Kingdom of Saudi Arabia
Saudi Food & Drug Authority

# GUIDE TO

# PRE-REGISTRATION EVALUATION FOR FOOD PRODUCTS

SFDA – Food Sector

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# FOREWORD

This Guide has been developed as part of efforts to keep FBOs informed about the services they can utilize to register their products in SFDA. The evaluation requirements outlined herein shall, by no means, infringe any terms, or provisions stated in the approved standards and regulations. Clients need to observe food laws and regulations as this Guide may undergo future updates if, for example, amendments are made to relevant standards, regulation or other SFDA official procedures

# OBJECTIVES

The purpose of this Guide is to address all technical requirements and FAQs pertaining to the registration process of food products which may include, but not be limited to, the following:

- Product types subject to pre-registration evaluation
- Pre-registration evaluation requirements
- Understanding and complying with commonly applicable technical regulations
- Normative references to be considered by applicants

# TARGET GROUP

This Guide applies to food business operators who are interested in registering their products with SFDA

# FOOD PRODUCTS SUBJECT TO PRE-REGISTRATION EVALUATION

The objective of pre-registration evaluation of food products is to ensure conformity of products with approved technical regulations and standards, to verify products' safety, to protect consumers and to prevent the use of misleading claims on food labels

## Food supplement

Food supplements are products designed to enhance one or more specific nutritional elements in the diet, containing other substances with a nutritional or physiological effect, which include, but are not limited to, vitamins, minerals, fatty acids, amino acids, enzymes, Prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or dietary herbal extracts

## Energy Drinks

Energy drinks are carbonated or non-carbonated drinks prepared mainly from water, with caffeine added and may contain taurine, inositol, glucuronolactone, carbohydrates, mineral salts, amino acids, sweeteners, permitted additives and vitamins. It is permissible to add juices or natural fruit pulp and permitted plant extracts

## Complementary Sport Foods

Complementary sport foods belong to the category of foods with special nutritional uses, and are high-content nutritional products, which can take liquid or solid forms (ex: protein bars and energy bars). They are consumed as part of a balanced diet to provide supplementary nutrition, but they are not intended to be used for weight loss, or as part of a medical treatment. Sport foods are produced mainly from proteins, fats, and carbohydrates in the form of powder, liquid, or tablets. One or more of the following components are included in the preparation of complementary sport foods: amino acids, vitamins, nutritious minerals, plant extracts, natural and artificial flavorings, fillers, and may contain natural sugars and dietary fibers

## Sports Drinks

Sport drinks are fluid replacement beverages consisting of carbohydrates, ionized salts and minerals. The basis of sports drinks: It is a solid or liquid product from which sport drinks are made

## Infant and Child Food

Infant and Child Food includes infant formula, follow-up milk, and milk intended for medical use. Infant and young child food (cereal-based and non-cereal-based foods)

## Foods for Special Medical Use

Foods for Special Medical Use are products processed and prepared specifically to meet special nutritional requirements due to certain physical or physiological conditions and/or disorders

## Other Food Products

Other food products refer to products containing ingredients for which safety limits have not been established yet in the approved technical regulations, pending scientific investigations

# PRE-REGISTRATION EVALUATION REQUIREMENTS

The evaluation of food products is carried out on the basis of a list of requirements for registration in SFDA electronic system. However, this list is not exhaustive and may extend to include the submission of additional documents depending on the outcome of application reviews

## Supporting Documents

- Scanned Copy of the labels
- Picture of the final product

## Label and Final Product Requirements

- Upload a scanned copy of complete labels.
- Make sure the final product's image is in high resolution artwork format
- Make sure you upload a clear final product's image including all packaging sizes and types
- Make sure the product's image is not uploaded in the field allocated for the label

# ADDITIONAL DOCUMENTS FOR THE EVALUATION

## Laboratory analyses

Lab analyses are required to verify claims such as gluten-free, lactose-free, for products the ingredients of which have certain established limits, for previously registered products whose compositions have undergone partial or complete change, or for ethanol-free verification purposes or other food safety purposes

**To access Accredited laboratories, click on the following link:**

https://www.sfda.gov.sa/ar/informationlist/65465

## Technical data sheet

It is an official document provided by the manufacturer listing all product's contents (including active, non-active ingredients, colors and other additives) against their amounts. TDS may also briefly indicate product's function, purpose of use, and target consumers

*** The TDS must show amounts in approved metric units (e.g., mg/kg for additives)**

## Scientific Studies

All products, subject to pre-registration evaluation, must be in line with the approved national standards and regulations. If a product is incompliant, scientific studies are carried out to ensure that the ingredients are safe, and fit for the consumption of the target age groups according to the amounts contained in the product

## Other

- Official documents explaining some of the phrases or emblems appearing on the label
- Official documents explaining the consumption purpose of the product and the target consumers
- A free-sale certificate.
- A valid certificate of Good Manufacturing Practice (GMP) or equivalent

  *Note: The certificate must be issued by an accredited certification body recognized by the Saudi Embassy
- A product stability study based on the shelf-life as proposed by the manufacturer
- An Official document showing the scientific/common name of the main ingredient

When re-submission is made because of missing documents, the label and final product's picture must be re-uploaded.

