

Chemical Regulatory Updates in Latin America

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Agenda

1. Overview of Latin American Regulatory Environment
2. Argentina
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4. Chile
5. Peru

Overview of the Latin American Regulatory Environment

Common Themes

1. Generally, few formal chemical inventories in place, but rapidly increasing;
2. Generally, no formal pre-notification schemes, but individualized ones do exist;
3. The Globally Harmonized System of Classification and Labeling (GHS) has been implemented to a fair degree;
4. Many unique, localized regulations exist;
5. Many “twists” on global regulations exist

Argentina

- Presently **no** chemical substance notification scheme/inventory in place;
- 2018: Memorandum of Understanding signed between Argentina and Brazil. Purpose was to strengthen regulatory instruments for managing chemical substances
- June 2019 – Finalized DRAFT bill for regulating industrial chemicals:
 - [Bill 4339-D-2019](#): “DRAFT National Law on the Management of the Risk of Chemical Substances”
 - Competent Authority would be the Ministerio de Medio Ambiente y Desarrollo Sostenible (“Ministry of Environment and Sustainable Development”; MAyDS)
 - Planned to establish national substance inventory and evaluate risks;
 - Under the DRAFT, producers or importers of chemicals would have three years to register them under the country’s Inventario de Sustancias de Uso Industrial (“Inventory of Substances of Industrial Use”);

Argentina

- No specific reporting requirements for new chemical substances.
- However: Regulations for packaging and labelling of hazardous chemical substances and mixtures exist
- Competent authority is [Administración Nacional de Medicamentos, Alimentos y Tecnología Médica](#) (National Administration for Drugs, Food and Medical Technology; ANMAT);
- Pre-notification requirements for **dangerous substances and preparations** ([Law No. 26.045](#) (07 July 2005);
 - Examples include:
 - Paints, lacquers and varnishes containing more than 0.06 grams of lead for every 100 grams of non-volatile mass (Resolution 7/2009 MOH);
 - Medium-chain chlorinated paraffins (a/k/a polychlorinated n-alkanes (PCAs)) - metalworking fluids and additives (POPs);

Argentina

- GHS is [in force](#) in the country, using the 5th Revision of the “Purple Book”
- Upon publication, industry raised substantial concerns as to whether they could meet the compliance deadlines;
- As Such. Resolution No. 3359/2015 had its entry into force postponed by SRT 310/03, SRT 497/03 and SRT 743/03, and ultimately became [SRT Resolution No. 155/2016](#)
- The revised implementation deadlines were **1 January 2017** for substances (initially 15 April 2016), and **1 June 2017** for mixtures (initially 1 January 2017)
- Argentina did not implement the following building blocks: Chemicals Under Pressure, All Categories (Flammable gas, Categories 1A and 1B) and Desensitized explosives (all categories); and
- Incoming SDS should follow the Argentine GHS format

Brazil

There is NO REGULATION OR GOVERNMENTAL ACTION regarding:

1. Registration and authorization process;
2. National chemical inventory (**however**, see following);
3. New chemicals notification process and confidentiality protection;
4. Polymers; and
5. Risk assessments carried out by manufacturers or distributors.

Brazil

- No Brazilian chemical agency (similar to U.S. EPA, ECHA) exists, so some overlap in regulation occurs;
- Currently, the following Ministries and Agencies cooperate to manage chemicals:
 - **Ministry of Transport** (UN dangerous goods enforcement);
 - **Ministry of Labor** (workplace chemical enforcement);
 - **Ministry of Health** (regulates cosmetics, pharma, sanitizers, etc.);
 - **Ministry of Agriculture** (pesticide regulation and enforcement);
 - **Ministry of Defense** (chemicals used in manufacture of explosives);
 - **Ministry of Justice** (chemicals used in illegal drug production); and
 - **Ministry of Industry and Trade** (import/export of “others”).

