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## Argentina and Chile - Overview on Chemical Control Legislation (Labeling, SDS, Existing and New Substances) and Aspects of GHS

Leticia Cuevas  
3E Company



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## **Argentina - Chile Overview on Chemical Control Legislation (Labeling, SDS, Existing and New Substances) and Aspects of GHS**

### I Chemical Control Legislation

- Existing and New Chemicals
- Registration/Permit
- Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)
- Restricted, Prohibited, or Banned Chemicals

### II Aspects of Global Harmonized Systems (GHS)



## I. Chemical Control Legislation

- No reporting requirements for new substances
- Notification of dangerous chemical substances and preparations
- Reporting obligations
- Requirements for packaging and labeling, and safety data sheets



## Existing and New Chemicals, Registration, Permit

**ANMAT (National Administration for Drugs, Food and Medical Technology)  
Provision 7292/98 (December 4, 1998, as modified through ANMAT provision No. 2659/2008 of May 8, published May 14, 2008)**

- Provides complementary standards to clarify the registration process for producers, re-packagers, importers or exporters of domestic use products.
- Provision indicates goal of hoping to be user-friendly, predictable and transparent registration process for entities wishing to register while ANMAT exercises its proper oversight functions.
- Annex V is a form that can be used for registration, as well as specific instructions as to where and how to register. The completed application is filed with the registration desk of the National Food Products Institute. An application fee is paid and a copy of the receipt is attached to the application.



## Existing and New Chemicals, Registration, Permit

### Resolution 709/98 (published September 10, 1998)

- For registration of domestic use chemical products produced, re-packaged, or imported into National Territory, or destined for inter-provincial commerce or commerce with the Autonomous Government of the City of Buenos Aires
- Creates the National Register for Domestic-Use Products
- The Ministry of Health authorizes ANMAT to administer the registration of these products and to publish guidelines.
- Certificate of registration valid for a five-year period.
- Products must be re-registered at that time, but this process is automatic if done by sworn statement.
- Failure to re-register results in cancellation of product registration without prior notice. (Article 5)
- Article 9 specifically prohibits the use in domestic-use products of substances which have been classified as Group I Carcinogenic Agents for Humans by the International Agency for Research on Cancer /World Health Organization. (IARC/WHO)
- Modifications affecting the conditions of a registered product should be brought to the attention of national health authorities.
- Risk Category II products require appropriate labeling and a prospectus if the distribution of free samples is contemplated.
- Any violations of the Resolution are punishable under Decrees 141/53 and 341/192. (Article 8)



## Existing and New Chemicals, Registration, Permit

### **Resolution No. 708/98 of July 9, 1998**

- **Registration of producers, re-packagers, importers, exporters of sanitary products of Domestic Use. This is a National Register for activities involving re-packaging, importing and exporting domestic use products within Argentina, among its provinces, and/or with the autonomous government of the city of Buenos Aires.**



## Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

### **Classification, Labeling, and Packaging**

- The European Union Directive 67/548/EEC on the classification, packaging and labeling of dangerous substances, as amended, is currently acceptable.
- IRAM Standard No. 3797 (May 12, 1986) regulates the labeling of chemicals for transport.
- Argentina adheres to the UN recommendations for labeling and packaging of hazardous materials.



## Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

### Classification, Labeling, and Packaging

Law No. 22.802/83 (a General Law for Labeling)

- Article 1 of Law No. 22.802/83 (supplemented by Resolution No. 252/00, published November 7, 2000, and as amended by Law No. 26179, December 2006) of the Directorate of Fair Trade (*Dirección de Lealtad Comercial*) under the Secretariat of Industry within the Ministry of the Economy states that the label for domestically produced and imported products must include: name of product; country of origin; quality, purity, or blending description; and net weight.
- Article 2 provides that products manufactured domestically will be labeled with a statement that reads, “*Industria Argentina*” (Industry of Argentina).
- If the products have been manufactured with foreign raw materials, or any other elements that do not modify the nature of the product, it is still considered to be an Argentine product. Indication of the foreign origin of components in the final product is allowed; however, these indications must be less visible than the original labels.
- Article 4 states that all labeling of products must be in the Spanish language; but it is permitted for the label to contain other languages in addition to the information provided in Spanish.
- Article 5 states that deceit or deliberate misrepresentation in relation to products is strictly prohibited. Article 6 indicates that importers, manufacturers, and assemblers will be held responsible for failure to adhere to the prohibition outlined in Article 5.



## Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

### Safety Data Sheet (SDS)

- Chapter 17 (Articles 145-149) of Decree No. 351/79 of February 5, 1979 on Hygiene and Safety in the workplace requires that the workers are informed about hazardous properties and safety measures to be taken during handling of substances and preparations at work.
- As a matter of practice, the industry voluntarily follows international and national standards in the field (ANSI, ISO 1401) and provides SDSs when substances and preparations are marketed in Argentina.
- According to industrial practice, SDSs should have 16 sections. Spanish is the preferred language for SDS.
- IRAM 4140/2006 standard of October 2, 2006 (in line with GHS) is an identical adoption of ISO 11014 1:1994 Safety data sheet for chemical products.



## Restricted, Prohibited, or Banned Chemicals

### **Mandatory Registration of Chemical Precursors**

Law No. 23.737, as modified through July 28, 2005, on National Register of Chemical Precursors requires registration in the National Registry.

The Secretariat for the prevention of drug addiction and campaign against drug trafficking, as implementing authority, controls all activity involving authorized chemicals and chemical products, their characteristics or components, which can serve as the basis for or be used in the manufacture of narcotic drugs.

Decree 1161 of December 6, 2000 (modifying Decree 1095/96) as to labeling and production of determined chemical substances, imposes a duty on those who, in any way, transact with the substances listed therein. This decree updates the list of precursors and chemical substances that can be used to manufacture illicit narcotics and psychotropic substances found in Annex I, Lists 1-3.



## Restricted, Prohibited, or Banned Chemicals

### **Mandatory Registration for the Control of the Diversion of Precursor Chemicals**

- **Regulatory Framework:** The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances was signed on December 20, 1988. Article 12 refers to the controls recommended by the states for chemical substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances.
- Law 26,045 (enacted on June 8 and promulgated on July 6, 2005) provides for the creation of a National Registry of Precursors within the Secretariat of Programming for the Prevention of Drug Addiction and the War Against Drug Traffic (SEDRONAR).



## Restricted, Prohibited, or Banned Chemicals

### **National Registry for Precursor Chemicals**

- Law 25,363 of May 27, 2010 mandates registration at the National Registry for Precursor Chemicals (RENPRE) for agents operating with controlled chemicals by presenting all the documentation specified in the forms to be filled.
- RENPRE issues the certificates for such organizations to operate in compliance with current legislation.



## Restricted, Prohibited, or Banned Chemicals

### Small Operators of Precursor Chemicals

- Resolution 1227/2010, September 29 creates the category of Small Operators of Precursor Chemicals. This category includes all those who are legally organized to acquire the pure substances listed in Schedules I and II of Annex I of Decree No. 1095/96 (amended by No. Decree No. 1161-1100) in amounts to be determined and that are exclusively for end users. As end users, they cannot store a larger amount each month than authorized to acquire, or re-sell substances in any way.

### Required Registration of Ozone Depleting Substances

- Decree 1609/2004 of November 17 was adopted to regulate the import/export of ozone depleting substances, and established a licensing system for that purpose as well as a National Registry for importers and exporters of ozone depleting substances per Article 1 of Law 24.040 of November 27, 1991.



