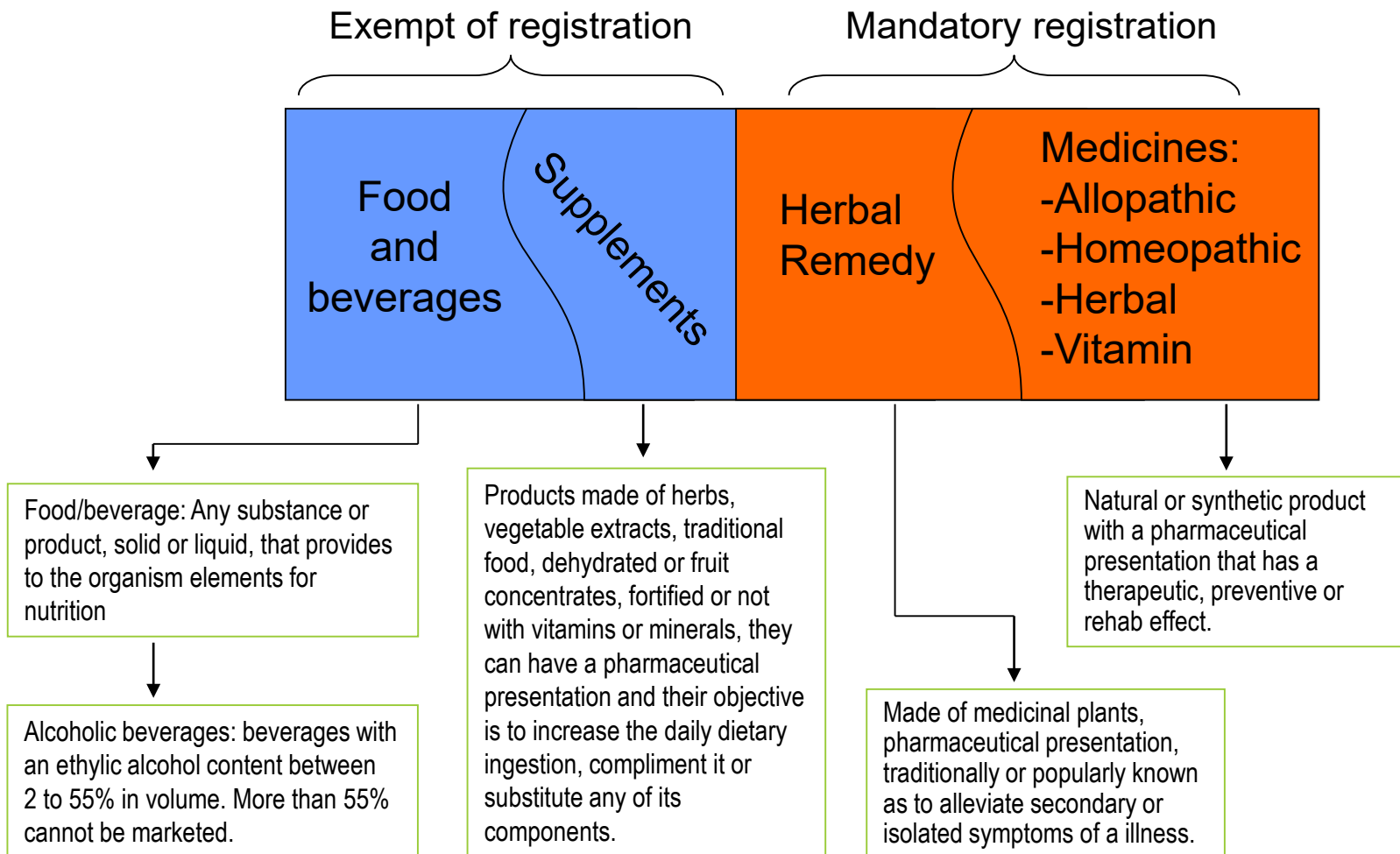


Classification of Products

MEXICO

October 17th, 2018

Ingested Products



Food and Beverages

- **Food:** any substance or product, solid or semi-solid, natural or transformed, that provides to the organism elements for nutrition
 - **Beverage:** any liquid, natural or transformed, that provides to the organism elements for nutrition
- They are exempt of registration but subjected to accomplish the following Regulations:
 - Labeling: NOM051
 - Ingredients: Additives Agreement
 - GMP: NOM252
 - Advertisement: only alcoholic beverages need sanitary approval for publicity