Brazil

- The Brazilian Congress and the Office of the President (along with Ministries and Agencies) has authority for managing chemicals;
- Congress issues Federal chemical management/control laws, but no comprehensive (e.g., REACh) law exists;
- Control laws exist for:
 - Pesticides;
 - Sanitizers;
 - Explosives; and
 - Workplace chemicals.
- Only pesticides and sanitizers must be registered before sale

Brazil

- GHS has been implemented in Brazil, via a “technical standard”;
- *Associação Brasileira de Normalização Técnica* (Brazilian Association for Technical Standardization; ABNT) is responsible for the preparation of all National Standards (voluntary, consensus based);
- The GHS regulation is NBR 14725:
 - *“Informações sobre Saúde, Segurança e Meio Ambiente - Aspectos Gerais do Sistema Globalmente Harmonizado (GHS), Classificação, SDS e Rotulagem de Produtos Químicos”* (Health, Safety and Environmental Information - General Aspects of the Globally Harmonized System (GHS), Classification, SDS and Labeling of Chemicals)
- First published in 2009, revised again in 2019

Brazil

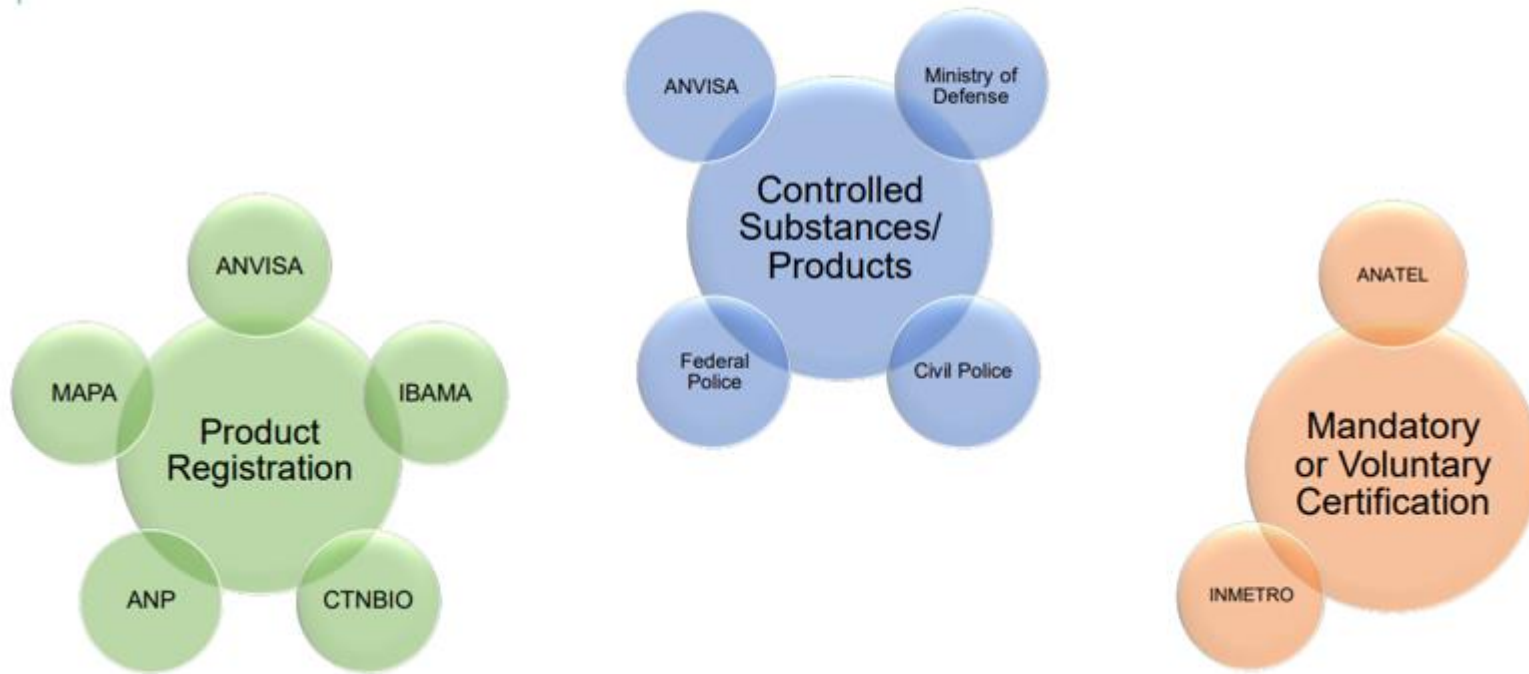
- NBR 14725 establishes labeling and informational requirements that generally apply to potentially hazardous chemical substances used in workplaces throughout Brazil;
- NOTE: Brazil uses the term “*Folha de Informações de Segurança Química*” (“Chemical Safety Information Sheet”) and the acronym FISPQ for same.
- Brazil does not employ all the building blocks of Rev. 5

