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Overview of Chemical Control Legislation and Trade Aspects in South America

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Overview of Chemical Control Legislation and Trade Aspects in

Venezuela



Uruguay



Peru



Paraguay



Colombia



Overview of Chemical Control Legislation and Trade Aspects in Venezuela, Uruguay, Peru, Paraguay, and Colombia

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Overview of Chemical Control Legislation and Trade Aspects in Venezuela, Uruguay, Peru, Paraguay, and Colombia

Trade Trends

- Venezuela departs Andean Community and G-3 (2006)
- Uruguay adopts Global Harmonized System (GHS) (2009)
- Peru and Ecuador implement Chemical Information Exchange Networks (CIEN), supported by the United Nations Environment Program (UNEP) for access to reliable regulatory data (2010)

I. Trade Aspects

Imports

- **Venezuela** rarely requires import licenses for non-agricultural, commercial goods; but not so in the case of arms and explosives that require an import permit from the Ministry of Defense.
- **Uruguay**, only commercial and industrial firms, or individuals listed in the registry of importers may legally import products into the country. Importers must use an agent to handle their customs entries.
- **Paraguay** - Imports and customs processes are handled through authorized banks with notification to the Central Bank of Paraguay.
- **Colombia** - All imports must be recorded at the Registry of Imports. A small percentage of the number of imports, however, require prior import licensing, which applies to closely monitored sensitive products such as precursor chemicals and weaponry.

I. Trade Aspects

Customs

- **Uruguay**, the National Customs Directorate, under the Ministry of Economy and Finance, dictates all customs regulations. Decree Law 15.691 dated December 7, 1984 regulates the current system.
- **Peru's** customs requires a Unique Customs Declaration (DUA), a commercial invoice, an airway bill or bill of lading, a packing list, and an insurance letter. If the product is imported from the Andean Community, a certificate of origin is required to qualify for tariff preferences.
- **Colombia** Tax and Customs Department verifies the description and classification for consistency with the importer's declaration; often conducting after-clearance random investigations to detect fraud, foreign exchange irregularities, and tax evasion. Colombia's foreign trade procedures are simplified with VUCE (Unified Portal for Foreign Trade – www.vuce.gov) to access forms, make online payments and follow-up processes and requests.



II. Uruguay Adopted Global Harmonized System (GHS)

- Presidential Decree 307/009 signed into law on July 3, 2009.
- Entry into force was 120 days after publication in Official Gazette
- Transition period for labeling of chemicals was one year after its publication in Official Gazette.
- GHS System is now fully implemented and mandatory in Uruguay

GHS Classification, Labeling, and Packaging

Decree 307/009 summarizes that users should refer to the GHS document where they can find all the necessary information on chemical classification and proper labeling of chemicals.

Labeling of chemicals must be under the guidelines of the Globally Harmonized System or GHS

- Companies using other labeling systems, such as rules based on the European Community labeling, such systems will be accepted during the transition to GHS. Now, labeling must comply with GHS
- GHS Pictograms (see below)
- The GHS purple book must be consulted as to product characteristics to determine the elements of hazard communication that should go on the label.
- Labels must have at least the following minimum content: the hazard pictogram; warning statement; danger indicator; hazard indicator; precautionary statements and precautionary pictograms; product identifier; supplier identification.



Uruguay GHS Labeling



The GHS document must be consulted as to product characteristics to determine the elements of hazard communication that should go on the label.

Labeling materials and size: Materials: The label may be printed on the packaging or securely attached to it, remaining legible and securely fastened under transport, storage and usage conditions. The label material is paper of at least 80 g/m² or PVC of at least 135 g/m². Any other substituting material may be used if it at least meets the resistance conditions indicated.



