - including Low Birth Weight Formula'; 'Hospital Discharge Formula'; 'Breast Milk Fortifier and Growing Up Milks'; 'Foods for pregnant and lactating women'; 'Foods for the elderly in good health'; ‘Foods for weight management’; ‘Foods for special medical purposes’; ‘Foods for sportspeople’; ‘Dietary foods for people with gluten intolerance’; ‘Lactose-free foods’.

In addition, the dietetic food industry emphasises the need for a transparent, efficient and effective procedure for the expansion of the Union list. They argue that science still emerges in this area and therefore a flexible procedure must be offered to promote innovation.

Nevertheless, this position is not shared by all parts of the industry; certain others believe that the same rules should apply to all foods and that there is no reason to foresee different rules except in very limited cases, where nutritional food safety issues are concerned. For certain categories of foods, additional rules may result in unnecessary burden on

the industry. In addition, they fear that a legal straight jacket may hamper innovation.

– Member States have reported that the legislation on dietetic foods is being used by some operators to circumvent the rules of subsequent food legislation such as the Regulation on claims, distorting the notion of a food for particular nutritional uses, and resulting, in certain cases, in confusion over its application that creates unfair competition between businesses and difficulties for enforcement.

  Member States underline that the most important aspect to maintain would be consumer safety.

  The Commission identified in its impact assessment supporting the proposal four options taking into account the aforementioned issues and compared them in light of the objectives of the revision (coherence, simplification, harmonisation and small businesses and innovation).

- **Collection and use of expertise**

  There was no need for external expertise.

- **Impact assessment**

  The Commission carried out an impact assessment which is presented in parallel to this proposal as a Commission Staff Working Paper.

  Four different options have been considered ranging from repealing the legislation to establishing a reinforced legislation for dietetic foods. These options were assessed taking into account their economic, social and environmental impacts on the various stakeholders and authorities. In addition, a no-change scenario was considered as a reference against which to assess the possible impacts of the different options.

  Two different approaches have been considered:

  (1) the notion of dietetic food is no longer needed to help the food market today and should be abolished;

  (2) the notion of dietetic food needs to be strengthened to bring it more into line with today's food market and consumers' needs.

  The four options (two following approach (1) and two following approach (2)) considered within the Impact Assessment have been developed to ensure that none of them would result in the removal of products from the market but they may necessitate potential label changes and/or reformulation of products or have an impact on their market value. In other words, the options considered for the revision of the dietetic food legislation do not foresee any ban *per se* of foods currently sold as foods for particular nutritional uses. In addition, the proposed rules within each option would allow for market adaptation and therefore a sufficient transitional period is foreseen to help have a smooth transition to the new legislation and minimise economic burden.

Summary of the options and the key impacts under each of them:

- **Option 1 – Repeal all the legislation on dietetic foods** (Framework Directive and all the specific Directives adopted under that Framework)

  Repealing the concept of dietetic food will prevent further distortions between 'dietetic' foods with suitability statements and 'normal' foods with nutrition and health claims. However, whilst such an option appears to be a good one in terms of simplification and reducing administrative burden, the trade off in terms of the introduction of national legislation to compensate the repeal of certain Union legislation (e.g. on foods intended for infants and young children) may be significant.

- **Option 2 – Repeal the Framework Directive on dietetic foods but maintain certain of the specific rules adopted under that Framework**

  This option provides the same simplification and administrative burden reduction benefits as option 1 but also gives the Union the possibility to maintain for certain categories of foods, rules the harmonisation of which has provided added value at EU level. Having no general rules on dietetic foods anymore and clearer rules for certain specific products should ensure better coordination between the requirements of different pieces of legislation.

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

  The main advantage of setting a positive list for dietetic foods with specific compositional and labelling rules is that standardised rules would apply to the dietetic food sector ensuring harmonisation across the European Union. However, the burden that would fall on the industry and Member States for having to comply with additional specific dietetic food legislation to be able to target food to certain groups of the population may be considered disproportionate particularly taking into account the minimal additional public health and consumer information benefits.

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

  The application of a standard prior-authorisation procedure would ensure more harmonisation across the European Union than the general notification procedure currently in place. However, the burden of prior authorisation before using a 'dietetic' suitability statement on a product seems to be disproportionate in terms of consumers' protection and information and would be highly costly for the industry and especially for SMEs.

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

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

Adoption of a Regulation of the European Parliament and of the Council establishing rules applicable to foods intended for infants and young children and to foods for special medical purposes and concerning a Union list of substances which can be added to the foods covered by this proposal.

