Summaries of Registration Requirements for El Salvador

**LAW ON PLANT AND ANIMAL HEALTH (DECREE Number 524)**

This law aims to establish basic rules for the protection of health of plants and animals.

**CENTRAL AMERICAN SANITARY AND PHYTOSANITARY GUIDELINES FOR TRADE FACILITATION OF SHIPMENTS AND GOODS [ANNEX OF RESOLUTION No. 338-2014 (COMIECO-EX)]**

To establish procedures to simplify the application of sanitary and phytosanitary measures with the aim of trade facilitation of shipments and goods, taking account of considerations of the risk associated with them, as well as production systems, areas or sites of production and processing establishments. The specific objectives are to:

* Improve the control on the application of sanitary and phytosanitary measures for trade facilitation of shipments and goods.
* Categorise by developing a list of shipments and goods, according to the associated risk.
* Simplify documents and streamline procedures relating to the trade of goods and shipments.

**ALCOHOLIC BEVERAGES (DISTILLED ALCOHOLIC BEVERAGES): LABELLING REQUIREMENTS (ANNEX 2 OF RESOLUTION No. 332-2013 (COMIECO-LXVI); RTCA 67.01.06:11)**

To establish the requirements the labelling of pre-packaged distilled alcoholic beverages for human consumption that must be complied. Applies to the labelling of all distilled alcoholic beverages, alone or mixed, in their final unit of presentation, and are marketed in the territory of the Central American countries.

**ALCOHOLIC BEVERAGES (FERMENTED ALCOHOLIC BEVERAGES): LABELLING REQUIREMENTS (Annex 1 of resolution No. 332-2013 (COMIECO-LXVI); RTCA 67.01.05.11)**

To establish the requirements to be met for labelling of pre-packaged fermented alcoholic beverages for human consumption. Applies to the labelling of all fermented alcoholic beverages, alone or mixed, in their final presentation unit and marketed in the territory of the Central American countries.

**FERTILISERS AND SOIL CONDITIONERS FOR AGRICULTURAL USE: REQUIREMENTS FOR REGISTRATION (ANNEX TO THE RESOLUTION No. 314-2013 [COMIECO-EX]; RTCA 65.05.54:09)**

To establish the requirements for granting the registration of fertilisers and soil conditioners for agricultural use. Applies to the registration of fertilisers and soil conditioners for agricultural use, which are manufactured, formulated, extracted from natural sources, packaged, repacked or repackaged, imported, exported, distributed and sold in the States Parties of the Central American Region.

**FOOTWEAR AND PARTS (LABELLING REQUIREMENTS): (RTCA 61.01.03:12)**

To establish the requirements that the labelling of footwear and parts must meet when sold separately. Applies to the labelling of new footwear and parts thereof[[1]](#footnote-1), when made available to the final consumer within the territory of the States Parties.

The following type of footwear is not considered for the purposes of this technical regulation:

1. The footwear which has characteristics of a toy;
2. Footwear designed to provide security and protection against risks arising from the realisation of a specific activity; and
3. The booties of light disposable materials or of little resistance, as textile, paper or synthetic, without soles applied.

Note: The labelling of footwear used will be dependent on the national legislation of each State party.

**PHARMACEUTICAL PRODUCTS (NATURAL MEDICINAL PRODUCTS FOR HUMAN USE): REGISTRATION REQUIREMENTS (ANNEX OF RESOLUTION No. 303-2013 (COMIECO-EX); RTCA 11.03.64:11)**

To establish the conditions and requirements under which the health registration of natural medicinal products for human use for marketing is granted. It applies to natural medicinal products for human use that is manufactured or imported, natural or legal persons for marketing in the Member States of the Central American region.

This excludes those products that are added to active substances of chemical synthesis or isolated from natural material responsible for pharmacological activity, as well as dosage forms that are applied via parenteral and ophthalmic administration.

**PHARMACEUTICALS (DRUGS FOR HUMAN USE): HEALTH REGISTRATION REQUIREMENTS (ANNEX 1 OF RESOLUTION NO. 333-2013 (COMIECO-LXVI); RTCA 11.03.59:11)**

To establish conditions and requirements under which the registration of medicaments for human use will be granted. Applies to drugs for human use that are manufactured or imported by individuals or entities for marketing in the Central American Territory. Compounded preparations are excluded from this Regulation.

NOTES:

1. Biological and biotechnological drugs shall be registered in accordance with the national legislation of each State Party.
2. If a State party does not have a national law for the registration of biological and biotechnological medicinal products, these rules will be applied to those products.

In the case of nutritional or dietary supplements, as there are no regionally harmonised rules, the laws of each state party shall apply.

**PHARMACEUTICAL PRODUCTS: LABELLING OF PHARMACEUTICALS FOR HUMAN USE (RTCA 11.01.02:04)**

The purpose of this technical regulation is to establish minimum requirements that the labelling of pharmaceutical products for human use must meet, both for products of the territory of Central America and abroad. This technical regulation applies to the labelling of all pharmaceutical products for human use, regardless of their mode of sale, shipment or delivery.

**MUTUAL RECOGNITION OF HEALTH REGISTRATION FOR PHARMACEUTICALS FOR HUMAN USE (ANNEX 2 OF RESOLUTION No. 333-2013 [COMIECO-LXVI])**

The Recognition applies to the health registration of pharmaceuticals originating in the countries.

1. The main parts are: heelcap, lining, vamp, heel, top piece, insole, bottom filling and sole, among others. [↑](#footnote-ref-1)