Uruguay GHS - Safety Data Sheets

Decree 307/009 Annex 2 - Safety Data Sheets (SDS). This legislation clearly states that it adopts the guidelines of the GHS in relation to the SDS. The SDS must be sent by the manufacturer, importer or supplier to distributors and other clients upon first delivery and whenever the product is subject to modification thereafter. There are 16 sections, with the SDS format and minimum content as proposed by the GHS. Annex 2, Table 1.5.5, shows a model matching the UN Purple Book GHS format. The SDS must be written in Spanish.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

- **Venezuela Classification, Labeling, and Packaging:** Venezuela's classification and labeling guidelines are found in COVENIN 3060-2002, First Revision, which references Dangerous Goods Regulations, IATA (1993), DOT Title 49 CFR – Chapter 1 Rev. October 1, 1999; DOT Chart 11 Hazardous Materials Markings, Labeling and Placarding Guide (2000 Edition) USA; National Fire Protection Association, NFPA 704 Standard System for the Identification of the Hazards of Materials for Emergency Response (2001 Edition) USA. It adopts the UN classification numbering system and risk classification into nine groups, with subdivisions within the groups.
- **Venezuela Safety Data Sheet:** FONDONORMA 3059:2006 is an adoption of ISO 11014-1:1994, replacing standard Venezuela Hazardous Materials 3059:2002 SDS. This ISO 11014-1 has been developed to be applied at the global level and modeled after the European Union's Directive 91/155/EEC, with only slight deviations in the text related to the sections.
- The standard contains information to elaborate SDSs for chemical products and defines the general format for an SDS; the 16 standardized sections; the enumeration and sequence for the 16 sections; the necessary information to complete an SDS and the conditions for application and use. Annex A is normative and B informative, showing the type of formatting to prepare an SDS.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

- **Peru Classification, Labeling, and Packaging:** While Peru has not adopted the Global Harmonized System of Classification, Labeling and Packaging, its Chemical Information Exchange Networks (CIEN), supported by the United Nations Environment Program (UNEP) makes reference to the GHS for Classification, Labeling, and Packaging of Chemicals.
- As a member of the Andean Community, Peru is under a duty to apply Decision 602, adopted on December 6, 2004. The Decision states that “Member Countries that have signed the 1988 United Nations Convention Against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, must abide by the recommendations of the Model Regulations for the Control of Chemical Substances Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances issued by the Organization of American States (CICAD/OEA); and the United Nations Manual for the Transport of Hazardous Goods.”
- Under Decision 602, Chapter IV - Import, Export, Traffic and Transfer Requirements, Peru is mandated to apply the provisions of the Decision to such activities when dealing with controlled substances, such as those under its NANDINA classification. The latter is on Annex I, which is the basic common list of the chemical substances that are subject to additional specific control measures within the territory of the Andean Community. As stated therein, some of those substances are also found in the Tables I and II of the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Annex II of the NANDINA classification are Tables I and II of the 1988 Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Marking and Labeling are in Chapter VII of Decision 602.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

- Article 24 provides that each shipment of controlled chemical substances must bear the “Standard Andean Label” visibly located on the original packages, including details of the designation as “controlled chemical substances.” Based on Annex IV, the label must be: a) visible and legible; b) capable of remaining in place despite wind and weather conditions without becoming deteriorated; c) must be placed on the surface of the piece, package or container; and d) must allow for marking of information identifying exporter or consignee. Annex IV is a sample of the Standard Andean Label Model.
- In addition to the above CLPs referenced for Peru, the INDECOPI Labeling Law for Manufactured Industrial Products was approved by Decree No. 1056, June 28, 2008, that amended Articles 3, 4, and the Labeling Law No. 28405, November 30, 2004.
- Decree No. 1056 contains provisions for implementing matters concerning compliance with rules of origin of goods under all of Peru’s Free Trade Agreements. Decree No. 1056 states that labeling must contain the name and product name, country of manufacture, expiration date, storage conditions (perishables), data from the manufacturer, importer, packer, tax ID number, the condition of the product when it is a used, rebuilt, or remanufactured product. The above information must be entered in the affidavit presented by the importer to customs and may also be required in verification of compliance with labeling standards by INDECOPI.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Supreme Decree No. 1-84-ITI/IND of January 18, 1984

