USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary - Public

Date: 9/2/2019
GAIN Report Number: EG-19011

Egypt

Post: Cairo

Egypt - National Food Safety Authority Modernizes Egyptian Regulatory Framework: Regulatory Management of Special Foods in Accordance with Decree No. 1 of 15 August 2018

Report Categories:
Agricultural Situation, Agriculture in the Economy, Agriculture in the News, Policy and Program Announcements, SP1 - Expand International Marketing Opportunities, SP3 - Build Demand in Developing Countries through Trade Capacity Building, Trade Policy Incident Report

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Report Highlights:
The National Food Safety Authority (NFSA) has developed special foods regulatory requirements for specialty foods as part of a renewed and modernized Egyptian regulatory framework. A category of foods for special dietary uses that are subject to this regulation is in Appendix I of this report.

EXECUTIVE SUMMARY:

The oversight to regulate special foods, including registration and control of this category of products was transferred to the National Food Safety Authority (NFSA) through the promulgation of Decree No. 1 of 15 August 2018. As a result, NFSA embarked on the development of a robust regulatory program for control of special foods, including the development of transition provisions to the new regulatory framework. The National Food Safety Authority regulatory oversight is based on the mandatory requirement of pre-market approval (or registration) of each special food, prior to its introduction into the Egyptian market.

The Special Foods Regulatory Program adopts three key principles:

1) Achieving the highest level of protection for the targeted consumers by these products.
2) Minimum disruption to the stream of commerce in enabling the transition period.
3) Transparency and inclusiveness in the development and continued improvement of the food regulatory program.

Appendix I – National Food Safety Authority Questions and Answers (attached) provides further information about the regulation.

KEY DECISIONS IN OPERATIONALIZING THE SPECIAL FOODS, REGULATORY FRAMEWORK

In developing the transitory measures, as well as shaping the final "special foods" regulatory framework, NFSA has followed and adopted best food regulatory practices to oversee the introduction of "special foods" into the Egyptian market primarily through:

- Pre-market oversight: registration of products based on set safety criteria.
- Verification of compliance with the established requirements using a risk-based approach.

The following decisions were adopted with regards to the management of the transitional period and the way to reach an on-going regulatory program for the management of special foods in Egypt:

- Pre-market oversight exercised through monographs developed for each category of Products. Although the management of special foods will be made on product-by-product basis, mandatory registration, considering the safety of the submitted product, common safety-based acceptability criteria will be developed for the same category of products, in the form of a product (category) monograph. Products meeting the monograph requirements for their composition and their labeling will benefit from immediate access to market. It is possible to submit to NFSA products with a composition and a labeling that is different from the monograph established, so long that it is accompanied by a safety evaluation demonstrating the safety of the product and the suitability of its labeling measures. The National Food Safety Authority will conduct a risk assessment to review this specific product, prior to its approval. Product category monographs may be altered based on a request from industry to account for more diversity in the product composition and consider innovation in the Special Foods Sector.

- Monographs are a set of product requirements, including composition requirements, labeling obligations.

- Monographs are being prepared progressively during a transition period: which will continue until December 31, 2022. Consultation with stakeholders will be pursued to ensure feed-back on the proposed composition and labeling requirements.

- Transition Period Management Provisions:

    - The transition period will cover the time interval from the moment of the promulgation of the updated "Special Foods Regulatory Requirements" as stipulated by Decree No. 1 of 15 August 2018, up to December 31, 2022 or the adoption and coming into force of the monograph for a given Special Foods Category, whichever is earlier.

    - The adoption and coming into force of a given product monograph will count with a phase in period, from the time a monograph is adopted to the time it comes into force. This time lag is meant to enable manufacturers and suppliers to adapt their product to the new set of requirements promulgated by NFSA through the monograph provisions.

    - In case of an application for registration of a product that has a valid license/ registration through the previous framework, this registration will be maintained up to the expiration

of the certificate or the adoption and coming into force of the relevant product monograph, whichever is earlier. Registration certificates will be issued promptly upon presentation of the proof of the registration under the previous framework.

- The National Food Safety Authority will establish a time schedule and a workplan for the development of acceptability criteria in the form of product category monographs, based on risk assessment considerations and best regulatory practices adopted by leading international food regulatory jurisdictions.

- Along with its premarket oversight, NFSA will develop a compliance verification program to target conformity of the registered products with NFSA's safety, composition and labeling requirements. The program will be risk-based and will address product categories with possible higher health risk consequences (in case of non-compliance).

- In view of its intended targeted and risk-based compliance verification and enforcement measures, certain practices that accompanied the previous product registration framework will no longer be followed, as deemed of little to no added value to support the safety of products and consumer protection. For example, providing samples of products to the authority, upon registration or upon access to market and import will no longer be required.

