

## Regulation on the Licensing of Food for Special Medical Purposes has been Published

6 Apr 2023

Regulation on the Licensing of Food for Special Medical Purposes ("Regulation") was published in Official Gazette on 28 January 2023. The Regulation covers the procedures and principles regarding the licensing of food for special medical purposes.

The Regulation will enter into force on 1 July 2023.

The prominent regulations in the Regulation are as follows:

- Foods For Special Medical Purposes are classified under three headings as:
  1. Products that are nutritionally complete, containing standard nutrients, which, when used in accordance with the manufacturer's instructions, can constitute the nutritional source of the users by itself,
  2. Nutritionally complete products developed specifically for a disease or health problem, which, when used in accordance with the manufacturer's instructions, can constitute the nutritional source of the users by itself,
  3. Nutritionally incomplete products that are not suitable for use as a sole source of nutrition, with a standard formula or with a specially adapted nutritional content for a disease or health problem.
- In the production of these foods classified in the Regulation, only vitamins, mineral substances, amino acids and other nitrogen-containing compounds and other nutrients listed in the relevant guide can be used to fulfill the nutritional needs.
- Foods for special medical purposes, developed to fulfill the nutritional needs of infants and young children, are prohibited from containing pesticide residues in an amount exceeding 0.01 mg/kg per active ingredient. These amounts will be determined by the Turkish Medicines and Medical Device Authority ("Authority") using generally accepted standard analysis methods.
- Within the scope of the Regulation, it is stated that no special medical purpose food can be placed on the market for which a license is not issued by the Authority.
- Foods for special medical purposes will be subject to the licensing procedure, as in drugs, and will only be sold in pharmacies dependently on a prescription issued by a physician.
- In the inner and outer packaging of the products, it is obligatory to include the expression "food for special medical purposes", and the explanations and information listed in the regulation such as the list of ingredients, the disease or health problem for which the product is intended to be used, the age group, it should be used under medical supervision.
- Nutrition and health declarations cannot be used on the packaging of foods for special medical purposes within the scope of the regulation.
- The provisions of the Turkish Food Codex and relevant legislation shall be taken into account in matters that uncodified in the Regulation and in the guides to be published regarding food for special medical purposes such as packaging, hygiene criteria, additives, flavorings and contaminants, microbiological criteria, sampling and analysis methods.
- It is obligatory to obtain a license in accordance with the provisions of the Regulation until 31 December 2025 at the latest for products which the permit was issued by the Authority before the date of entry into force of the Regulation and placed on the market.

Please see this [link](#) for the full text of the Regulation published in the Official Gazette dated 28 January 2023 and numbered 32087 (only available in Turkish).

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