- Provides the labeling requirements for industrial products manufactured abroad for sale in Peru.
- Article 1 mandates that industrial products manufactured abroad, to be offered for sale in the national territory, must have at the time of arrival at least the following information:
 - the brand name for final consumer products;
 - country of manufacture;
 - expiration date for foodstuffs, medicines for human and veterinary use, material photography, and other, subject to expiration.
- The above information must be printed clearly and located visibly on the product label, and if the label has physical limitations that do not allow such writing, then label aids such as stickers, packaging or other similar means should be used.
- Article 4 mandates that foreign manufactured products packaged in Peru will in addition to the registration information mentioned in Article 1, include the phrase “Packaged in Peru” followed by the name and address of the party responsible for the operation.
- Article 5 states that violation to requirements of Article 1 will result in no clearance by customs.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Peru Safety Data Sheet: Technical standard No.G.050 for the construction industry at Section 19.1 on Materials, states that all chemical substances including hydrocarbons and their derivatives must have an SDS. Section 19.1 on Training, provides that storage personnel and all project personnel are to be trained specifically on SDSs on the product handled, which should be duly registered.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Colombia Classification, Labeling, and Packaging:

- Colombia follows the United Nations (UN) guidelines on packaging and labeling requirements. These requirements apply to any substance defined as dangerous by Article 6 of Law No. 55, July 2, 1993.
- Colombia has also adopted the UN classification system for dangerous substances. When a substance presents more than one risk, the classification is determined by the greater risk. Article 7 of Law No. 55 states that all dangerous substances must be labeled in a manner that provides their identity.
- The labels must be easily understood by those individuals handling the dangerous substances, and must provide information regarding classification, hazard, and all necessary safety precautionary measures that must be observed.
- The specific criteria appropriate for classification requirements are to be determined by the competent authority, or an approved organization in conformance with the national or international norms.
- The hazardous properties of mixtures composed of two or more chemicals may be determined by assessments based on the intrinsic hazards of their component chemicals.
- In addition, insecticides and other toxic products must display the skull and crossbones, the word 'poison' in Spanish, as well as information regarding usage and antidotes.
- Those products for which no antidotes exist cannot be licensed and may only be used in programs under the direct control of public health authorities.
- Article 133 of Law No. 9 states that the Ministry of Health is responsible for regulating all activities related to the classification, packaging and labeling of hazardous substances, and for creating norms used to mitigate risks caused by these substances.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Colombia Safety Data Sheet: Article 8 of Law No. 55, as cited above, states that any firm handling hazardous substances must provide an SDS containing detailed essential information regarding its identity, manufacturer, classification, risk, safety precautions and emergency procedures for all such substances. The law also includes a listing of the specific information that must be included in the SDS. The competent authority or an approved organization in conformity with the national or international standards may determine the criteria for the preparation of an SDS. The chemical or common name used to identify the substance must be the same as the one that appears on the label. Note that while Spanish is the preferred language for an SDS used in or created for Colombia, English is also acceptable.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Paraguay Classification, Labeling, and Packaging: Paraguayan Decree 14.390/92 of July 28 was issued to approve ILO general technical regulation on health and medicine in the workplace.

The regulation states that hazardous chemicals in Paraguay are classified as having one or more of the following effects: narcotic; toxic, with slight, acute or chronic effects on any organ; corrosive or irritant; allergic or sensitizing; carcinogenic; teratogenic or mutagenic; reproductive effects; flammable, explosive, combustible or reactive.

Dangerous chemicals in Paraguay must be clearly marked so that workers can easily recognize and distinguish between products. Moreover, dangerous chemicals must be clearly labeled with the following information: name of the product; commercial name; danger symbol; nature of risks; safety precautions; name, address and telephone number of supplier; a statement that safety data sheets are available from the employer.

III. Chemical Control Legislation Classification, Labeling, and Packaging (CLP), and Safety Data Sheet (SDS)

Paraguay Safety Data Sheet: The information on SDSs also stems from Decree 14.390/92. Employers in Paraguay who use dangerous chemicals must obtain SDSs which contain a 16-section format. The chemical name used to identify a substance on the safety data sheet should be the same name as that used on the label. SDSs must be supplied to employers free of charge.