NEXT STEPS

The National Food Safety Authority is developing the special foods regulatory requirements as part of a renewed and modernized Egyptian regulatory framework, as envisaged by the decisions that supported the creation of NFSA and confirmed its mandate for the benefit of enhanced consumer protection and strengthening of the food production sector in the Arab Republic of Egypt.

APPENDIX I – NATIONAL FOOD SAFETY AUTHORITY QUESTIONS AND ANSWERS

Questions and Answers

1. What are the principles followed for the registration of foods for special dietary uses?

The National Food Safety Authority (NFSA) has adopted three main principles for the formulation of the requirements for the registration of special food products:

1- Ensuring the safety of the product and protecting consumers, targeted by these products

2- Ensuring fair practices in the trade of special foods in the Egyptian market, with minimum disruption to the stream of commerce.

3. Transparency, fairness and continued engagement with stakeholders from private food operators and traders.

2. What is the approach followed of the National Food Safety Authority to manage special foods registration after the decree No.1 of August 2018?

In accordance with the decree and the executive regulations, stakeholders are required to register their products with the NFSA. Therefore, the NFSA has established a policy to support seamless and smooth transition of registration procedures aiming for a minimum disruption to the stream of commerce and hoping to achieve the highest levels of safety of the targeted products, optimum protection of consumers. The NFSA is developing a rapid means to access the market for products through the adoption of product category monographs. Monographs are common safety-based acceptability criteria for the same category of products. Monographs will be developed in an incremental fashion during the transition period extending from January 2019 to December 31, 2022. During this period, industry will be granted a minimum period of six months from the time of the issuance of a given a monograph to the time of their expected compliance with the new specifications, to help them adapt their products to the new requirements.

3. What is the monograph?

A monograph is defined as a set of composition and labeling requirements developed to ensure the safety of special food products and to inform consumers of their safe consumption conditions.

Monograph requirements include composition (active ingredients to be included and their acceptable amounts, where relevant) and labeling conditions, including health claims. The requirements are to be set based on risk assessments and on best practices in science-based regulatory decisions reached out by international regulators.

4. What kind of foods should be registered with the National Food Safety Authority under the umbrella of foods for special dietary uses?

Food products meeting the definition of Special Foods according to decree No.1 of August 2018, are subject to registration with the NFSA. They include:

1. Infant formula and formulas for special medical purposes intended for infants (breast-milk substitute), and supplemental feeding stuffs.
2. Processed cereal-based foods for infants and young children.
3. Canned baby foods.
4. Foods intended for persons with special physiological conditions.
5. Foods for individuals with medical conditions.
6. Foods that are marketed with health claims as stated in items 1, 2 and 7 of Article (1) of the same regulation, and in accordance to the CAC standards, guidelines, and code of practice, and other international legislation;
7. Low-energy diets (800 – 1200 kcal) and very low energy diets (400 – 800 kcal) used in weight control or reduction and presented as a total or partial replacement for daily food, with the exception of the prepackaged foods put up for sale as conventional foods.
8. High-energy diets for use in weight gain,
9. Low-sodium foods including salt substitutes that bear health claims.
10. Foods to which vitamins or minerals are added by (15%) or more of the reference value per 100 g of solids, or by (7.5%) of the reference value per 100 ml of liquids.
11. Foods to which prebiotics, or other fortifying substances, compounds or elements are added in accordance with international legislation.
12. Foods containing stimulant, fortifying and appetizing substances.
13. Food supplements provided they do not contain any substances with a therapeutic pharmacological effect.

14. Food supplements for athletes and foods intended for intense muscular effort.
15. Individual herbs and spices or mixtures thereof bearing health claims.
16. Prepacked artificial sweeteners (table sugar substitutes).

5. Are dietary supplements formulated in various pharmaceutical dosage forms part of products to which the provisions of decree No. 1 relating to the registration and regulation of the control of special foods circulation should apply?

According to decree No. 1 issued on 15 August 2018 and published in the Official Gazette of the Arab Republic of Egypt and in accordance with the Executive Regulations of February 18th, 2019[1] related to the National Food Safety Agency of Egypt, special foods are under the oversight of the National Food Safety Agency of Egypt and shall be subject to the procedures and policies approved by the NFSA in this regard. Therefore, dietary supplements prepared in various pharmaceutical dosage forms, including capsules, tablets and oral ampoules, are subject to the provisions of the decree regarding special foods, which must be evaluated and registered prior to their placement in the Egyptian market.

6. How long does it take to register the product and receive the registration certificate?

The product will undergo a scientific and technical evaluation during a period of a maximum of 60 working days after it was deemed that the file submitted to the NFSA was complete. Upon approval of the registration of the product, the petitioner shall be notified to receive registration certificates for their products within two business days included in the prescribed period of registration.

7. What are the fees for obtaining a product registration certificate?

Infants' formula products and sports foods for athletes are registered for EGP 15,000. Other remaining special food products are registered for EGP 10,000. This is in addition to EGP 2,000 payable in return for opening a file for the product to be registered. The validity of the registration certificate is 5 years from the date of issuance of the certificate.

