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New EU Rules on Dietetic Foods

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Report Highlights:

The EU's new dietetic foods regulation 609/2013, adopted in June 2013, will become 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. Under the new rules, pictures of infants are no longer allowed on labels and no pictures or text may idealize the use of such formula. Foods that no longer fall with the scope of Regulation 609/2013, such as protein bars for athletes, low calorie cereal bars and slimming products, will be regarded as "normal foods" and regulated under the general labeling and nutrition and health claims regulations. This report provides an overview of the new rules set out in Regulation 609/2013.

NEW EU RULES ON DIETETIC FOODS

New EU Regulation:

On June 12, 2013, the European Union adopted [Regulation 609/2013](#) on “Food Intended for Infants and Young Children, Food for Special Medical Purposes and Total Diet Replacement for Weight Control.” This new regulation will apply as of July 20, 2016, and repeal the general rules on “Foods for Particular Nutritional Uses” currently set out in Directive 2009/39/EC, as well as the complementing directives and regulations 96/8/EC (energy-restricted diets), 1999/21/EC (special medical purposes), 2006/125/EC (processed cereal-based foods and baby foods), 2006/14/EC (infant and follow-on formula) and 953/2009 (substances that may be added to dietetic foods) and 41/2009 (gluten-free foods).

As a general rule, labeling requirements established by the EU’s “Food Information to Consumers” Regulation 1169/2011 also apply to the categories of food covered by Regulation 609/2013. However, Regulation 609/2013 provides for the introduction of additional labeling requirements and derogations from Regulation 1169/2011. By July 20, 2015, the European Commission should adopt “delegated acts” establishing the following: specific requirements on the use of pesticides and allowable pesticide residues; specific compositional requirements; labeling requirements that relate to the authorization of nutrition and health claims; requirements concerning promotional and commercial practices relating to infant formula; and notification requirements for placing the food on the market. More information on “delegated acts” is available on our website at <http://www.usda-eu.org/eu-basics-questions/how-is-eu-legislation-adopted/>.

Regulation 609/2013 also requires the Commission to present by July 20, 2015, a report on the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children and food intended for athletes. These reports may be accompanied by an appropriate legislative proposal, if necessary.

Scope and Definitions:

The scope of Regulation 609/2013 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. The three existing lists of substances that may be added to these foods will be consolidated into a single European Union (EU) list.

Under the current rules, definitions of products covered are scattered over several directives, annexes and regulations. Under the new rules, updated definitions of all products covered are set out in a single article. Article 2 of Regulation 609/2013 provides for the following definitions:

Infant formula: food intended for use by infants during the first months of life that solely satisfies the nutritional requirements of such infants until the introduction of appropriate complimentary feeding.

Infant: a child under the age of 12 months.

Processed cereal-based food: food intended to fulfill the particular requirements of infants in good health as they are being weaned and of young children in good health as a supplement to their diet and/or their progressive adaptation to ordinary foods.

Young Child: a child between 1 and 3 years.

Baby food: food intended to fulfill the particular requirements of infants in good health as 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.

Food for special medical purposes: food specially processed or formulated and intended for the dietary management of patients, including infants, 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, metabolize, or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, or whose dietary management cannot be achieved by modification of the normal diet alone.

Total diet replacement for weight control: food specifically formulated for use in energy restricted diets for weight reduction which, when used as instructed by the food business operator, replaces the whole daily diet.

Labeling and Compositional Rules:

Under the new rules, pictures of infants are no longer allowed on labels and no pictures or text may idealize the use of such formula. The label and advertising should be designed so it does not discourage breast feeding. Also, the labels should provide information for the appropriate use of the food and shall not mislead or attribute to such food the property of preventing, treating or curing human disease, or imply such properties.

The Annex to Regulation 609/2013 establishes a list of approved substances that may be added to the following categories: vitamins, minerals, amino acids, carnitine and taurine, nucleotides and choline and inositol.

The suitability of substances which are engineered nano-materials (intentionally produced materials with a dimension of less than 100nm) must be demonstrated on the basis of adequate test methods, where appropriate. Products or substances produced through new technologies, such as nanotechnology, will be evaluated under the EU's [Novel Food Regulation 258/1997](#). The EU's new general labeling regulation 1169/2011 sets out the definition of "engineered nano-materials" for labeling purposes.

Foods for persons with gluten intolerance currently fall within the scope of the foods for particular nutritional uses rules. [Commission Regulation 41/2009](#) established harmonized compositional and labeling rules. However, with the adoption of Regulation 609/2013 it was decided that gluten-free foods should be regulated under the EU's "Food Information to Consumers" Regulation 1169/2011. [Commission Delegated Regulation 1155/2013](#), applicable as of July 20, 2016, transfers the provisions relating to "gluten-free" or "lower gluten" food to Regulation 1169/2011.

Labeling and compositional rules on foods for people with lactose intolerance are currently not harmonized at the EU-level. Such rules will also be established under Regulation 1169/2011.

Implications for U.S. Products:

Foods that no longer fall within the scope of Regulation 609/2013 - such as protein bars for athletes, low calorie cereal bars, fortified foods suitable for older people, supplements for pregnant women, slimming products and single diet meals - will be regarded as “normal foods” and regulated under the “Food Information to Consumers” Regulation 1169/2011 unless they make a nutrition or health claim. In this case, they will have to comply with the EU’s [Nutrition and Health Claims Regulation 1294/2006](#).

Products labeled in conformity with the current dietetic food rules may remain on the market until July 20, 2016. Products entering the EU market after this date will need to be re-labeled and reformulated as required. Producers wishing to continue using dietetic suitability statements must ensure compliance with the Nutrition and Health Claims Regulation. More information on the EU’s nutrition and health claim rules is available on our website at <http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/nutrition-health-claims/>.

Background:

This new regulation was proposed to remedy inconsistent Member State interpretation of Directive 2009/39/EC on “Foods for Particular Nutritional Uses” and to close legal loopholes. The Impact Assessment that accompanied the European Commission proposal revealed that some business operators abuse the current legislation on dietetic foods to circumvent compliance with stricter regulations such as the Nutrition and Health Claims Regulation 1924/2006. More detailed information on the proposal can be found in [GAIN report “Commission proposes to abolish concept of dietetic foods”](#).