Brazil

- NBR 14725 is comprised of four separately published documents:
 - **Terms and Definitions:** ABNT NBR 14725-1;
 - Amended June 19, 2019
 - **Classification:** ABNT NBR 14725-2;
 - Amended June 19, 2019; and
 - Key: The new values are equivalent to those used by the CLP Regulation (EC No 1272/2008)
 - **Labeling:** ABNT NBR 14725-3;
 - Amended June 19, 2019
 - **Hazard Communication (HAZCOM):** ABNT NBR 14725-4;
 - Amended June 19, 2019

Brazil

Main Brazilian Regulatory Agencies



Brazil - Updates

- ABNT NBR 14725 was updated in July 2023;
- One key aspect was to align it with GHS Rev. 7;
- Will enter into force **4 July 2025**;
- The revision consolidates the previous 4 part standard into one part;
- The term “SDS” will be renamed from the previous *Ficha de Informações de Segurança de Produtos Químicos* (FISPQ) to *Ficha com Dados de Segurança* (“Safety Data Sheet”; FDS);
- Unclear if previous FISPQs will need to be revised in name, or just new ones;
- Additionally, a 24-hour local emergency contact number will be required;

Brazil - Updates

The update will also:

1. Change the classification criteria of the hazard classes "flammable gases" and "acute toxicity", among others;
2. Update the hazard (H) and precautionary (P) language on labels; and
3. Update the rules for labeling small packages and products for internal use.

Chile

- Official title: “*Decreto 57 de 2019, Reglamento sobre Clasificación, Etiquetado y Notificación de Mezclas y Químicos Peligrosos*” (“Decree 57 of 2019, Regulation on **Classification, Labeling**, and **Notification** of Hazardous Chemicals and Mixtures”);
- Published in *Diario Oficial de la Republica de Chile* (Official Gazette of the Republic of Chile), 09 February 2021
- The various entry into force dates are calculated from this date;
- **Two key aspects:**
 - Formally implements the Globally Harmonized System of Classification and Labeling (GHS); and
 - Initiates a chemical inventory and reporting system
- Joint effort between the *Ministerio de Salud* (Ministry of Health; MOH) and the *Ministerio de Medio Ambiente* (Ministry of Environment; MOE);
- **Chile was the first Latin American country to implement a chemicals inventory and management system;** and
- Relatively complex regulation, with many parts.

Chile

- English translation is – 203 pages, Spanish – 146 pages
- 7 Titles, 243 Articles:
 - I: General Provisions;
 - II: Hazard Classification
 - III: Hazard Criteria for Classification of Substances;
 - IV: Safety Labeling of Substances and Mixtures;
 - V: SDS;
 - VI: Notification of Hazardous Substances;
 - VII: Risk Assessment; and
 - VIII: Oversight and Sanctions.
- Scope:
 - Those substances and mixtures not addressed by special regulations (see below). Includes classification, labeling and notification;
 - **DOES NOT COVER:**
 - Nuclear substances, cosmetics, pesticide residues in food, hazardous waste, articles that contain dangerous substances or mixtures (explosive articles are covered), substances in transit, non-isolated intermediates, medical devices, unmodified minerals of natural origin, fertilizers that are currently regulated, pharmaceutical products for human and veterinary purposes (raw materials are not excepted), food additives (raw materials are not excepted), and animal feed (raw materials are not excepted).
 - Active ingredients in pesticides for agriculture, health and home use

Chile

- Manufacturers and importers with hazardous substances in > 1 tpy are subject to Decree 51;
- Substances in mixtures must only be reported when they are above the threshold;
- Submissions must be made electronically through the MOE portal (www.plataformasqi.mma.gob.cl);
- Initial notification must be completed before **timeline below** and updated every two years.

