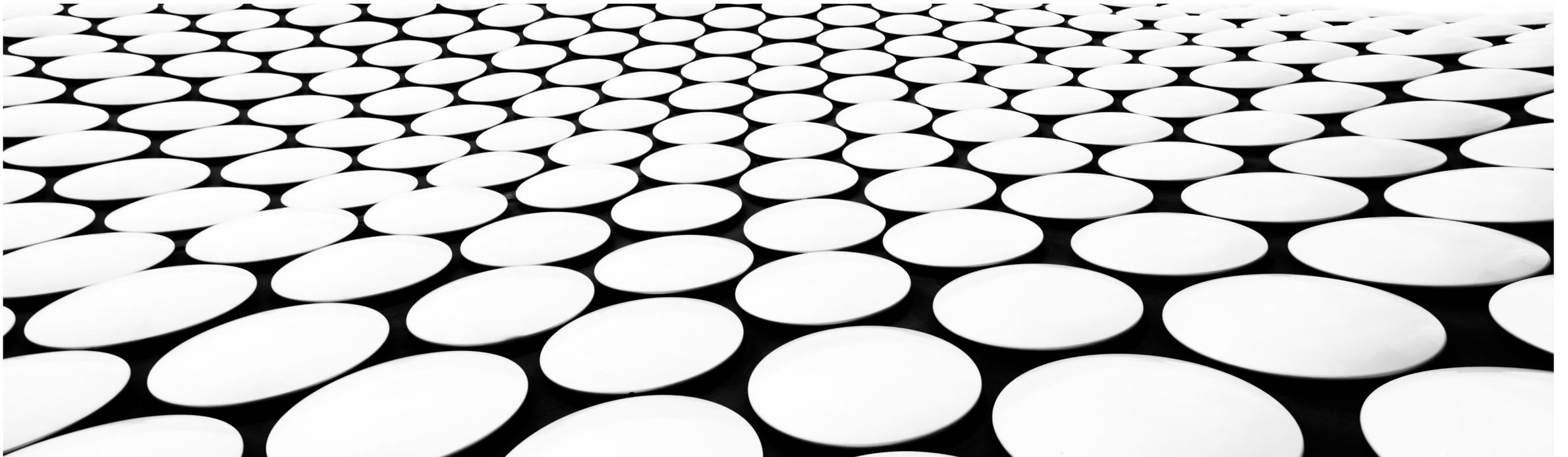

CHILE'S NATIONAL CHEMICAL INVENTORY

MELISSA OWEN, AMBIENTELEGAL 2021





SUPREME DECREE 57/2019

Regulation on Classification, Labeling, and Notification of Hazardous Chemical Substances and Mixtures

- Published in the *Diario Oficial* on February 9, 2021
- Link to Regulation:
- <https://www.bcn.cl/leychile/navegar?idNorma=1155752>

SUBSTANCES EXEMPT FROM THE REGULATION

- a) nuclear substances (as defined in Law No. 18,302, on nuclear safety)
- b) pharmaceutical products (defined in the Sanitary Code), except for the raw materials used for their manufacture or preparation
- c) pharmaceutical products for veterinary use (defined in Supreme Decree No. 25 of 2005 of the Ministry of Agriculture, which approves the regulation of pharmaceutical products exclusively for veterinary use), except for additives and raw materials used for their manufacture or preparation.
- manufacture or preparation
- d) food products for human consumption (regulated in the Sanitary Code and in Supreme Decree No. 977 of 1996, which approves the Sanitary Regulation of Foodstuffs), except for food additives and raw materials used for the manufacture or preparation of food products
- e) food products for animal consumption (defined in Supreme Decree No. 4, of 2016, of the Ministry of Agriculture, which approves the Animal Feed Regulation), except additives and raw materials used for their manufacture or preparation
- f) cosmetic products (defined in Supreme Decree No. 239, 2002, of the Ministry of Health, which approves the Regulation of the National Cosmetics Control System)
- g) pesticide residues in food (defined in Exempt Resolution No. 762 of 2011 of the Ministry of Health, which sets tolerances for pesticide residues in food)
- h) hazardous waste (defined in Supreme Decree No. 148 of 2003 of the Ministry of Health, which approves the Sanitary Regulation on Hazardous Waste Management)
- i) articles containing hazardous substances or mixtures, with the exception of explosive articles, as defined in Title III of the regulation
- j) substances and mixtures subject to customs supervision, in accordance with the pertinent regulations, provided that they are not subject to any type of treatment or transformation, and that they are kept in temporary storage for the purpose of export or in transit
- k) substances and mixtures intended for scientific research and development, which are not commercialized, provided that they are used under controlled conditions in accordance with the regulations in force
- l) non-isolated intermediates, in accordance with the provisions of these regulations
- m) medical devices (defined in Supreme Decree No. 825, of 1998, of the Ministry of Health, which approves the Regulation for the control of products and elements for medical use)
- n) minerals of natural origin, whose composition has not undergone chemical modifications, extracted mechanically and transported directly to where they will be processed, provided that their extraction does not exceed 5,000 Dry Metric Tons of mineral per month
- o) fertilizers regulated by Decree Law No. 3,557, of 1981, issued by the Ministry of Agriculture