## Restricted, Prohibited, or Banned Chemicals

- Argentina's Chemical Weapons Law 26.247, published in the Official Bulletin on May 2, 2007, implemented the Convention on the Prohibition of the Development, Production, Storage, and Use of Chemical Weapons and on their Destruction (CWC). A list of chemicals is found therein, prohibiting substances that include chlordane, DDT, aldrin, arsenic, barium salts, PCBs, chlordane, dieldrin, hexacholocyclobenzene and white phosphorus.
- According to the 2009 update by the National Program of Chemical Risk, the substances that are strictly regulated include aldicarb, aminotriazol, mercury bichloride, potassium bromate, methyl bromide, lindane and carbofuran.
- Substances for which export is restricted by the national government under Resolution 125/98 of January 22, 1998, Convention on The Prohibition of the Development, Production, Storage and Use Of Chemical Weapons and on their Destruction and in compliance with Argentina's ratification of CWC under Law 24.534 of August 9, 1995, include: thiodiglycol, phosphorus oxychloride, phosphorus trichloride, hydrochloride dimethylamine, and sodium fluoride.
- Argentina banned asbestos through Resolution 823/01, signed on July 26, 2001, published July 31, 2001 in the Official Bulletin.
- Argentina prohibits the use of substances classified as Group 1 carcinogens by the International Agency for Research on Cancer (IARC) for household products (Article 9 of Resolution No. 709/98, published September 10, 1998). It also outlines requirements for domestically used chemical substances classified as Risk I and II in the resolution (Articles 4 and 8).



## II. Aspects of Global Harmonized Systems (GHS)

Uruguay became the first South American country to adopt the Global Harmonized System (GHS) on July 3, 2009. Brazil adopted the GHS soon after on September 26, 2009. It is expected that Argentina and Chile will follow suit in the very near future. In the case of Argentina, however, although Uruguay is also a member country of Mercosur and implemented GHS of its own initiative, Mercosur is working on legal instruments to ensure harmonized implementation of their members. Argentina's standard on Safety Data Sheets (IRAM 41400-2006) is in line with the GHS requirement for SDS.

The Inter-American Development Bank is negotiating cost effective measures to implement GHS in Mercosur member countries, and Chile.



## I. Chemical Control Legislation

The Sanitary Code makes the Ministry of Health and Health Services accountable for the elimination or control of environmental factors affecting the health, safety and welfare of the inhabitants. Through this instrument it is empowered to control Health Sector activities related to chemicals and waste, including the manufacturing, importation, distribution, transportation, sale, possession and disposal. Articles 90 to 93 of the Code relate to the control of the stages of the life cycle of substances that are hazardous to health. Article 90, specifically, mentions that the regulation will set the conditions for production, import, dispensing, distribution, utilization, and disposal of toxic or hazardous substances. Also indicated by Article 90 is that the importation and manufacture of these substances requires the authorization of health services.



## Existing and New Chemicals, Registration, Permit

Chile has no national inventory of existing chemical substances and no requirement for the notification of new substances. However, Law 18.164, published September 17, 1982 in the Official Gazette, establishes a requirement by customs in that toxic or dangerous substances, and substances used in food or cosmetics may not clear customs without presenting customs authorities with a certificate from the proper health authority indicating where the goods will be deposited and the route and condition of transport.

Law 18,164 on Customs Destinations gives instructions for the clearance of hazardous chemicals and pesticides and indicates that to process any customs destination involving toxic substances or those that are dangerous to health, among other national services, customs shall require a certificate from the respective health service in which the authorized locations will be for the deposit of said goods, the route and conditions of transport to be used or to transfer from the customs area to the specified location. Once the processing of documents of destination and the goods are removed from storage at customs, they are deposited under the responsibility of the consignee of same, who can not use, consume, sell, assign them under any title without obtaining authorization and prior approval required by law.

The Ministry of Health also issued a list of chemical substances in Chilean standard (NCh) No. 382, Annex A, which require authorization from health services prior to clearing customs.



## Existing and New Chemicals, Registration, Permit

Exempt Resolution No. 714 of July 16, 2002 of Ministry of Health was modified by Exempt Resolution No. 274/2006 of June 2, 2006 regarding the list of dangerous substances to health. This resolution provides the list of substances that are hazardous to health in application of Law 18.164 on customs destinations, and the application of import authorization established in articles 90 and 93 of the Sanitary Code, which must be granted by Health Services. This list includes chemicals, active ingredients and nonagricultural pesticide formulation.



