OVERVIEW OF THE REGISTRATION PROCESS OF DIETARY SUPPLEMENTS IN BRAZIL

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Dietary supplements are defined as:

“Product for oral administration, presented under pharmaceutical dosage forms intended to supplement the diet of healthy individuals with nutrients, bioactive substances, enzymes or probiotics, alone or in combination.”

- Dietary Supplement are NOT:
  - Medicines and therefore do not treat, prevent or cure illness.
  - Have any medical claims on their labeling

Supplements that must have Sanitary Registration from Anvisa are:

- Supplements containing enzymes or probiotics
- Supplements with functional and/or health claims
DEFINITION (Continued)

Dietary Supplements include:

1. Vitamin and mineral supplements;
2. Bioactive substances and probiotics;
3. Novel foods;
4. Foods with claims of functional properties;
5. Athlete supplements;
6. Supplements for pregnant women and nursing mothers;
7. Specific non-prescription medicines.
## Difference between Dietary Supplements and Specific Medicines

<table>
<thead>
<tr>
<th></th>
<th>Dietary supplement</th>
<th>Specific Medicine</th>
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<tbody>
<tr>
<td><strong>Purpose of Use:</strong></td>
<td>Supplementing the diet of healthy people</td>
<td>must have a proven therapeutic or medicinal purpose.</td>
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<tr>
<td><strong>Therapeutic indication:</strong></td>
<td>It is not indicated to treat or prevent conditions</td>
<td>It is indicated for specific diseases or conditions</td>
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<tr>
<td><strong>Scientific Studies</strong></td>
<td>There are NO scientific studies that support this indication</td>
<td>• There are scientific studies that support this indication.</td>
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<td>• its efficacy has been proven by taking into account the concentration, the dosage and the pharmaceutical form.</td>
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INSTITUTIONS INVOLVED IN THE REGISTRATION PROCESS

**Ministry of Health**

**Brazilian Health Surveillance Agency (ANVISA)**

**General Food Management (GGALI)**

**ANVISA:**
Coordinates, supervises, and controls the activities related to the registration, information, inspection, norms and standards establishments, compliance with regulations concerning the sanitary surveillance of food, water, beverages and their ingredients.

**GGALI:**
Provides supplementary assistance to state and municipal health surveillance agencies in the development and implementation of health inspection and risk monitoring programs; and food legislation.
Dietary Supplement Registration Process

1. Appoint a Local Representative
2. Step 1: Check the list of ingredients
3. Step 2: Check the compliance of the label
4. Step 3: Check the compliance of the claims
5. Anvisa Inspection
6. Receive Sanitary License
7. Anvisa reviews application (~180 days)
8. Submit all necessary documents to Anvisa

Products that are exempt from Registration must only be notified for importation license. (Process specified in Blue)

Products that are not exempt must apply for Sanitary license from Anvisa and complete entire process (Start in Blue and continues into Green section)
REGISTRATION PROCESS
Step 1: Check the status if the Ingredients

Ingredients included in Dietary supplements that are a sources of nutrients, bioactive substances and enzymes must fully comply with the identity, purity and composition specifications established in at least one of the following references:

1. Brazilian Pharmacopoeia;
2. Foreign pharmacopoeias officially recognized (German, American, Argentina, British, European, French, International Pharmacopoeia (WHO), Japanese, Mexican and Portuguese);
3. Food Code (Codex Alimentarius);
4. Joint FAO/WHO Expert Committee on Food Additives - JECFA;
5. Food Chemicals Codex - FCC;
6. USP Dietary Supplement Compendium - DSC;
7. European Food Safety Authority - EFSA
Step 2: Check the Compliance of the Label

The Labeling of the dietary supplements should include the following information:

- The products shall be designated\(^{(1)}\) as "Food Supplement" in addition to their pharmaceutical form.

- The name must be declared close to the product's brand and in legible characters:
  
  I - uppercase;
  
  II - bold;
  
  III - contrasting color with the label background; and
  
  IV - minimum size equivalent to 1/3 (one third) of the size of the largest font used for the product's brand

\(^{(1)}\) All food supplement designations must follow the requirements in Annex V or VI of the Normative Instruction n° 28/2018.
The labeling of food supplements shall have the following information:

I. the recommendation for use according to population group\(^{(2)}\) and age range in the case of children;

II. the quantity and frequency of consumption\(^{(2)}\) for each of the population groups indicated on the label;

III. highlight and bold warning:
   - "This product is not a medicine"
   - "Do not exceed daily recommendation of consumption indicated on the packaging"
   - "Keep out of the reach of children"

IV. the instructions for storage, including after opening the package.

\(^{(2)}\) The population groups and the daily consumption recommendation are described in Annexes III and IV of the Normative Instruction n° 28/2018.
Step 2: (Continued)

- The nutritional information shall contain:
  
  I. the quantities of all nutrients, bioactive substances, enzymes and probiotics provided by the product;
  
  II. the percentage daily value (%VD) should be declared for each of the specific population groups indicated on the label, based on the recommended daily intake values.