- “New substances” are non-exempt hazardous chemical substances that are not included on the Resolution of Notified Substances
- New substances need to be notified prior to manufacture, import or sale

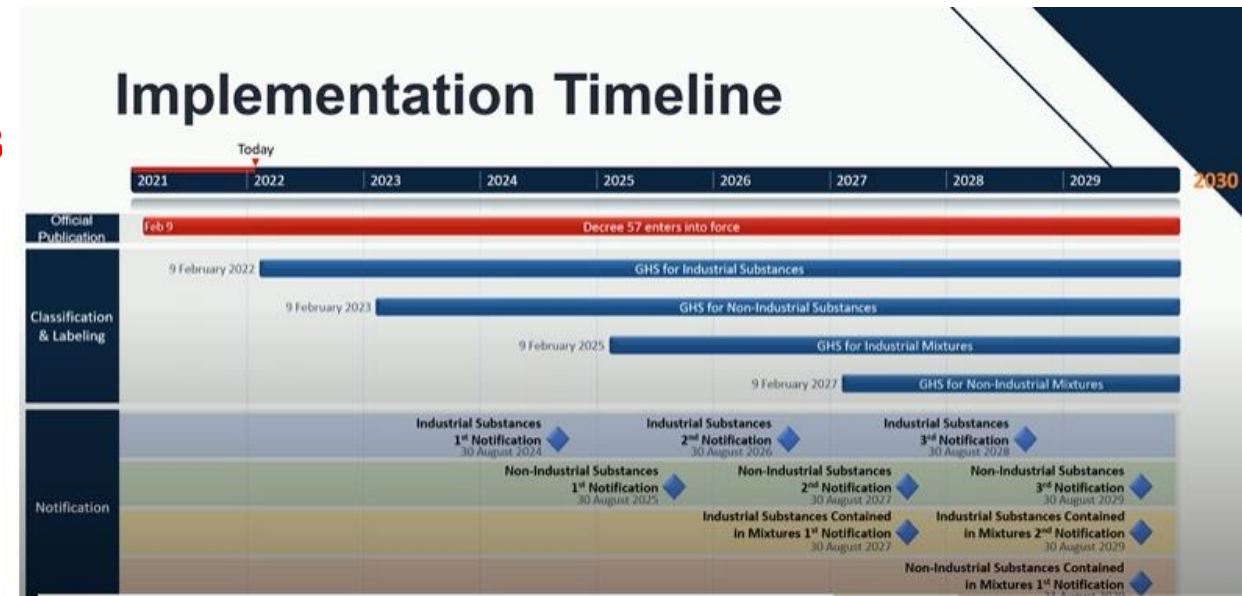
- Implementation dates for chemical registration (NOT GHS compliance!):
 - Substances for industrial use: **9 February 2024**
 - Mixtures for industrial use: **9 February 2027**
 - Substances of non-industrial use: **9 February 2025**
 - Mixtures of non-industrial use: **9 February 2029**

Chile

- Substances defined as “chemicals of interest” by the MOE and MOH will have risk assessments required;
- The MOE and MOH will determine the list of “chemicals of interest” based on the substances notified through the process;
- Such assessments are required to be performed by the manufacturer/importer;
- The “Risk Evaluation Resolution” will lay out the technical criteria for the risk assessments, as well as the criteria for defining “chemicals of interest”.