[1] Official Journal of the Arab Republic of Egypt. Vol 7(2). 18 February 2019. Decision of the Prime Minister, #412 of 2019.

8. How will the National Food Safety Agency handle products registered, with valid registration certificates under the previous regime?

Based on the provisions of decree No. 1 / the technical regulations on special foods issued in August 2018, petitioners must register their special food products with the NFSA. Products that have been licensed by other agencies or institutions, as part of the previous regulatory framework will be transitioned into the new regime: the NFSA will issue a registration certificate for any given product meeting this situation for the remaining valid period of time in the initial registration / license. It should be noted that, this certificate will be issued free of registration charges except for 2000 EGP paid as part of the administration fees to open a new file with the NFSA (paid once and does not apply for the renewal of the registration of the product).

9. What are the general requirements for acceptance of products to achieve product registration?

As explained above (Q2), products meeting the monograph conditions, based on their submitted file, will be considered acceptable for registration. However, and while monographs are being developed (the work is still under way), acceptance of products submitted for registration will be based on a valid registration of the same / similar product in one of 22 reference countries. The product submitted to the NFSA review must adhere to all requirements of the product allowed in the reference market / by the reference authorities in all aspects: following the same labeling guidelines, compositions, direction of use etc.... In the absence of a similar product made available and deemed acceptable by the relevant authority of one of the 22 reference jurisdictions, petitioners will be asked to submit a scientific assessment that attests to the safety of the product, for consumption, by Egyptian consumers. The assessment should also make the demonstration of the validity of any health claim associated with the product, either through an assessment follow8ng best scientific assessment practices and / or international scientific publications published in recognized and reputable peer reviewed literature, as well as possible recommendations from international organizations.

10. What countries/jurisdictions are considered reference countries?

The list of reference countries accredited by the National Food Safety Authority for the import of special food products includes 22 countries:

1. Portugal	12. Germany
2. Denmark	13. Ireland
3. Sweden	14. Iceland
4. United Kingdom	15. Belgium
5. Norway	16. Switzerland
6. Austria	17. France
7. United States of America	18. Finland
8. Japan	19. Canada
9. Italy	20. Luxembourg
10. Spain	21. New Zealand
11. Australia	22. Netherlands

11. Can I import from non-reference countries?

Yes, as there is nothing to prevent this as long as the approval requirements, explicited above are met.

12. Can infant formula be imported from non-reference countries?

Importation of infant formula is permitted only from reference countries, with the exception of EU countries not included in the list of reference countries, provided that the same product is demonstrated as having an approval for sale in any other given EU country.

13. What are the other reference requirements that can be considered to make the demonstration of the acceptability of Special Food Products, during the transition?

During the transition period, and while the NFSA is working on the development of product category monographs, international decisions reached by food regulators in reference countries, shall be the basis of the issuance of NFSA approvals for submitted special foods. The petitioner has to make the demonstration of such approval in the reference country.

14. Is it possible to submit a product for approval with a composition that represents some deviations from the product monograph that has been issued by the NFSA?

It is possible to submit to NFSA products with a composition and labelling conditions that are different from the conditions set in the monograph established, so long that it is accompanied by a safety evaluation demonstrating the safety of the product and the suitability of its labeling measures. NFSA will need to conduct a risk assessment to review this specific product, prior to its approval. Product category monographs may be altered based on a request from industry to account for more diversity in the product composition and consider innovation in the Special Foods Sector.

15. Should samples be submitted for analysis during registration?

The NFSA does not require submission of samples during registration process.

16. Should samples be submitted for analysis during production?

The NFSA does not require samples to be submitted to the agency upon production.

17. Why does the National Food Safety Authority not require sampling for analysis during registration and after production?

Providing samples of products to the agency, upon registration or upon access to market and import will no longer be required, due to the comprehensive regulatory approach that is pursued by NFSA to oversee the products, pre-market and post-market.

Along with its premarket oversight, NFSA will develop a compliance verification program to target conformity of the registered products with the NFSA's safety, composition and labelling requirements. The program will be risk-based and will address product categories with possible higher health risk consequences (in case of non-compliance). As a result of the **intended targeted and risk-based compliance** verification and enforcement measures, certain practices, such as delivering samples of products that used to be applied under the former special food regulatory framework will no longer apply.

18. What measures will be taken against the violation of registration requirements by stakeholders?

The compliance policy will determine all procedures that will be followed and applied in case of the violation of the registration conditions by the stakeholders. These violations will be determined

as a result of compliance verification campaigns. The enforcement measures to be adopted will be made commensurate to the possible impact of such violations.

19. Who can I communicate with to review the product and approve it for placement in the Egyptian market?

Petitions or their representatives may communicate with the special foods department of the National Food Safety Agency through the Department's e-mail to obtain information on the required documents and registration requirements, etc. The website of the NFSA will be regularly updated with new information related to the registration process and product acceptability criteria.