# DOCUMENTS FOR (GELATIN, JELLY, TABLET, PILL ...ETC.) CAPSULE PACKED PRODUCTS

## Package Leaflets

For products packed in pills, tablets, capsules or other drug-like shapes, the package must include leaflets describing the instructions for use, dosage per age group, contraindications, side effects, cautions, storage methods, and general recommendations.

## Packing

For the registration of products susceptible to the effects of inclement conditions such as heat, humidity or sunlight and thus requiring special storage conditions, the applicant must submit a document which describes the packaging material, and verifies its safety for use

**Note:** All warnings and preservation methods must be clearly indicated on the label

## Shelf-life Based Product Stability Studies as Proposed by the Manufacturer

The manufacturer is responsible for determining the appropriate shelf-life during which the product's physical, (e.g.: purity), chemical, sensory and other compositional stability factors are maintained. The stability studies must incorporate Compositional Stability Data during the proposed shelf-life (SFDA retains the right to set up the necessary regulatory verification framework)

**Note:** the maximum permitted shelf-life to be applied to the final package is five years

## Pharmaceutical GMP Certificate

For pills, tablets and other pharmaceutical formals, a GMP certificate (or equivalent) must be submitted

**Note:** The certificate must be issued by an accredited certification body recognized by the Saudi Embassy

## Product Size and Shape (capsule - tablet - pills)

The size and shape of the capsule, tablet, or pills must be indicated

## Product Solubility study

Safety Analyses

A comprehensive laboratory report on product's safety, incorporating tests such as heavy metal, pesticide residue, and pathogenic microorganisms, must be submitted

# GUIDELINE 1.
# HOW TO COMPLY WITH NUTRITIONAL CLAIMS

Technical Regulation "2333 FD. SFDA" ("Requirements for Health and Nutrition Claims") is concerned with the use and advertisement of health, functional and nutritional claims as well as related labeling requirements, including trademark and product's name

- For the approval of novel claims, applicants must submit an evaluation request, along with the supporting documents and studies, to the Health and Nutritional Claims Committee. For more information, please scan the QR code or click on the link below to access the Guide to Claims

  https://www.sfda.gov.sa/ar/regulations/74218

## Health Claim

A health claims is any statement about a relationship between food or food group and health

**Example**

Vitamin A contributes to the normal function of the immune system

**Please scan the following QR code or press on the link below to access the calculator and check nutritional claims**

https://sfda.gov.sa/ar/calculators

## Nutritional Claims

A nutritional claim is any claim which states, suggests or implies that a food has particular beneficial nutritional properties

This food product is low in energy

**It is not allowed to either implicitly or explicitly use product's name, or trade mark within the claim statement. Claims must be connected to the main ingredient establishing the plausibility of the claim**

# GUIDELINE 2.
# HOW TO LOOK UP TECHNICAL REGULATIONS FOR FOOD ADDITIVES

FD. SFDA 2500 “Additives Permitted for Use in Food Stuffs” lists a number of food additives which are permitted for use in food products

## Technical regulations for food additives can be looked up in many ways, including:

- By using the International Numbering System for Food Additives (INS No.)
- By using the name of the additive
- By using the classification of food items

In all the above search methods, food classes per item must be known

**TABLE (B)**

To search for additives permitted generally for use in foods, according to Good Manufacturing Practices (GMP)

**TABLE (C)**

To search food and foodstuff categories

**TABLE (E)**

To show notes concerning each food item listed in the food additive tables

# GUIDELINE 3.
# REQUIREMENTS YOU MAY NEED TO KNOW.

- Collagen requirements
- Aloe vera juice requirements
- Moringa requirements
- Requirements for products that contain royal jelly - propolis – pollen
- Requirements for food products that contain Agave syrup as part of their ingredients

**Published requirements** can be found by scanning the following QR code or by clicking on the link below:
https://beta.sfda.gov.sa/ar/imported-food

## GUIDELINE 4.
## HOW TO ACCESS TECHNICAL STANDARDS AND REGULATIONS

- Select the sector from a drop-down list
- Type in the regulation/standard's title or number of interest
- After you click on search, the list of related standards/regulations and their corresponding numbers appear on the screen

**Technical regulations and standards** can be found by scanning the following QR code or by clicking on the link below:
https://mwasfah.sfda.gov.sa/

## GUIDELINE 5.
## HOW TO ACCESS TECHNICAL STANDARDS AND REGULATIONS

**Product Classification Guidance** can be found by scanning the following QR code or by clicking on the link below:
https://sfda.gov.sa/ar/regulations/65896

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