Chile

- Reminder: initial notification due by **09 February 2024**;
- Any substances notified after 30 August 2024 will be considered as new;
- **GHS** classification transitional periods
 - Industrial substances: **09 February 2022**
 - Non-industrial substances: **09 February 2023**
 - Industrial mixtures: **09 February 2025**
 - Non-industrial mixtures: **09 February 2027**



Source: GPC Regulatory

Chile

- Resolution 777/2021 from MOH, August 2021, contains an official list of substance classifications;
- Less restrictive categorizations must send supporting documents to MOH;
- Manufacturers and importers must update information within six months of it becoming known to them;
- Searchable by CAS number, chemical names are in Spanish;
- The [Substance Classification List of Resolution 777/2021](#) is a 718-page document (4,000+ substances);
- The Ministry will re-assess the classifications every two years

Chile

- SDS
 - 16 section format, similar to most other global requirements;
 - Must be printed in Spanish;
 - Must be provided to the recipient if the substance/material is determined to be hazardous; and
 - The following phrase should be included under Section 16 of the SDS:
 - “In this act, it is recorded that the information provided in this document is timely and transparent, in accordance with the requirements of national and international standards; in turn, it is established that the inappropriate use of this product, kit or substance could cause damage to people, private property and/or the environment. It is advisable to read this document carefully and contact an expert for guidance if you require assistance.”
 - In Spanish: “En este acto se deja constancia que la información vertida en el presente documento es oportuna y transparente, conforme a los requerimientos de las normas nacionales e internacionales, a su vez, se establece que el uso inapropiado de este producto, kit o sustancia podría generar daños en las personas, propiedad privada y/o medio ambiente. Se aconseja, leer detenidamente el presente documento y contactar a un experto para que lo oriente en caso de requerir asistencia.”
- NOTE: The Spanish translation above is **specifically included** in the Decree. As such, our recommendation is to use this translation only.

Chile-Updates

- **Disinfectant Products**

- July 2023 – Departamento de Salud Ambiental (“Department of Environmental Health”) released a [draft regulation](#);
- Aim - to establish a comprehensive framework governing the registration, manufacture, importation, storage, distribution, and dispensing of disinfectants in any form;
- Intended for use on surfaces, inanimate objects, environments, water, fabrics, textiles, chemical products, and many other materials where action is carried out by chemical reactions;
- Far reaching, but there are considerable exemptions: use on the skin of individuals as pharmaceutical products or cosmetics, additives in food, medical devices, descaling agents that do not claim effectiveness on biofilm or microorganisms...
- Also addresses **product registration**, manufacturing standards, importation controls, storage requirements, and guidelines for packaging and labeling.
- Regulation adopts the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for substances falling within its scope.
- 60 day comment period was held – 03 July to 03 September 2023
- Implementation date TBD

Peru

- On 28 May 2023, *Ministerio del Ambiente* (Ministry of the Environment; MINAM) approved Legislative Decree No. 1570, that implements the *Ley de Gestión Integral de Sustancias Químicas* (Law of Integral Management of Chemical Substances; “Ley”);
- The Ley will become effective as of the day following its publication, and which must be approved by MINAM within a period of no more than one year;
- It will establish requirements and responsibilities for both public entities and users of chemical substances;
- “User of chemical substances” natural or legal person who carries out activities with chemical substances such as manufacturing, importing, distribution, commercialization, packaging, storage and/or final use;
- Chemical substances must have a standardized hazard classification, which will be communicated in the labeling and in the Safety Data Sheet (SDS), and which must be made according to GHS and the provisions of the Regulation;
- Relatively standard requirements – similar to many other national chemical substance management programs;
- One new aspect – users must provide information to the Registro Nacional de Sustancias Químicas (National Registry of Chemical Substances; RENASQ) – new office;
- RENASQ will be in charge of MINAM - must have updated data on the chemical substances manufactured and imported into the country, as well as their manufacturers and importers.
- The information contained in the RENASQ will be **public**. However, the manufacturer or importer may request MINAM to keep confidential the IUPAC nomenclature and the CAS registry for a period of **five years**.

Thank you

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