Pharmaceuticals Export Promotion Council of India (Set up by Ministry of Commerce Industry, Govt. of India)

“India: Mexico & Colombia Cooperation in Pharmaceutical Sector”

The regulatory framework in Mexico, Ms. Consuelo Albarran,
DG of Business Development

DEFILATINA HEALTHCARE
Authorized COFEPRIS Third Party

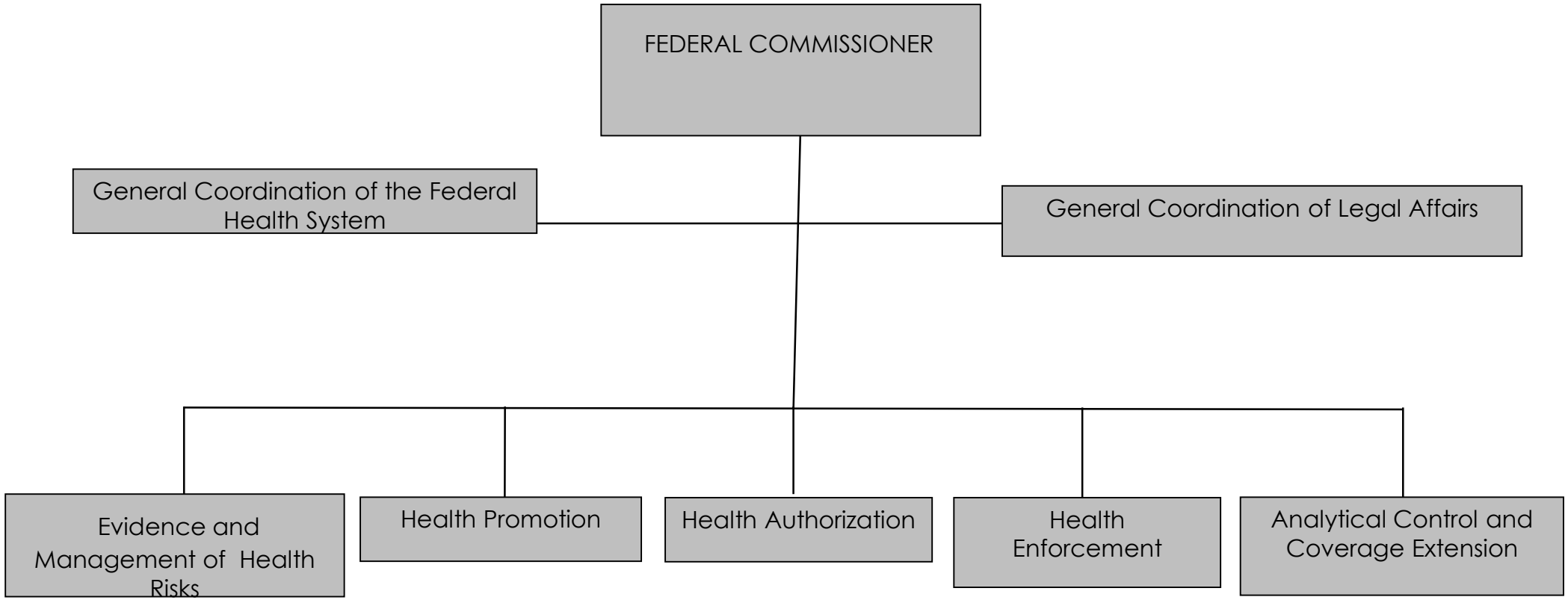
DEFI
LATINA HEALTHCARE

COFEPRIS

The Federal Commission for the Protection against Health Risks (COFEPRIS) is a decentralized organ with management, operative, and technical autonomy. Its objective is to protect the population's health.

CAS (Health Authorization Commission)

It issues official documents for the import and export of supplies for health and food products, amongst others, as well as inflow and outflow of cells, tissue and blood. It also issues publicity permits, establishment licenses, product registries and health condition certificates for medicines, biologic products for human usage, biotechnological and medical devices, health services, food, tobacco, pesticides, vegetal nutrients and chemical precursors.


FEDERAL COMMISSIONER
General Coordination of the Federal Health System
General Coordination of Legal Affairs
Evidence and Management of Health Risks
Health Promotion
Health Authorization
Health Enforcement
Analytical Control and Coverage Extension

MEDICATIONS

Any substance or mixture of substances of natural or synthetic origin that has a therapeutic, preventive or rehabilitative effect, that is presented in pharmaceutical form and is identified as such by its pharmacological activity, physical, chemical and biological characteristics.