SUBSTANCES EXEMPT FROM NOTIFICATION

- Substances uses as explosives
- Substances used as active ingredients in pesticides for agriculture, household, or health use

WHO MUST NOTIFY?

- (A) Manufacturers and importers of a substance and (B) importers of a substance contained in a mixture that is (C) classified as hazardous per Chile's GHS (D) in quantities equal or greater than 1 ton per year ... must notify the new system with the required information.
- For substances contained in mixtures, it will only be necessary to notify (a) those that present risks to environment and health and (b) whose concentrations are greater than the cut-off values in Paragraph II of Title II.

WHAT INFORMATION IS REQUIRED FOR EXISTING SUBSTANCES?

- **Identity of the notifier:**
 - 1.1. Name, address, telephone and e-mail of the notifier.
 - 1.2. Name, address, telephone number and e-mail address of the legal representative.
 - 1.3. Name, address, telephone number and e-mail address of the contact person.
 - 1.4. In the case of manufacturers, indicate the address(es) of the manufacturing site(s).
- **2. Identity of the substance(s).**
 - The information to be provided for the identification of the substance(s) should be sufficient to identify the substance(s) and include at least the following:
 - 2.1. Name(s) as given in the IUPAC nomenclature or other internationally recognized chemical name(s).
 - 2.2. Other names (common name, trade name, abbreviation).
 - 2.3. CAS number.
 - 2.4. The hazard classification of the substance, indicating the hazard class and category, as set out in the regulation.
 - 2.5. Quantity of the substance manufactured or imported per year, expressed in mass ranges.
 - 2.6. Intended uses. In the case of substances contained in mixtures, the intended use of the mixture must be indicated.
 - 2.7. Attach the safety data sheet for the substance.

NOTIFICATION PORTAL

- The Ventanilla Unica system houses the Notification Platform
Plataforma Notificación Programa Químico Industrial
- Url: <http://plataformasqi.mma.gob.cl/>
Beta account:
- Email: productor1@mail.com
- Password: 123123



NOTIFICATION OF NEW SUBSTANCES

- New Substances are non-exempt hazardous chemical substances not included on the Resolution of Notified Substances to be published by MMA
- New Substances need to notify PRIOR to sale, import, or manufacture of the substance
- In addition to the information for existing substances, new substances must submit information on:
 - oral acute toxicity,
 - dermal acute toxicity,
 - dermal corrosivity,
 - ocular corrosivity, and
 - acute ecotoxicity.
- New substances will not be issued their import authorization from the SEREMIs until it has been verified that the substance has been properly notified into the new system



RISK ASSESSMENTS

- Risk assessments required for “chemicals of interest”
- Risk assessments performed and provided by the manufacturers and importers
- MMA and the Ministry of Health will jointly determine “chemicals of interest” from the chemicals notified through the new system
- By June 30, 2022, MMA and Ministry of Health to issue joint Risk Evaluation Resolution with the modalities and technical criteria for the risk assessments and the criteria for defining “chemicals of interest” subject to assessments

IMPLEMENTATION SCHEDULE FOR NOTIFICATION OF HAZARDOUS SUBSTANCES

Type of Use	Type	Notification Deadline
INDUSTRIAL	Substances	2024
	Substances contained in mixtures	2027
OTHER THAN INDUSTRIAL	Substances	2025
	Substances contained in mixtures	2029

- Gracias / Thank you!

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