

Q&A

REGULATORY FRAMEWORK FOR SPECIAL FOODS IN EGYPT



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Introduction

The monitoring and regulation of special foods in Egypt, including the registration and monitoring of this category of products, was transferred to the National Food Safety Authority (NFSA) in 2018, through the NFSA's Decree # 1 issued on August 15, 2018. Since then, the NFSA embarked on developing a regulatory system and a robust program for special foods in Egypt. This includes the development of provisions for the transition to the new regulatory framework. The regulatory oversight of the NFSA is based on mandatory requirements for the prior approval or registration for each particular food before its introduction into the Egyptian market.

According to the NFSA, the Authority's "Special Food Regulatory Program" aims to achieve:

- Highest safety measures for the intended consumers of these products
- Minimum disruption to the trade flow in the Egyptian market during the transition period
- Transparency and inclusiveness in the continuous development and improvement of the special food regulation program.

The NFSA's approach on monitoring the introduction of special foods into the Egypt is based on:

- Pre-market control through registration of products based on established safety standards.
- Verification of compliance with specified requirements using a risk-based approach.

What's the mandate of the National Food Safety Authority?

NFSA is the central regulatory authority responsible for food monitoring and safety in Egypt. It is an independent authority reporting directly to the President of the Republic. NFSA is mandated to inspect and monitor food to ensure that it is produced, distributed, marketed, consumed, imported from, or exported to Egypt according to the standards of food safety and hygiene. The NFSA's authority includes the following:

- Licensing, inspecting and supervising the handling of food
- Granting compliance certificates necessary for exporting locally produced food
- Issuing mandatory rules to ensure food safety and hygiene
- Monitoring and inspecting imported food
- Adopting rules and regulations associated to advertising and labeling of food products.
- Regulating the use of food additives and substances.

What types of foods are considered “special foods”?

Food products that are manufactured, prepared or formulated to meet special nutritional requirements or diseases. This includes:

- 1- Formulas prepared for infants and complementary milk formulas (alternatives to mother's formula)
- 2- Infant food prepared from grains
- 3- Canned food intended for infants and young children
- 4- Food prepared for people with special physiological conditions
- 5- Food intended for treating illness.
- 6- Food that is marketed with health claims (supplements / infant and child nutrition), provided that they don't contain any substances that have a medicinal effect
- 7- Formulations of food products that are low in energy (1500-1500 kcal) or very low in energy (500-700 kcal) for the purpose of controlling or losing weight and are provided as a full or partial substitute for the daily diet. (This does not apply to prepacked meals presented in the form of traditional meals.)
- 8- Food products/supplements high in energy for weight gain
- 9- Foods low in sodium, including table salt substitutes, having therapeutic claims
- 10- Foods with vitamins or mineral salts added (15%) or more than the reference value per 100 grams of solids, or (7.5%) of the reference value per 100 milliliters of liquids
- 11- Food with added fortified cereals, materials, compounds, or elements with (subsidized) nutritional benefits
- 12- Food containing stimulant, boosting or appetizing substances
- 13- Food supplements for athletes and foods intended for use in cases of intense muscle exertion
- 14- Herbs and spices that have therapeutic benefits
- 15- Industrial sweeteners (sugar substitutes).

Which foods cannot be considered “special foods”?

- 1- Low-calorie foods that don't address special groups (such as sugar-free or low-calorie foods and drinks)
- 2- Foods that are, by nature, a source of vitamins or minerals
- 3- Foods containing vitamins and minerals less than 15% of the reference value per 100 grams of solids, or 7.5% of the reference value per 100 ml of liquids and other nutrients
- 4- Bottled natural drinking water and bottled mineral drinking water
- 5- Foods low in sodium, including table salt substitutes, have no therapeutic claims
- 6- Fiber-enriched products that are less than 3 grams/ 100 grams (30 grams per day) or (10%) the daily reference value.

What should the label of prepackaged foods intended for special foods include?

- 1- The name of the special food
- 2- The list of ingredients arranged in descending or ascending order
- 3- Ingredients, add-ons and foods that may cause allergies
- 4- Permitted food add-ons and flavorings, except for manufacturing aids
- 5- Net weight or net volume.
- 6- Name and address:
 - The name and address of the producer and his/her trademark, if any, shall be placed on the food package
 - The name, address and country of origin of the importer, in case of import
 - In case of imported products where it is difficult to write the name and address of the product in Arabic, it may be written in English or French.
 - In case of packaging, the name and address of the packager should be written down.
- 7- Country of origin (production)
- 8- Production batch
- 9- Expiry date
- 10- Storage instructions according to the type of product.
- 11- In the case of local production, products must be labelled with (Made in Egypt).
- 12- Nutrition data / facts.