Food Supplements

- Products made of herbs, vegetable extracts, traditional food, dehydrated or fruit concentrates, fortified or not with vitamins or minerals, they can have a pharmaceutical presentation and their objective is to increase the daily dietary ingestion, compliment it or substitute any of its components.
- Importation of food supplements requires a sanitary authorization prior to importation (**PSPI** in Spanish).
- Process involving these products (manufacturing, storage, sale, etc.) require a notification submitted to MoH (**Aviso de Funcionamiento**). These activities should follow internal control based on Mexican official norms.
- Advertisement materials require sanitary authorization (**Permiso Publicitario**)
- These products should also accomplish with regulatory requirements for food

Herbal Remedy

- Products made of medicinal plants or their parts, individual or combined and their derivatives, presented in pharmaceutical form and traditionally or popularly known as to alleviate secondary or isolated symptoms of an illness.
 - Formulation should not contain drugs, psychotropic or any other allopathic substance that generates hormonal activity, anti-hormonal or any other substance in a concentration that represents a risk for health.
- Requires sanitary notification.
 - Once dossier is submitted and approved product receives an **alphanumeric id.**
 - Process involving herbal remedies require a sanitary notification (**Aviso de Funcionamiento**)
 - Free sale
 - Labeling and transportation must follow the regulatory requirements for medicines or “**insumos**”

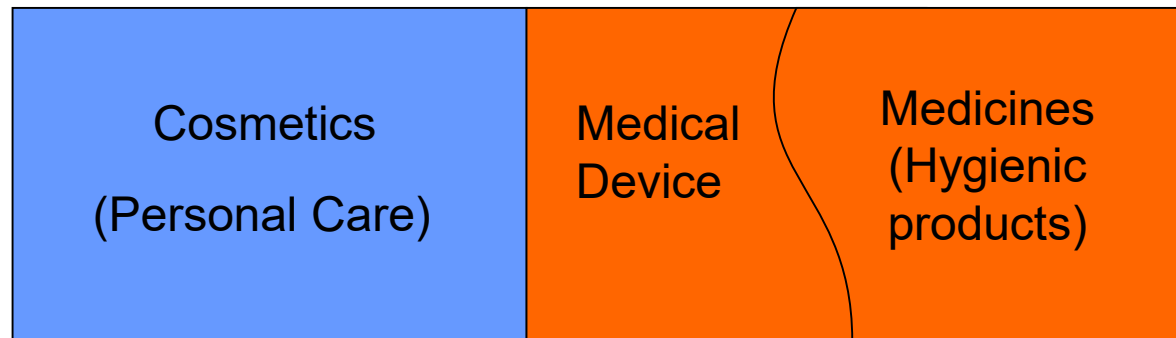
Medicines

- Substances or mix of substances of natural or synthetic origin, with a pharmaceutical presentation, that have a therapeutic, preventive or rehab effect and that are identified as such due to its pharmaceutical activity, physical, chemical and biological characteristics.
 - When a product contain nutriments, it will be considered medicine if it contains vitamins, minerals, electrolytes, amino acids or fatty acids single or associated, in a higher concentration than natural food and also if they have a pharmaceutical presentation and the use instructions consider therapeutic, preventive or rehab effects.
- Require sanitary registration.
 - GMP and production process is verified as well as the certification of analysis of actives.
 - Sale needs receipt
 - Medicines classification:
 - Allopathic
 - Homeopathic
 - Herbals
 - Vitamins
 - Others

Cosmetics and Personal Care Products

Exempt of registration

Mandatory registration



Substances or formulations that are designated to get in contact with superficial parts of the human body: epidermis, hair and capillary system, nails, lips, genital external organs, or in contact with tooth and dental mucosa, with the main or exclusive objective of cleaning, perfume, help to modify aspect, protect, maintain in good condition or correct corporal smell or attenuate deficiencies or alterations in the function of healthy skin

Medical equipment, diagnosis agents, dental inputs, surgical materials, prothesis.

Materials and substances applied over the skin or body cavities and produce a therapeutic or preventive action.