## Existing and New Chemicals, Registration, Permit

Circular No. 15AF/23, August 8, 2002 on the List of Hazardous Substances Health for the application of Law No. 18,164 on Customs Standards

- This circular provides instructions on the method of application of the list of hazardous substances established therein.
- This circular clarifies to which substances both the Law 18,164 and the corresponding articles in the Health Code are applicable, emphasizing that substances not included in the listing do not require authorization from Health Services for their importation.



## Existing and New Chemicals, Registration, Permit

Decree-Law No. 1 of November 8, 1989, sets activities listed requiring express sanitary authorization by Health Services for operation, which include the manufacture and importation of substances hazardous to health and the manufacture and importation of pesticides.



## Existing and New Chemicals, Registration, Permit

Decree No. 298 of February 11, 1995 on Transportation of Dangerous Cargo for Streets and Roads, establishes the conditions, rules and procedures applicable to streets and roads transport of substances or products which are, by their nature, dangerous or that represent health risks to people, public safety, or the environment. Radioactive materials and explosive products are excepted because these have their own regulations. For purposes of the application of this decree, hazardous substances are those found in Standard NCh 382/2004.



## Existing and New Chemicals, Registration, Permit

Decree No. 144, Organic Solvents Harmful to Health of May 10, 1985, as modified by Decree 650/88, published May 17 regulates the production, distribution, sale and use of pure organic, mixtures of these products and industrial or for domestic use that contain them. It also states that all organic solvents and products containing them must have the following legend printed on their label: "The prolonged inhalation of this product produces irreparable brain damage." The regulation prohibits the use of benzene as a solvent or diluent, or in the manufacture of common products that expose users to dermal contact, ingestion or inhalation of the vapors. The regulation only allows certain exceptions found in Article 10.



## Existing and New Chemicals, Registration, Permit

- Decree No. 114 is Regulation on Safety of Toys of June 17, 2005 regulates toys so they do not compromise safety or health of users when used for their normal and intended use, considering the usual behavior of children.
- Decree No. 157 is Regulation on Pesticide for Sanitary and Domestic Use of June 30, 2007. This decree regulates the conditions for registration, authorization, manufacture, import, storage, packaging, sale, possession, transport, distribution, promotion, advertising, application and disposal of pesticides for sanitary and domestic use, as well as in the manipulation of those that may affect human health.



## Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

- Standard NCh No. 382 of.2004, promulgated by Decree 29, of February 23, 2005, published in the Official Gazette March 30, 2005 is used for the general classification of dangerous substances. This standard concurs completely with the classification and numbers assigned to dangerous substances under the 2001 UN Model Regulation.
- Chilean standard (NCh) 2190 of.2003 (Decree 43, promulgated April 23, 2004 published in the Official Gazette of June 21, 2004) is the standard for transportation of dangerous goods, and hazardous identification of risks labeling.



## Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

Decree No. 78, promulgated September 11, 2010 governs storage of dangerous chemicals. This regulations excludes pesticides, alcoholic beverages, and cosmetic products, which are controlled under specific regulations.

- The regulation on storage of dangerous chemicals applies to labeling of all dangerous substances and is found in Title XIII under Labeling.
- Containers and packages are to be labeled in Spanish, legibly written with black lettering over a white background, placed horizontally when the container is in upright position.
- Labels should include at the very least minimum information coinciding with the Safety Data Sheet (SDS). Dangerous substance should be identified with their chemical name and UN numbers. In case of mixtures, each one of the substances that contribute to the hazard or the dangerous mixture, or that substitute it, should be identified, in accordance with NCh 382 of 2004,
- Also included should be the name of the provider, name, address, and telephone number of the manufacturer or importer, and safety indications, per the SDS. The substances should be labeled according to NCh 290 of.2003. Substances for exportation in compliance with GHS labeling, should also have this labeling.