III. Chemical Control Legislation Core Document For Chemical Control Regulations

- **Venezuela's** Law on Dangerous Substances, Materials, and Wastes, published in Extraordinary Official Gazette No. 5.554, was decreed on November 13, 2001 and became its first inclusive regulation for control of hazardous substances. As such, it is the authority for handling of substances, hazardous materials and waste per Articles 65 and 66. In addition to the 2001 legislative framework, chemical substances management is regulated by Decree 2635, Norms on the Control of Recovery of Hazardous Materials and Handling of Hazardous Waste of July 22, 1998; published in Official Gazette No. 5245, August 3, 1998. The latter together with standards formerly issued by COVENIN—now issued by FONDONORMA—complement this area of chemical regulation in Venezuela.
- **Paraguay** has actively participated in International Labor Organization (ILO) conventions on Workplace Safety. Decree 14.390/92 was issued July 28 to ratify ILO Convention No. 155, which is the general technical regulation on health and medicine in the workplace. Along with that ratification and implementation into its national legislation, Paraguay also ratified Protocol 2002 and Recommendation 164.
- Similarly, **Colombia's** Law No. 55 of July 2, 1993 approved ILO Convention 170 and Recommendation 177 on the Safety of Using Chemical Products at Work. Articles 6, 7, and 8 of Convention 170 concern classification, labeling, and SDS, respectively. Article 6, 7, 8, and 9 of the Recommendation concern the same.
- **Peru's** General Law on Health, Title II, Chapter 6, (Law 26842 of July 9, 1997) establishes a framework for the regulation of dangerous substances and products.

III. Chemical Control Legislation

Existing and New Chemicals, Registration, Permit

- There are no new chemical notification requirements in the five countries of South America, nor are there any national inventories of registered substances. There are, however, chemical substances registration frameworks, which vary.
- **Venezuela's** Resolution No. 40, Requirements for Registration and Authorization of Operators of Dangerous Substances, Materials and Waste of May 27, 2003, published in Gazette No. 37.700 May 23, 2003, requires that persons register activities that are likely to degrade the environment.
- Article 1 in concordance with Articles 65 and 66 of the Law on Dangerous Substances, Materials, and Wastes, mandates registration with the Registry for Activities that are Susceptible to Degrading the Environment and Natural Resources.
- Venezuela's "Organic Law against Illicit Trafficking and Consumption of Narcotic and Psychotropic Substances" (Official Gazette No. 38.337, December 16, 2005) mandates registration (Articles 125, 131-137) for any person or entity involved in the production, manufacture, preparation, use, processing, storage, marketing, brokerage, export, import, transport, waste and any other transaction where controlled chemicals are involved.
- **Uruguay** requires registration by companies engaged in manufacturing, imports, exports, stored, distributed, used, and the sale of precursors and chemical substances under Law 14.294/974, October 31, 1974; and Decree 454/976, July 20, 1976; Law 17.016/998, October 22, 1998 and Decree 391/2002 October, 10, 2002. Annex II of Decree No. 391/2002 is a company registry form, and Annex IV is a sworn statement of the precursor's or chemical's movement. Chapter XI, Article 68 of Law 17.016/998, which regulates narcotic and psychotropic substances, enunciates mandatory registration by all who, in any way, conduct business with the precursors and chemicals listed in tables 1 and 2 of Decree 391/002.

III. Chemical Control Legislation

Existing and New Chemicals, Registration, Permit

- The **Paraguayan** Health Code (Law 836 of January 12, 1999 at Articles 190-206) concerns toxic and dangerous substances. These provisions say that in order to import, manufacture, store, sell, transport, distribute, or supply toxic or dangerous substances or products, registration is required with the corresponding ministry. While this registration has been established for pesticides, none yet exists for commercial or industrial chemicals.
- **Peru's** General Law on Health, Title II, Chapter 6, (Law 26842 of July 9, 1997)
 - Establishes a framework for the regulation of dangerous substances and products. Under this law, the import, production, storage, transport, sale, handling and disposal of dangerous substances and products should comply with corresponding regulations, and precautions should be taken to prevent harm to human health, animals, or the environment.
 - To this end, the Ministry of Health is mandated to establish norms on the classification of dangerous substances and products, and requirements for information provision, packaging, transportation, and labeling.
 - Medicines and cosmetic products must be registered with Peruvian health authorities. The government has abolished import licenses for the vast majority of products. Among the few remaining are chemical precursors used in cocaine production. Decree-Law 25623 of July 21, 1992 states that chemical products which can be used in the production of basic cocaine paste, washed paste, and chlorohydrate of cocaine shall be subject to control and supervision for manufacture, import, transport, possession and use.

