

CHAPTER VII: FOOD AND DRUGS REGISTRATION

Panamanian legislation requires sanitary registry for food and beverages, as well as for pharmaceutical specialties and other similar products, cosmetics, pesticides for domestic use and public health, as well as house cleaning products with antiseptic, fungicidal, bactericidal and disinfecting action that will be considered hereinafter.

Summarizing, registration before the Health Ministry shall satisfy the following procedure:

1. Checking of the petition and accompanying documents
2. Laboratory analysis of the product
3. Certification issuance.

Petition for registration shall be done through Panamanian lawyer or law firm.

The following requirements per product shall be fulfilled.

1. Food and Beverages

Applications for Sanitary Registry for food and beverage shall be filed before the *Departamento de Protección de Alimentos*, or Food Protection Department of the Ministry of Health.

Basic requirements for Registry are:

- Power (of Attorney) and application filed by lawyer;
- For imported products, Certificate of original free sale issued or endorsed by the sanitary authority of the country of origin during the six months immediately previous to the application, duly authenticated;
- Valid sanitary certification of the plant or the operation permit (copy) issued by sanitary competent authority, stating the manufacturing, packing, distribution or other activity authorized thereby;
- List of ingredients (formula), indicating the additives employed. Both ingredients and additives shall be presented under a qualitative-quantitative form (name and percentage of addition);
- Specifications of the type and the material of the package;
- Elaboration method (including time and temperature);
- Two original labels or the composite identical to the original (with complete information and according to labeling standards);
- Four samples of the product, pertaining to the same lot, representative and duly identified according to labels that will be used in marketing. Canned products require six (6) samples;
- Average life of the product;
- Code of the lot (statement and interpretation), according to what is declared in the label of the product;
- Phyto-Zoo-sanitary Import Permit/license issued by the **Ministerio de Desarrollo Agropecuario** or Ministry of Agricultural and Livestock Development, for fresh or raw pre-packed and processed meat, fish and dairy products, stating that there are

no impediments or restrictions on the country, region or zone of departure of the said products.

- Food and beverage registry shall have a duration of five (5) years, as of the issuance date and may be extended for five (5) years periods indefinitely.
- Obligation to obtain sanitary registry for food and beverage result from provisions of the Sanitary Code, enacted by Law 66 of November 10, 1947, Decree No.256 of June 13, 1962, Decree No.1195 of December 3, 1992, Law No. 29 of February 1st, 1996, Executive Decree No.259 of October 24, 1996, Resolution No.252 of December 16, 1996, Law No.23 of July 15, 1997 and Law 38 of July 31st, 2000.

2. Pharmaceutical Specialties and Similar Products

Sanitary Registry of pharmaceutical specialties and other similar products, cosmetics, pesticides for domestic use and public health, as well as house cleaning products with antiseptic, fungicidal, bactericidal and disinfecting action is legally supported by Law No.1 of January 10, 2001, that supersedes all previous legislation on the matter, and by Executive Decree No.178 of July 12, 2001 that regulates it.

Applications for Sanitary Registry of these products shall be filed before the *Dirección Nacional de Farmacia y Drogas*, or National Directorate of Pharmacy and Drugs of the Ministry of Health.

a) Medicines and Pharmaceutical Products

- Basic requirements for registry are:
- Power of Attorney,
- Petition filed by a lawyer, endorsed by a certified pharmacist;
- Method for analysis;
- Certificate of Analysis;
- Free sale certificate issued by health authority of the country of departure or World Health Organization;
- Certificate of good manufacturing practices of the laboratory, issued by the sanitary authority of the country of origin;
- Clinical studies (for innovator products, new indications and those so regulated by the Health Authority);
- Two labels and packages (primary and secondary, according to the case);
- Monograph on the product in question;
- Samples (one for the *Dirección Nacional de Farmacia y Drogas*, and the quantity of samples for analysis, as required by the Specialized Analysis Institute or any other laboratory authorized by the Health Authority);
- Qualitative and quantitative formula of the product;
- Stability studies for those products applying by the first time for registry;
- Specifications of the completed product, and
- Analytical standard with its analysis certificate.

The sanitary registry shall have a duration of five (5) years and may be extended and the end of each period upon application.

b) Cosmetic Products and Medicated Cosmetics

The basic requirements for registration are:

- Power of Attorney and application filed by lawyer;
- Certificate of good manufacturing practices, issued by the competent authority of the country where is located the plant, duly legalized, or notarized statement of the legal representative of the laboratory, duly credited before the *Dirección Nacional de Farmacia y Drogas*, and authenticated, attesting to the laboratory compliance with manufacturing good practices;
- Certificate of free sale issued by the official sanitary authority of the manufacturing country or of the competent authority of the said country;
- Qualitative and Quantitative formula
- A sample of the product or of each of its forms with their original labels, as it is sold in the country of origin or the country of departure, with the corresponding lot number printed on the label or the package;
- Two labels of the products or of each of its forms, or two photocopies of the labels or lithography of the package, if structured as a whole;
- Specifications of the completed product;
- Corresponding life backing studies, in case the product contains substance of biological origin, vitamins or easy decomposing substances;
- In case of products accompanied by statements concerning properties, such as “dermatology tested”, “Not irritant”, “Not sensitizer”, “Hypoallergenic”, “Clinically tested”, “Water resistant”, or similar expressions, documents backing said qualities or statements shall be produced.
- Sanitary registry of these products shall have duration of ten (10) years as of issuance date and may be renewed.

c) Pesticides for Domestic Use and Public Health and House Cleaning Products with Antiseptic, Fungicidal, Bactericidal and Disinfecting Action

Basic registry requirements are as follows:

- Power of Attorney and application filed by lawyer;
- Certificate of good manufacturing practices, issued by the competent authority of the country where is located the plant, duly legalized, or notarized statement of the legal representative of the laboratory, duly credited before the *Dirección Nacional de Farmacia y Drogas*, and authenticated, attesting to the laboratory compliance with manufacturing good practices;
- Certificate of free sale issued by the official sanitary authority of the manufacturing country or of the competent authority of the said country;
- Qualitative and Quantitative formula;
- A sample of the product or of each of its forms with their original labels, as it will be marketed. The rest of samples and, if necessary, analytical standards shall be submitted at the time of the analysis.

- Specification of the finished products and copy of the physical-chemical and microbiological specifications of the finished product, accompanied by the information sheet on the safety of product's material (Toxicology data)
- Original and copy of the statement on the concentration of ingredients of each product under its chemical or generic name, signed by the person responsible for manufacturing or by the concerned laboratory, with indications of the ranks according to minimal or maximal quantities used, according to the International System of Units.
- To indicate clearly the name of the product and its variations, if applicable.
- Physical-Chemical analysis employed by the manufacturer to analyze the product. If the manufacturer employs a Pharmacopoeia analytical method, reference of edition and year thereof shall suffice.

Residuum studies and eco-toxicity data shall be produced in the case of pesticides.

Sanitary Registry of these products has duration of ten years, and is renewable for the same time span.