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NOTE

from : General Secretariat of the Council
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Subject : EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS
COUNCIL MEETING ON 1 AND 2 DECEMBER 2011

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
– *Presidency's progress report*
(Other business item)

Delegations will find in the Annex a progress report from the Presidency on the above mentioned subject.

Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes

Progress report by the Presidency

I. THE PROPOSAL

On 24 June 2011, the Commission submitted a 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 Proposal) on the basis of Article 114 of the Treaty.

The ordinary decision making procedure is applicable.

The Environment, Public Health and Food Safety (ENVI) Committee of the European Parliament should adopt its report at first reading on 29/02/2012. The date indicated by the Parliament for the vote in Plenary is 17/4/2012.

The European Economic and Social Committee was consulted on 5/7/2011 and did not adopt its opinion yet.

The Proposal aims to revise and replace the legislation on foods intended for particular nutritional uses covered by the Directive 2009/39/EC (*"the Framework Directive on dietetic foods"*).

According to the Commission, after more than 30 years of application, the evolution of both the food market and food legislation makes an overall revision necessary. The application of the concept of "foodstuffs for particular nutritional uses" on which the Framework Directive is based 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 is being recognised.

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 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 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 the Proposal. The current three different lists of substances included in three different legal measures would be combined into a single one. The improvement of clarity for stakeholders and Member States and better Union administration would be the outcome of such a single legal measure.

II. CURRENT STATE OF WORK WITHIN THE COUNCIL

During the four meetings of the Working Party on Foodstuffs organised under the Polish Presidency¹, the major issues concerning the Proposal were identified.

- **Scope of the Proposal**

Directive 2009/39/EC on foodstuffs intended for particular nutritional uses was completed by specific measures adopted for certain categories of foods:

- 1) *Commission Directive 2006/141/EC on infant formulae and follow-on formulae*² intended for infants from birth up to 12 months of age.
- 2) *Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children*³ intended to be part of a diversified diet of infants and young children.

¹ 15 July, 3 and 24 October and 21 November.

² OJ L 401, 30.12.2006, p.1.

- 3) *Commission Directive 1999/21/EC on dietary foods for special medical purposes*⁴ intended for the exclusive or partial feeding of patients with a disturbed capacity to take ordinary food and whose dietary management cannot be achieved by modification of the normal diet or by other dietetic foods. These foods are to be used under medical supervision.
- 4) *Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction*⁵, which 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.
- 5) *Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten*⁶, with a transitional period applicable until 1 January 2012. It fixes gluten thresholds and associated labelling rules for the indication of the absence of gluten in products when placed on the market for people suffering from a permanent intolerance to gluten (celiac people). The Regulation establishes that the statement 'gluten-free' can be used on foods for normal consumption as well.

Directive 2009/39/EC further stipulates (in Annex I) that specific provisions could be adopted regarding *food intended to meet the expenditure of intense muscular effort, especially for sportsmen*.

Only the categories of foods covered by the Directives referred in points 1), 2) and 3) were included within the scope of the Proposal.

³ OJ L 339, 6.12.2006, p. 16.

⁴ OJ L 91, 7.4.1999, p. 29.

⁵ OJ L 55, 6.3.1996, p. 22.

⁶ OJ L 16, 21.1.2009, p. 3.

The positions of the delegations regarding the scope of the Proposal may be summed up as follows:

- a) The products proposed by the Commission (formula for infants; processed cereal based food and baby food; food for special medical purposes) to be included within the scope of the Proposal were accepted by the delegations;
- b) The possibility of specifically addressing foodstuffs suitable for people intolerant to gluten and lactose in the Regulation on the Provision of Food Information to Consumers was generally welcomed by the delegations;
- c) It was argued by some delegations that foods intended for use in energy-restricted diets for weight reduction should, for reasons of food safety, be included within the scope of this framework Regulation.
- d) It was recognised that clarification was needed at EU level as regards food intended to meet the expenditure of intense muscular effort, especially for sportsmen. The need for a definition of those foods was referred.

Concerning the question whether very low calorie diet (VLCD) foods and growing-up milks should be dealt with at EU level, a large number of delegations consider that VLCD foods could be deemed to be covered by point c) of Article 1(1) of the proposed Regulation (*foods for medical purposes*). Regarding growing-up milks, it was considered that EFSA's opinion might help to clarify if there are nutritional needs that would be met by this kind of products, and if so, to define compositional requirements and age range of the target population. Transitional measures until the EFSA opinion would be available might need to be considered accordingly.

- **Adaptation of the definitions**

The Proposal provides for the adaptation of 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, by delegated acts to be adopted by the Commission.

The question of whether the definitions were an essential element of the Proposal was raised and, in such a case, whether it was possible to adapt them by delegated acts.

- **Information requirements**

It was recognised by the Working Party that Article 9(3) and (4) of the Proposal had to be adapted to:

- prevent information attributing properties to the products for the prevention, treatment or cure of human disease or implying such properties;
- avoid obstacles to the dissemination of useful information intended for persons having qualifications in medicine, nutrition and pharmacy.

- **Relations with third countries**

Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries, also adopted to complement Directive 2009/39/EC, established the rules for infant formulae and follow-on formulae exported or re-exported from the European Union to third countries.

It was noted that it was necessary to confirm that all the provisions that were still useful will stay in force after repealing this Directive. It was recalled that, in this respect, Article 12 of Regulation (EC) No 178/2002⁷ should be taken into account.

⁷ OJ L 31, 1.2.2002, p. 1.

- **Transitional measures**

The Proposal provides for a transitional measure allowing the marketing of foods that comply with the legislation currently in force and labelled during the 2-year period following the entry into force of the Regulation until the stocks are exhausted.

It was observed that it was preferable to establish a clear cut-off date for the presence of the products on the market given the difficulties of verifying the labelling date and, consequently, the date on which the products should no longer be on the market. It was also mentioned that 2 years were insufficient as a transitional period.