CLASIFICATION OF MEDICATIONS IN MEXICO BY NATURE

ALLOPATHIC: Any substance or mixture of substances of natural or synthetic origin that has a therapeutic, preventive or rehabilitative effect, that is presented in pharmaceutical form and is identified as such by its pharmacological activity, physical, chemical and biological characteristics, and is registered in the Pharmacopoeia of the United States of Mexico for allopathic drugs.

HERBAL: Products made with plant material or any derivative thereof, whose main ingredient is the aerial or underground part of a plant or extracts and tinctures, as well as juices, resins, fatty and essential oils, presented in pharmaceutical form, whose therapeutic efficacy and safety has been scientifically confirmed in national or international literature.

OTHER

VITAMINS

BIOTECHNOLOGICAL

BIOLOGICAL OR BLOOD PRODUCTS

HOMEOPHATIC

DEFI LATINA HEALTHCARE

Types of Registration

	Homeopathic & Herbal		
Source	Homeopathic	Herbal	
	Medicine	Medicine	Remedy
Type of product	**Marketing authorization / Health permit (Remedies)**		
Manufacturing site:	**International / Domestic**		

HEALTH REGISTRATION REQUEST FOR A HERBAL MEDICINE

The application file for the Health Registration of Herbal Medicines is structured by Modules:

SECTIONS Registration for a Herbal Medicine

- Module I — Legal-Management Information
- Module II — Summary of the medicine characteristics.
- Module III — Quality
- a) Raw Materials
- - Active Ingredient
- - Additive
- b) Fabrication Process
- c) Container material
- d) Finished Product
- e) Stability studies
- Module IV — Scientific information, clinical studies.

SUPPLEMENTS

SUPPLEMENTS

What are food supplements?

- They are herbal products, vegetable extracts, traditional foods, dehydrated or fruit concentrates, added or not of vitamins or minerals, that can be presented in pharmaceutical form * and whose purpose of use is to increase the total dietary intake, complement it or supply any component, according to article 215, section V, of the General Health Law.
- A food supplement provides nutrients such as proteins, fats, carbohydrates or carbohydrates, vitamins, minerals.
- * The accepted pharmaceutical forms are those that are ingested orally as: capsule, emulsion, suspension, syrup, powder, solutions and tablets, among others contemplated in the Pharmacopeia of the United States of Mexico. Forms of other categories of products are not allowed, such as: confectionery (candies, lollipops, gum), patches, injectable solution, among others.

What are they for?

- **Its only function is to increase, complement or supplement a**ny **of the components that we acquire through the diet**, that is, from the foods and meals that we eat daily; because some people do not get all the nutrients they need in their diet and therefore they turn to food supplements to complement their diet.
- **It is not a product intended to treat, cure, prevent or alleviate symptoms of any disease.**
- **They do not serve to lose weight, fight obesity or overweight**.
- **They are not for aphrodisiac use.**

It should be taken into account that products aimed at treating or curing a disease or illness are medicines OR remedies, which must be prescribed by a health professional, and require a health registration issued by the Ministry of Health that guarantees its safety, quality and efficacy (art. 22 General Health Law).

DEFI LATINA HEALTHCARE

SUPPLEMENT INGREDIENTS ALLOWED

Food supplements are allowed to contain one or more of the following ingredients*:

- **Carbohydrates**
- **Protein**
- **Amino acids**
- **Fatty acids**
- **Metabolites**
- **Plants**
- **Algae**
- **Dehydrated traditional foods**
- **Others established by the Secretariat**
- **In combination with the aforementioned ingredients, it can be included in its composition:**

    - **Vitamins and minerals as long as they do not exceed the allowed limit, established in appendix XVII 1.1 and 1.2 of the Regulations for the Health Control of Products and Services.**
    - **Allowed additives, included in the Agreement that determines the substances allowed as additives and adjuvants in food, beverages and food supplements (DOF, 07/16/12) and its latest modification (DOF, 05/16/16).**

https://www.gob.mx/cofepris/acciones-y-programas/aditivos-alimentarios-no-publicados-en-el-dof

DEFI LATINA HEALTHCARE

INGREDIENTS NOT ALLOWED

Food supplements shall not contain*:

- Procaine
- Ephedrine
- Yohimbine
- Germanium
- Animal or human hormones
- Substances with pharmacological action.
- Nor those that pose a health risk
- The plants that are not allowed for infusions or tea, according to the first point of the Agreement that determines the prohibited or allowed plants for teas, infusions and edible vegetable oils (DOF, 12/15/1999)

*Art. 169, Regulation of Sanitary Control of Products and Services.