# Classification, Labeling, Packaging (CLP), and Safety Data Sheet (SDS)

## Safety Data Sheet (SDS)

Chile has implemented specific workplace safety requirements. The Chilean Ministry of Health Decree 594 as amended through November 10, 2003, now requires Safety Data Sheets to be maintained where hazardous substances are stored.

Chilean standard (NCh) No. 2245 of 2003 (Decree No. 254, published in the Official Gazette of November 26, 2003) of the Chilean National Standards Institute has established standards for the content and order of sections of Safety Data Sheets and hazard labels. These standards are consistent with International Standard Organization (ISO) 11014-1994 Safety Data Sheet for Chemical Products.

Part I, Content and Order of Sections is not equivalent to it since it has some major deviations, which are due to the need to make it compatible with Supreme Decree No. 298/1994 of November 25, 1994 regulating transport of dangerous cargo on the streets and roads from the Ministry of Transport.

There are 16 Sections to be filled out in the Spanish language. The information must be clear and concise. Under the Ministry of Health Decree 594/99, as modified through November 7, 2003, there is a duty for employers to keep safety data sheets in locations where chemicals are stored and ensure basic sanitary and environmental protection for the health and well being of workers. Moreover, Decree No. 594/99 establishes occupational exposure limits. Law 16.744/68 of January 23, 1968 (published February 1, 1968), establishes reporting requirements and practices with regard to workplace accidents and illnesses.



## Restricted, Prohibited, or Banned Chemicals

Under Decree 594/99, the following substances are generally banned from the workplace except under specific conditions approved by the health authorities: Aldrin, benzene or gasoline except in combustion engines; benzidine; beta-naphthylamine; beta-propiolactone; chloromethyl methyl ether; dibromochloropropane; DDT; dieldrin; dimethylnitrosamine; endrine; 2-4-5T; 4-nitrodiphenyl, 4-aminodiphenyl.



## Restricted, Prohibited, or Banned Chemicals

- Also restricted is the list of dangerous substances found in Annex A of NCh 382 of 2004.
- Decree No. 374/97 promulgated August 25, 1997 on maximum lead in paints.
- Decree No. 754/98 of December 12, 1998 prohibiting Toluene in adhesives and glues.
- Decree No. 158/2003, as amended by Decree 135/2004, regarding chemical substances in toys.



## II. Aspects of Global Harmonized Systems (GHS)

- On a national level, in 2008, Chile published in its National Security Policy for Chemicals where it defined the short and medium term goals to comply with the implementation of the GHS.
- Chile's reported National Situation: Chile's goal is to adopt GHS to meet the objectives of the Environmental Policy for Sustainable Development of Chile. The activities on this issue began in 2006 with a series of meetings with stakeholders from public and private sectors. At the end of 2006 there was a first year seminar on GHS which were attended by 25 institutions of public and private sectors. That seminar was to have a second version in late 2008 anticipating attendance by 100 institutions of both sectors. Parallel to that, Chile has entered into a second set of meetings from which emerged the first national technical committee that is studying the Purple Book in its second revised version.
- The Inter-American Development Bank (IADB) issued its September 2010 INTAL monthly letter announcing that it will support chemicals trade in Mercosur and Chile. The cost of about US\$347 million has three components: The first is the introduction of a regional strategy to implement standards, guidelines, and tools for GHS and reduce the costs of maintaining different regulations across countries. The second is to define a common strategy with which to engage REACH to obtain cost effectiveness for compliance and the ability to access the Europeans markets. Finally, the IADB seeks to strengthen chemical manufacturers enabling access to speedy and accurate classification of their products in compliance with GHS. This can be accomplished through training of their personnel and mechanisms for information transfer.
- The IADB expects that an increase of competitiveness will lead to increased inter and intra exports at the regional level of chemicals. This will also allow the region's countries to join global production chains. The IADB hopes that this joint strategy will allow chemical manufacturers to successfully participate in international marketing of these goods. Because the chemical industry has important ties to other manufacturing and agricultural activities, this effort has great bearing on the regional economies.



Thank you!  
¡Muchas Gracias!