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New EU Rules on Dietetic Foods - Update

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Report Highlights:
The EU's new Dietetic Foods Regulation 609/2013, adopted in June 2013, becomes applicable on July 20, 2016. Regulation 609/2013 required the European Commission to adopt a number of delegated acts setting out specific compositional and labeling requirements. This report provides an overview of the new EU requirements.

New EU Rules on Dietetic Foods – Update

The EU's new dietetic foods regulation 609/2013, adopted in June 2013, becomes applicable on July 20, 2016. The scope of this regulation is limited to infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes and total diet replacement for weight control. Article 11 of regulation 609/2013 required the European Commission to adopt by July 20, 2015, a number of delegated acts on specific compositional and information requirements. This report updates and complements GAIN report E14010 "New EU Rules on Dietetic Foods."

Specific Compositional and Labeling Requirements

As a general rule, labeling requirements set out in the EU's "Food Information to Consumers" (FIC) regulation 1169/2011 also apply to the food categories covered under regulation 609/2013. However, given the specific nature of the products covered, regulation 609/2013 provided for the introduction of additional labeling requirements and derogations from FIC regulation 1169/2011. In order to implement the principles set out in regulation 609/2013, the European Commission was required to adopt detailed rules in the form of delegated acts on the following:

- Specific compositional requirements for all products falling within the scope of regulation 609/2013
- Specific requirements on the use of pesticides in the production of foods covered under regulation 609/2013 and on pesticide residues in such foods
- Specific labeling, presentation and advertising requirements, incl. nutrition and health claims
- Notification requirements
- Specific requirements for food for special medical purposes

Food for Special Medical Purposes

Commission Delegated Regulation 2016/128, published in the EU's Official Journal on February 2, 2016, sets out specific requirements for food for special medical purposes. Because of the wide diversity of food for these purposes, regulation 2016/128 sets principles and requirements specific to them rather than detailed compositional requirements.

Name of the Food

Annex IV to regulation 2016/128 lists the translation in all official EU languages of the term "food for special medical purposes."

Nutrition and Health Claims

Nutrition and health claims are not allowed on food for special medical purposes.

Labeling

Food for special medical purposes has to comply with FIC regulation 1169/2011. Article 5 of Regulation 2016/128 introduces additional mandatory labeling requirements relating to the properties and characteristics such as special processing and formulation, nutritional composition and rationale of use of the product. Article 6 sets out specific requirements on the nutrition declaration. The nutrition declaration is mandatory on all food for special medical purposes, irrespective of the package or container size. The indication of the energy value and the amount of nutrients as a percentage of the daily reference intake set out in FIC regulation 1169/2011 is not allowed on food for special medical purposes. Article 8 stipulates that the labeling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants must be designed in such a way that consumers can easily make a distinction between such products and regular infant formula and follow-on formula. Pictures of infants or other pictures or text idealizing the use of these products are not allowed.

Composition

Products developed to satisfy the nutritional requirements of infants must contain the vitamins and minerals substances and respect the minimum and maximum levels specified in Table 1 of Annex I. Table 2 of Annex I sets values for other foods for special medical purposes

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Notification

Food business operators must send a model of the label and any other information demonstrating compliance with regulation 2016/128 to the competent authority of each Member State where the product is being marketed.

Pesticides

Residue levels in products developed to satisfy the nutritional requirements of infants and young children may not exceed 0.01 mg/kg per active substance. Annex II provides for a derogation from this rule. Annex III lists the active substances prohibited in the production of food for special medical purposes for infants and young children.

Transitional Period

The requirements set out in regulation 2016/128 become applicable on February 22, 2019 with the exception of the rules on food for special medical purposes developed to satisfy the nutritional requirements of infants which will apply from February 22, 2020.

Infant Formula and Follow-On Formula

Commission Delegated Regulation 2016/127, also published in the EU's Official Journal on February 2, 2016, sets out specific compositional and information requirements for infant-formula and follow-on formula. It also introduces conditions for the voluntary addition of ingredients not covered under regulation 2016/127.