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;

– establishes a single legal measure for substances that can be added to the foods covered by this proposal;

The new proposal will repeal Directive 92/52/EC, Directive 2009/39/EC, Directive 96/8/EC and Regulation (EC) No 41/2009.

The specific compositional and information requirements will be laid down in delegated Regulations, adopted by the Commission, in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) taking into account the general requirements laid down in this proposal as well as Commission Directives 2006/141/EC, 2006/125/EC, and 1999/21/EC.

The adoption of the Union list implies the application of criteria set out in this proposal therefore implementing powers shall be conferred on the Commission

in that respect. Those powers shall be exercised in accordance with Regulation (EU) No 182/2011.

Emergency procedures are foreseen in situations where food covered by this proposal constitutes a serious risk to human health. For this purpose, implementing powers shall be conferred on the Commission in that respect. Those powers shall be exercised in accordance with Regulation (EU) No 182/2011 of the TFEU.

- **Legal basis**

This proposal is based on Article 114 TFEU. This legal basis is justified both by the objective and the content of the proposal. Measures adopted under Article 114 TFEU should have as their object the establishment and functioning of the internal market. The proposal establishes a harmonised legal framework concerning the composition and information requirements for infant formulae and follow-on formulae, processed cereal-based foods and baby foods for infants and young children and foods for special medical purposes as well as a Union list of substances that can be added to such foods since it is necessary to keep a harmonized framework for products addressed to particular vulnerable parts of the population for which categories of food constitute the sole source of nourishment. The objective of the proposal is to avoid any differences between national laws relating to the categories of food at issue impeding their free movement and thus having a direct impact on the establishment and functioning of the internal market.

- **Subsidiarity principle**

The subsidiarity principle applies insofar as the proposal does not fall under the exclusive competence of the Union.

The objectives of the proposal cannot be sufficiently achieved by the Member States for the following reason(s):

Prior to the adoption of the Framework Directive, the national measures in the Member States differed from one Member State to another. The differences between these laws obliged the dietetic food industry to vary their production according to the Member State for which the products were intended. To respond to this, general rules and a number of specific measures have been adopted at Union level.

In order to harmonise intra-union trade and trade with third countries the Union does have the right to act. However, this should be balanced against the proportionality of the measure and the added value Union rules will have for citizens across all Member States.

Individual action by Member States could lead to differing levels of food safety and protection of human health and confuse consumers. In addition, it would endanger the free movement of these foods in the Union.

The core of the Union action would maintain existing rules for certain products that are traded widely within the Union and where there is agreement amongst Member States for the continuing need for specific composition and labelling rules to ensure the free movement of these goods. It also aims to simplify the regulatory environment as regards the addition of substances to the foods covered by this proposal.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s):

The proposal harmonises the regulatory framework establishing general provisions applying to certain categories of foods where the need for additional compositional and labelling provisions to the general rules applying to all foods is demonstrated. Such additional provisions contribute to consumer protection by ensuring that consumers receive nutritionally adequate foods and appropriate information.

The proposed measures are sufficient in terms of reaching the objectives of ensuring that consumers make informed and safe choices and securing the smooth functioning of the internal market. At the same time they do not impose an excessive or unjustified burden.

The absence of harmonisation for these categories of foods would result in a proliferation of national rules resulting in different levels of consumer protection between the Member States and increased burden for the industry.

The financial burden is minimised as the current specific provisions exist already, the general provisions are only simplified and clarified as to their scope of application.

- **Choice of instruments**

Proposed instruments: Regulation.

Other type of measure would not be adequate for the following reason(s).

The existing framework is, in general, prescriptive with little flexibility for Member States in how it should be applied. A Directive would have lead to an inconsistent approach in the Union leading to uncertainty for both consumers and the industry. A Regulation provides a consistent approach for industry to follow and reduces the administrative burden as operators do not need to familiarise themselves with the individual national legislation in the Member States.

Soft law instruments such as guidelines would be a flexible approach to addressing certain changes needed in the current legislation but not all of them. In addition, due to the non-binding status such instruments are considered not

sufficient to tackle differences in the interpretation and implementation of the legislation.

4. BUDGETARY IMPLICATION

None.

5. ADDITIONAL INFORMATION

- **Simulation, pilot phase and transitory period**

  There will be a transitory period for the application of the proposal.

- **Simplification**

  The proposal provides for simplification of legislation. This is one of the main objectives of the revision of the legislation on foods for particular nutritional uses.