The recording of facts on the data sheet shall be as follows:

 - a) The nutritional value shall be indicated numerically, and any other additional means may be used.
 - b) Energy values are expressed in kilocalories or kilojoules per 100 grams or per 100 ml of the product, as well as for each specific amount suggested to be consumed.
 - c) The quantities of (protein, carbohydrates and fats) / (essential vitamins and minerals) in food need to be expressed in grams per 100 grams or per 100 ml, as well as for each specific quantity suggested to be consumed.
 - d) Information on quantities of essential and non-essential amino acids, or essential fatty acids can be expressed in metric units.
 - e) Nutrient quantities may be expressed in percentages of the relevant recommended daily consumption quantities (internationally recognized) whenever possible.
 - f) Data on osmolality or osmolarity or the acid-base balance in the product can be mentioned whenever possible.
 - g) The nature of proteins, whether animal or vegetable, or hydrolyzed proteins must be clarified.
 - h) The phrase "use under medical supervision" shall be clearly written on the food marking card used for illnesses in addition to the previous basic information in Arabic (to be visible to the consumer.)

Moreover, information regarding the method of preparation (including other ingredients required to be added for food use) should be noted.

- i) The data list should explain if ingredients are treated with radioactivity next to the name of the product.

Which nutritional and medical claims are prohibited?

- 1- False, vague, or misleading
- 2- Claims that raise doubts about the safety or nutritional competence of other foods
- 3- Encourages or condones the excessive consumption of the food product
- 4- Implies that a balanced and varied diet cannot provide adequate amounts of nutrients in general
- 5- Refers to changes in body functions that may stimulate consumer concern, either through written text or through pictorial or symbolic representations.

What are the regulations on advertising of special foods?

- 1- Special foods cannot be traded and advertised, whether locally manufactured or imported from abroad, except after registration and obtaining a license from the NFSA.
- 2- It is prohibited to manufacture or prepare food products except in authorized factories that abide by the relevant health requirements.
- 3- It is prohibited to advertise special foods with words, pictures, or writing in any audiovisual media before notifying the NFSA with the text of the advertisement at least one week before the date of publication. It is prohibited to advertise the foods that are used for medical cases to the public. Moreover, it is not allowed to use any kind of advertisement for breast milk substitutes.

What are the registration procedures for special foods?

- 1- Registration, follow-up, and the scientific file are submitted either through paperwork or through the authority's website/e-mail.
- 2- The required documents are determined by a decision of the Chairman of the Authority's Board of Directors.
- 3- The registration period shall not exceed 60 days from the date of receiving the required documents in full, and 30 days in the case of registering through notification from the date of receiving all documents.
- 4- The validity period of the product license is five years since the date of its registration.
- 5- Registration through notification should be made for imported special foods, as long as the products' home country has food safety systems compatible with their Egyptian counterparts. A Free Sale

Certificate should also be provided in addition to submitting all the documents required for registration.

- 6- Upon commitment to the terms and specifications of the registered product and the desire to re-register, the registration shall be by notification.
- 7- The NFSA will issue a list of special foods, foods designated for illnesses, and nutritional supplements subject to registration in accordance with these regulations.
- 8- A database is being created to include all registered companies and factories dealing in special foods.

What are the required fees prior to trading special foods?

- 1- EGP 10,000 for food products with special dietary purposes.
- 2- EGP 15,000 for baby milk products and athletes' food/supplements.
- 3- Food is traded for special nutritional uses in the markets in accordance with the storage and handling conditions specified and approved by the NFSA for each product.
- 4- It is prohibited to circulate special foods intended for medical cases outside pharmacies or hospitals.

What are some measures that the NFSA can take in order to monitor special foods?

- 1- Samples are taken in light of the risk analysis rules.
- 2- Samples are drawn randomly from the special display locations and matched to the recording file.

What might the NFSA test/analyze?

- 1- The samples of raw materials and products shall be analyzed in accredited laboratories to ensure compliance with the registration conditions. This will be done in accordance with the binding technical regulations and the applicable specifications adopted by the NFSA.
- 2- The microbiological limits for special foods shall be in accordance with the applicable legislation and specifications, and in accordance with the following mentioned limits, whichever is less:
 - The product shall be free of salmonella microorganism in 25 g.
 - The product is free of staphylococcus aureus at 25 g.
 - The product is free of Enterobacteriaceae gm (in dried and canned infant formula and baby food).
 - The product is free of Bacillus cereus / g (in infant formula and dried and canned baby food).
 - The product is free of Enterobacter sakazakii / 25g.
 - The product is free of Listeria monocytogenes / 25g.
- 3- The maximum limits for pesticide residues/ pollutants shall be in accordance with the international legislations issued in this regard.
- 4- Residues of veterinary drugs shall be in accordance with relevant international legislation

Which producers / importers of special foods are required to register with the NFSA?

Producers and importers of food for special nutritional purposes are required to apply to the NFSA for the purpose of registration in accordance with the following:

- 1- Companies that have products currently registered must apply for registration in the NFSA records with the original registration document issued by the Ministry of Health to issue a license from the NFSA for the remaining period of the valid license.
- 2- Companies that have unregistered products (new / re-registered) must apply to the NFSA for registration.
- 3- Companies whose products are undergoing registration at the Ministry of Health should apply to the NFSA to complete the registration procedures
- 4- With regard to imported special food products, the registration issued by the Ministry of Health shall continue for a period of three months from the date of publication until the company adjusts its status in accordance with the NFSA regulations.