When the label is not in Portuguese, an additional tag or cover label should be placed, containing the mandatory information in Portuguese with appropriate size, highlight and visibility characters. This label can be placed in the country of origin or destination. In both cases, the application must be made before commercialization.
Step 3: Check the Compliance of Claims

The Claims made on the Dietary Supplement Labeling and packaging should:

- Have no textual variations of the authorized claims are allowed, except when:
  1. the claims for the same substance are brought together in a single sentence; or
  2. the identical claims for different substances are brought together in a single sentence.

- The use of the claims is optional, **Except** for food supplements with probiotics or enzymes.

- Claims concerning the content and properties of food additives and technology adjuvants are not permitted.

- The labelling of food supplements may not present words, brands, images or any other graphic representation, including in other languages, which state, suggest or imply, expressly or implicitly, that:
  1. the product has a medicinal or therapeutic purpose;
  2. the product contains unauthorized or prohibited substances;
  3. the food is not capable of providing the components necessary for health; or
  4. the product is comparable or superior to conventional foods.

The claims authorized for use in food supplements are established in Annex V of the Normative Instruction n° 28/2018.
Documents Required for Registration for Supplements Containing Probiotics and/or Enzymes:

- Reason for the request
- Completed Application **Forms 1** and **Form 2**
- In addition to Application **Form 2**, a table containing the name, address and respective production stages performed at each of the establishments involved in manufacturing must be submitted. The product storage locations must also be identified.
- Labelling Specifications or Label Template
- Company Registration Form (FCE) - for unregistered company
- Copy of the valid sanitary permit or equivalent document
- In the case of imported products, the license or sanitary permit of the warehouses where the products subject to registration will be stored must be presented.
Step 4: (Continued)

About the supplement:

- Information proving the use of constituents authorized for use in the composition of food supplements or approved in the application assessment and safety and efficacy assessment
- Information proving the use of authorized food additives and technology adjuvants
- Information that the other ingredients used in the preparation of the supplement to provide flavor, color or aroma or to dissolve, dilute, disperse or change their consistency or shape are:
  1. traditionally used in the preparation of foods;
  2. meet the respective identity and quality standards;
  3. are not classified as food additives or technology adjuvants;
  4. are not classified as new foods or new ingredients;
  5. are not sources of amino acids, vitamins, minerals, bioactive substances, enzymes or probiotics.
- Quality control information, including analytical reports on the final product (minimum and maximum limits; declaration on nutrition labelling)
- Stability study reports ensuring that the characteristics of the supplement are maintained until the end of the shelf life, considering the storage instructions and the method of preparation indicated by the manufacturer.
Import the of Dietary Supplements to Brazil

Products Exempted From Registration:

- Foreign companies through the importer located in Brazil must submit the **Form for the Communication of Importation of Products Exempted from the Registration Requirement** at Anvisa and at local Health Surveillance.
- The importer must be licensed (local health license) for the import of food.

Products with Mandatory Registration:

- The application for registration must be made by the importer, subsidiary company or manufacturer’s representative.
- The Sanitary Permit or Operating License of the warehouse where the registered product will be stored must be presented.

**The procedures and forms for registration and exemption from registration of imported products will be the same as those established for national products.**
Mandatory Inspection

Domestic Manufacturers

- Health inspection at the factory unit is necessary only in cases of manufacturer. The companies must inform the beginning of the manufacture of the product(s) to the health authority of the State, Federal District or Municipality, through the **Form of Communication of the Beginning of Manufacture of Products Exempted from Registration** and may already start the marketing.

Imported Products:

- In the case of imported products, the storage unit may be inspected by a health authority.

Inspection Deficiencies:

- In case the company is not approved in the inspection, it will be notified to adopt the following procedures, without prejudice to the application of other penalties provided for in the legislation:

  1. suspend production;
  2. collect the product(s) from the market when the health authority deems it necessary, incurring the costs of disclosure for notification to the population.
References

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