  The use of a Regulation as the legal instrument supports the objective of simplification because it guarantees that all actors have to follow the same rules at the same time.

  National administrative procedures following the implementation of the general notification procedure will be abolished reducing the administrative burden associated with the implementation of the legislation.

  The provisions adopted in and under Directive 2009/39/EC that have become unnecessary, contradictory and potentially conflicting will be removed.

  The proposal is included in the Commission Working Programme for 2011 – Annex III – Simplification Rolling Programme and Administrative Burden Reduction initiatives under the reference 2009/SANCO/004.

- **Repeal of existing legislation**

  The adoption of the proposal will lead to the repeal of existing legislation.

- **Recasting**

  The proposal involves recasting.

- **European Economic Area**

  The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

- **Detailed explanation of the proposal**

  The Regulation 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.

2011/0156 (COD)

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

(presented by the Commission pursuant to Article 114 of the Treaty on the Functioning of the European Union)

(Text with EEA relevance)

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 ordinary legislative procedure[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.

(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.

(3) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[2] 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

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

majority of the provisions laid down in that Directive date back to 1977 and should therefore be reviewed.

(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 their suitability for the claimed nutritional purposes.

(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[3], 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[4]. 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[5], Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[6] and Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable people intolerant to gluten[7].

(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[8].

(7) Directive 2009/39/EC foresees that specific provisions could be adopted regarding the two following specific categories of food falling within the definition of foodstuffs for particular nutritional uses: 'food intended to meet the expenditure of intense muscular effort, especially for sportsmen' and 'food for persons suffering from carbohydrate metabolism disorders (diabetes)'. With regard to food intended to meet the expenditure of intense muscular effort, no successful conclusion could be reached as regard the development of specific provisions due to widely diverging views among Member States and stakeholders concerning the scope of the specific legislation, the number of sub-categories of the food to be included, the criteria for establishing composition requirements and the potential impact on innovation in product development. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report[9] concludes that the scientific basis for setting specific compositional requirements is lacking.

(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

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3 OJ L 401, 30.12.2006. p. 1.
4 OJ L 339, 6.12.2006, p. 16.
5 OJ L 55, 6.3.1996, p. 22.
6 OJ L 91,7.4.1999, p. 29.
7 OJ L 16, 21.1.2009, p. 3.
8 OJ L 179, 1.7.1992, p. 129.
9 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.

down in Union law, prior to their placing on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.

(9) A report from the Commission to the European Parliament and the Council on the implementation of that notification procedure[10] 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.

(10) A study report[11]concerning the 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 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.

(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[12], Regulation (EC) No 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims made on foods[13] 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[14]. 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.

(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.

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10 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.

11 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..

12 OJ L 183, 12.7.2002, p. 51.

13 OJ L 404, 30.12.2006, p. 9.

14 OJ L 404, 30.12.2006, p. 26.

(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.

(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 Safety Authority and laying down procedures in matters of food safety[15] 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.

(15) A limited number of categories of food constitutes the sole source of nourishment of certain groups of the population or represent a partial source of nourishment; such categories of food are vital for the management of certain conditions and/or are essential to maintain the intended nutritional adequacy for certain well-established vulnerable groups of the population. Those categories of food include infant formulae and follow-on formulae, processed cereal-based food and baby food and food for special medical purposes. Experience has shown that the provisions laid down in Commission Directive 2006/141/EC, Commission Directive 2006/125/EC, as well as Commission Directive 1999/21/EC ensure the free movement of such food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for infant formula and follow-on formulae, processed cereal-based food and baby food for infants and young children and to food for special medical purposes, taking into account Commission Directive 2006/141/EC, Commission Directive 2006/125/EC and Commission Directive 1999/21/EC.

(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.

(17) It is important that ingredients used in the manufacture of the categories of food covered by this Regulation are appropriate to satisfy the nutritional requirements of, and are suitable for the persons to whom they are intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

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[15] OJ L 31, 1.2.2002, p. 1.

(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[16]. Those general labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, the provisions of Directive 2000/13/EC, where necessary, in order to meet the specific objectives of this Regulation.

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

(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 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[17]. 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.

(21) At present, pursuant to the Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[18] 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

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16 OJ L 184, 17.7.1999, p. 23.

17 OJ L 55, 28.2.2011, p. 13.

18 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.

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.

(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**.**

(23) It is necessary to establish procedures for the adoption of emergency measures in situations where food covered by this Regulation constitutes a serious 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.

(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.

(25) 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[19] 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.