III. Chemical Control Legislation

Existing and New Chemicals, Registration, Permit

Colombia has an extensive Environment, Health and Safety legal framework. Colombia's Health Code (Title III of Law 9 of January 24, 1979) establishes norms for the preservation and improvement of workers' health, requiring that the risks derived from the production, handling or storage of dangerous substances be communicated to persons exposed to such substances.

- The communication must include a clear indication of the products involved and an unmistakable marking of the areas where the substances are used.
- Moreover, information on preventive and emergency measures in the case of ambient air contamination or worker intoxication must be provided.
- The law further allows the Colombian Ministry of Health to prohibit or establish restrictions on the import, manufacture, transport, storage, sale, or use of a substance or product, when it is considered highly dangerous for reasons of public health.
- In addition, the Ministry of Health may regulate the classification of dangerous substances, set requirements concerning information provision, packaging, transport, labeling, and establish other norms to prevent the harm that these substances may cause.

IV. Restricted, Prohibited, or Banned Chemicals

Dangerous Chemicals and Precursors

Venezuela's "Organic Law against Illicit Trafficking and Consumption of Narcotic and Psychotropic Substances" (Official Gazette No. 38.337, December 16, 2005) prohibits the substances listed in Annex I of the Law, Lists I and II.

Uruguay issued a regulation on dangerous chemicals and precursors: Decree No. 554/007, promulgated December 31, 2007; published January 16, 2008.

- This regulation added three substances, lidocaine, procaine and benzocaine, to the list of substances listed on Annex I of Table II of Decree No. 391/2002, issued October 10, 2002, approving the Regulation on Chemical Precursors and Substances.
- Annex I, Table 1 is the listing of precursors; and Table 2, the list of Chemicals with Mercosur Nomenclature.
- Annex II has the requirements for company registry; and
- Annex III is a sworn statement of movement under the listed terms for companies.
- Law No. 14.222 of July 11, 1974 internalizes the substances found on List I of the Convention on Psychotropic Substances held in Vienna, Austria on February 1971, as well as the narcotics schedules I, II, III, and IV; and the Vienna Convention's list of substances found on Lists I – IV.

IV. Restricted, Prohibited, or Banned Chemicals

Peru's Law 28.305 July 27, 2004, modified by Law 29.037 June 12, 2007:

- Controlled chemicals must be registered because they are subject to diversion for the manufacturing of illicit drugs, and
- Any person or corporation that lawfully commercializes with the controlled substances listed in the regulation is subject to registration and authorization of lawful limits for use in manufacturing.

Colombia's Law 30 of January 31, 1986 is the basic regulation through which the National Statute on Narcotics was adopted.

- Resolution No. 009 of February 18, 1987 regulates the importation, manufacture, distribution, transport and use on national territory of acetone, chloroform, ethyl ether, hydrochloric acid and other substances referred to in paragraph (f) of Section 20 of Law 30 of 1986.
- Another two substances, toluene and acetic anhydride, are regulated through Resolution No. 007 of December 1, 1992 (whereby substances to be added as regulations contained in Resolution 009 of 1987 were issued by the National Narcotics Board and Legislative Decree 1146 of 1990 that adopted as permanent legislation a fourth article of Decree 2272 of 1991)
- Resolution No. 0012 of May 30, 2003 regulates the use of chemicals under administrative control through "Certificate for Lack of Drug Traffic", regulating potassium manganate and manganese dioxide.

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Thank you!
¡Muchas Gracias!