

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

2011/0156(COD) - 20/06/2011 - Legislative proposal

**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 take as 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.