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

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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.