- **It should be taken into account that botanical species, contemplated in the list of plants of known toxicity of the Herbal Pharmacopeia of the United States of Mexico (FHEUM), are not allowed in the formulation of food supplements.**

- In addition to the above, it is recalled that the composition of food supplements must also comply with the additives and processing aids, established in the Agreement that determines the additives and aids in food, beverages and food supplements, their use and health provisions, in force.

- Therefore, manufacturers and distributors are urged to avoid the manufacture of products that contain ingredients considered prohibited, or to stop their importation.

https://www.gob.mx/cofepris/documentos/ingredientes-prohibidos-o-restringidos

DEFI LATINA HEALTHCARE

FORMALITIES FOR SUPPLEMENTS

1. **Product classification query as a food supplement**

- **It is a free procedure, through which the health authority, based on the formulation and labeling of the products, corroborates whether or not they comply with the legal framework of food supplements and in case of refusal, it notifies the corresponding regulatory figure.**
- **The classification query is a technical opinion. It does NOT count as a health authorization.**
  - **The query is made by product**
  - **Maximum response time: 90 days**

- **All food supplements, prior to their advertising permit process, must have a positive response to the classification query.**

- **Possible answers are:**

- **IT IS A FOOD SUPPLEMENT**
- **ADITIONAL INFORMATION REQUEST**
- **IT IS NOT A FOOD SUPPLEMENT**

2 Notice of Establishment /Operation

- **Food supplements do not require a health registration, manufacturers and/or those responsible for their marketing in the country must submit 30 days before starting operations a formality called "Notice of establsihment/operation."**

- **In the event that your food supplement complies with the required content, labeling, and safety, you can carry out the following procedure at the COFEPRIS front desk or at any of the health regulation addresses of your federal entity:**

  - **Notice of establishments and of operation**
    - **Storage as warehouse for supplements**
  - **Homoclave: COFEPRIS-05-018**
  - **SCIAN code (2): 325412**
  - **Industry: Manufacture of pharmaceutical preparations (only food supplements)**
  - **This procedure is free and is subject to a subsequent review by the authority, so any irregularity that is detected will be subject to a verification visit to the establishment.**

https://www.gob.mx/cofepris/acciones-y-programas/suplementos-alimenticios

DEFI LATINA HEALTHCARE

SUPPLEMENT IMPORT

Food supplements Import

- **The supplements require a Prior Health Import Permit (PSPI) and to grant it, COFEPRIS reviews the labeling and the ingredients of the product. There are three types of permits:**

- **Prior health permit to import products**
- **Prior health permit to import products by return**
- **Health permit for importing samples or for personal consumption (For donation, personal consumption, scientific research, laboratory tests and exhibition).**

- **The requirements are detailed in the Agreement that establishes the classification and codification of merchandise and products whose import, export, admission or exit is subject to health regulation by the Ministry of Health (DOF October 19, 2012) and its modifications (DOF September 1, 2015 and February 5, 2016).**

- **Any product that enters the country for the first time is subject to sampling and release by the authority; in the following imports the sampling is carried out randomly.**

DEFI LATINA HEALTHCARE

ADVERTISING FOR SUPPLEMENTS

To advertise a food supplement, regardless of the origin of manufacture, you must have an advertising permit issued by COFEPRIS

The features that supplement advertising must meet are:

- **To post precautionary messages regarding the effects that its consumption may cause.**
- **Limit the advertising to the features of the product. In this case, it can only be mentioned the intended use related to increasing the total dietary intake, supplementing it or substituting any of its components.**
- **Incorporate in your advertising the legend: "This product is not a medicine".**
- **Include other legends determined by the Ministry based on the health risks that the product represents.**

What cannot be included in the advertising of dietary supplements is:

- **Describing them as diet products or that serve to modify the proportions of the body.**
- **Presenting them as modifiers of physical or mental state.**
- **Stating that the product alone meets the nutritional requirements of a human being.**
- **Attributing a nutritional value different from the one they actually contain, undermining natural foods.**
- **Claiming that it provides a human with extraordinary abilities.**
- **Attributing properties that cannot be verified or that are useful to prevent, alleviate, treat or cure a disease, disorder or physiological state.**
- **Stating that they themselves are useful to prevent, alleviate, treat or cure a disease, disorder or physiological state.**
- **Induce unhealthy eating habits.**