Name of the Food

Annex VI, Part A, lists the translation in all official EU languages of the terms “infant formula” and “follow-on formula.” Annex VI, Part B, lists the translations of the terms “infant milk” and “follow-on milk.”

Nutrition and Health Claims

Nutrition and health claims are not allowed on infant formula

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Labeling

Infant formula and follow-on formula have to comply with FIC regulation 1169/2011. Article 6 of regulation 2016/127 introduces additional mandatory labeling requirements. The use of the terms “humanized”, “maternalized”, “adapted” or similar terms are not allowed. To avoid any risk of confusion, the labeling and presentation must be designed in such a way that consumers can easily make the distinction between infant formula and follow-on formula.

Article 7 sets out specific requirements on the nutrition declaration. The mandatory nutrition declaration for infant formula and follow-on formula must include the amount of each vitamin and mineral substance (except molybdenum) listed in Annex I or Annex II to regulation 2016/127 as well as the amount of choline, inositol and carnitine. Information included in the mandatory nutrition declaration may not be repeated on the label. The nutrition declaration is mandatory irrespective of the packaging or container size. The energy value and the amounts of nutrients must be expressed per 100 ml of the food ready for use after preparation and, where appropriate, the information may **in addition** refer to 100 g of the food as sold. The energy value and the amounts of nutrients may not be expressed as a percentage of the reference intakes set out in Annex III to FIC regulation 1169/2011. However, in the case of follow-on formula, the declaration of vitamins and mineral substances listed in Annex VII to regulation 2016/127 may be declared as a percentage of the reference intakes set out in that Annex. Article 7.2 also stipulates which information may be provided on a voluntary basis.

Article 9 sets out conditions for the statements “lactose only” and “lactose free.” The statements “contains Docosahexaenoic Acid” or “contains DHA” may only be used for infant formula placed on the market before February 22, 2015.

Composition

Infant formula and follow-on formula must comply with the compositional requirements set out in Annex I and Annex II to regulation 2016/127 respectively taking into account the values for amino acids set out in Annex III. The use of ingredients not listed in one of the Annexes is allowed only when food business operators can demonstrate their suitability.

Notification

For infant formula and follow-on formula manufactured from protein hydrolysates or follow-on formula containing other ingredients than those listed in Annex II to regulation 2016/127, food business operators must send a model of the label and any other information demonstrating compliance with

regulation 2016/127 to the competent authority of each Member State where the product is being marketed.

Pesticides

Residue levels in infant formula and follow-on formula may not exceed 0.01 mg/kg per active substance. Annex IV to regulation 2016/127 provides for a derogation from this rule. Infant formula and follow-on formula may only be produced from agricultural products produced without the use of active substances listed in Annex V.

Transitional Period

Regulation 2016/127 will apply from February 22, 2020. The existing rules currently set out in Directive 2006/141 will be repealed on February 22, 2020, with the exception of the provisions on infant formula and follow-on formula manufactured from protein hydrolysates which will continue to apply until February 21, 2021.

Processed Cereal-Based Food and Baby Food

The Commission Delegated Regulation on processed cereal-based food and baby food was vetoed in the European Parliament on January 22, 2016. The Members of the European Parliament (MEPs) objected to the compositional requirements that would allow up to 30 percent of the energy in baby foods to be provided by sugar. According to the MEPs, the delegated regulation should substantially lower the allowed maximum sugar level in line with the World Health Organization's (WHO) recommendations in order to protect infants and young children against obesity. WHO recommendations limit the intake of free sugars to 10% of total energy intake. The resolution also objects, invoking the precautionary principle, to the use of GMOs and nanotechnologies and calls on the Commission to prohibit the use of new technologies in processed cereal-based food and baby food. With this veto, the proposed delegated regulation could not enter into force which means that the Commission has to present a new delegated regulation. Until a revised delegated regulation is presented, the existing rules set out in Directive 2006/125 will continue to apply.