(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[20]. Such statements could be construed as nutrition claims, as defined in Regulation (EC) No 1924/2006. For the sake of simplification, those statements should be regulated solely by Regulation (EC) No 1924/2006 and comply with requirements therein. It is necessary that technical adaptations pursuant to Regulation (EC) No 1924/2006, incorporating the nutrition claims 'gluten-free' and 'very low gluten' and their associated conditions of use as regulated under Regulation (EC) No 41/2009 be completed prior to the entry into application of this Regulation.

(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

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19 OJ L 404, 30.12.2006, p. 9.

20 OJ L 14, 20.1.2009, p. 5.

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 96/8/EC be completed prior to the entry into application of this Regulation.

(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.

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

HAVE ADOPTED THIS REGULATION:

CHAPTER I
SUBJECT MATTER AND DEFINITIONS

Article 1
Subject matter

1. This Regulation establishes compositional and information requirements for the following categories of food:

   (a) infant formula and follow-on formula;

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

   (c) food for special medical purposes.

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.

Article 2
Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

   (a) the definitions of 'food' and 'placing on the market' set out in Articles 2 and 3(8) of Regulation (EC) No 178/2002;

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

(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,

(d) the definition of 'other substance' set out in Article 2(2) of Regulation (EC) No 1925/2006.

2. The following definitions shall also apply:

(a) 'Authority' means the European Food Safety Authority established by Regulation (EC) No 178/2002;

(b) 'infants' means children under the age of 12 months;

(c) 'young children' means children between one and three years;

(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;

(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;

(f) 'processed cereal-based food' 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;

(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 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;

(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.

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.

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.

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.

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.

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).

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 with the procedure referred to in Article 14(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.

CHAPTER III
REQUIREMENTS

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.

2. The requirements laid down in this Regulation shall prevail over any other conflicting requirement of Union law applicable to food.

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.

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.

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.

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

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.

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.

2. Subject to the general requirements of Articles 7 and 9 and taking into account Directive 2006/141/EC, Directive 2006/125/EC and Directive 1999/21/EC as well as any technical and scientific progress, the Commission shall be empowered to adopt delegated Regulations, no later than *[2 years after the date of the entry into force of this Regulation],* in accordance with Article 15, with respect to the following:

   (a) the specific compositional requirements of food referred to in Article 1(1);

   (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;

   (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;

   (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;

   (e) the requirements on promotional and commercial practices relating to infant formulae; and,

   (f) the requirements on information to be provided on infant and young child feeding in order to ensure adequate information on appropriate feeding practices.

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.

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.

CHAPTER IV
UNION LIST OF PERMITTED SUBSTANCES

Article 11
Union list of permitted substances

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:

   (a) they do not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer; and,

   (b) they are available for use by the human body.

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).

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.

4. The application shall include:

   (a) the name and the address of the applicant;

   (b) the name and a clear description of the substance

   (c) the composition of the substance;

   (d) the proposed use of the substance and conditions thereof;

   (e) a systematic review of the scientific data and appropriate studies performed following generally accepted expert guidance on the design and conduct of such studies;

(f) scientific evidence demonstrating the quantity of the substance which does not endanger the health of the persons to whom it isintended and its suitability for the intended uses;

(g) scientific evidence demonstrating that the substance is available for use by the human body;

(h) a summary of the content of the application.

5. When a substance is already included in the Union list and there is a significant change in the production methods, or there is a change in particle size, for example through nanotechnology, the substance prepared by those new methods shall be considered as different substance and the Union list shall be modified accordingly before it can be placed on the Union market.

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.

2. Information relating to the following shall not, in any circumstances, be regarded as confidential:

(i) the name and address of the applicant;

(ii) the name and description of the substance;

(iii) the justification for the use of the substance in or on specific food;

(iv) information that is relevant to the assessment of the safety of the substance;

(v) where applicable, the analysis method(s) used by the applicant.

3. Applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases.

4. The Commission shall decide after consulting with the applicants which information can remain confidential and shall notify applicants and the Member States accordingly.

5. After being made aware of the Commission’s position, applicants shall have three weeks in which to withdraw their application so as to preserve the confidentiality of the information provided. Confidentiality shall be preserved until this period expires.

CHAPTER V
CONFIDENTIALITY

Article 13
General confidentiality clause

The Commission, the Authority and the Member States shall, in 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.

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.

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.

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
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.

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

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 therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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.

Article 16
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.

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.

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 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.

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]*.

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 19
Entry into force

This Regulation shall enter into 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.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*