DEFI LATINA HEALTHCARE

SUMMARY

- **COFEPRIS**
  - **CAS**
    - **REGISTRATION REQUIRED**
      - **HERBOLARY AND ALLOPATHIC MEDICINES**
      - **COFEPRIS DECIDES WHICH CATEGORY FITS EACH PRODUCT ACCORDING TO ITS THERAPEUTIC ACTION AND INGREDIENTS.**
    - **NO REGISTRATION REQUIRED**
      - **FOOD SUPPLEMENTS**
      - **CONSULT COFEPRIS.**
      - **IMPORT PERMITS**
      - **COMPLY WITH ADVERTISING.**

DEFI LATINA HEALTHCARE

THANK YOU

DEFILATINA HEALTHCARE
Consuelo Albarrán
General Manager and Legal Representative
consueloalbarran@defihealthcare.com.mx
Mobile: (51) 55 13 20 89 62

BACK UP CHARTS.

DEFILATINA HEALTHCARE
Authorized COFEPRIS Third Party

Health registration requirements for herbal medicines of foreign fabrication COFEPRIS

It allows you to obtain the authorization of a herbal medicine that is manufactured outside the national territory and that complies with the current health legislation of our country for its subsequent manufacture, import, marketing and distribution in the national territory.

Required documents:

• Authorizations format, certificates and visits, properly filled.	Original
• Proof of rights payment, according to the Federal Law of Rights.	Original and 2 Copies
• The technical and scientific information that demonstrates:	
◦ The identity and purity of its components in accordance with the provisions of the special pharmacopoeias, or otherwise, the sources of international scientific information.	
◦ Description of the primary and secondary packaging	
◦ Method of identification of the active ingredient or ingredients	Copy

Technical and scientific information that demonstrates the stability of the finished product

• Taxonomic identification certificate of each of the plants used or the document containing the information on the identity of the components.	Copy
• Therapeutic indications.	Original and Copy
• Label projects.	Original and Copy
• Instructions for usage (if applicable).	Original and Copy
• Description of the manufacturing process of the medicine to be registered.	Original
• Information to prescribe in its wide and reduced versions.	Original and Copy
• Free sale certificate issued by the competent authority of the country of origin.	Certified copy
• Letter of representation from the manufacturer, authenticated by the legal procedure that exists in the country of origin, in Spanish or any other language, with its respective translation into Spanish by an expert translator, whenever the laboratory that manufactures it abroad is not a subsidiary or house matrix of the laboratory requesting the Sanitary Registry.	Certified copy
• Certificate of analysis issued by the manufacturer of the medicine on letterhead and endorsed by the health officials of foreign and national companies.	Original

DEFI LATINA HEALTHCARE

EXAMPLE OF A REQUEST FOR A QUERY OF PRODUCT CLASSIFICATION FOR FOOD SUPPLEMENTS

It is presented on the company's letterhead, with the autograph signature of the owner, legal representative, or health officer, when it applies, addressed to the: Health Operation Commission of the Federal Commission for Protection against Health Risks (COFEPRIS).

NAME OF COMPANY
CDMX. as of April 1, 2017
FEDERAL COMMISSION FOR THE PROTECTION AGAINST HEALTH RISKS
COMMISSION OF SANITARY OPERATION (COFEPRIS)

Subject: Product classification inquiry

I hereby request a product classification query according to article 172 of the Regulation of Sanitary Control of Products and Services:

1. PRODUCT DESCRIPTION:

Product name: PROTEIN CASOY VANILLA FLAVOR
Generic name: Food supplement
Specific name: Powder to reconstitute
Intent for use: Supplement the intake of proteins, amino acids, vitamins and minerals.

2. QUALI-QUANTITATIVE FORMULA:

Ingredients Per serving (20 g) Per 100 g Function Soy protein 8g 40g Protein contribution Sodium caseinate 5g 25g Protein contribution L-glutamine 0.5g 2.5g Amino acid contribution Pregelatinized starch 3g 15g Thickener Maltodextrin 3.45g 17.25g Bulking agent Hydrochloride of pyridoxine (of which 5 mg are equivalent to vitamin B6) 0.05g 0.25g TOTAL vitamin supply 20g 100g.

3. INSTRUCTIONS FOR USE: Take 1 sachet a day with food.

4. SAMPLE LABEL: Original or graphic arts print (legible and in Spanish). In the case of imported products, they must additionally send the origin label. XXXX

_____ Lic. XXXXXXXXXXX Legal representative of XXXXXXXXXXXXXXXX

DEFI LATINA HEALTHCARE