



←
Back

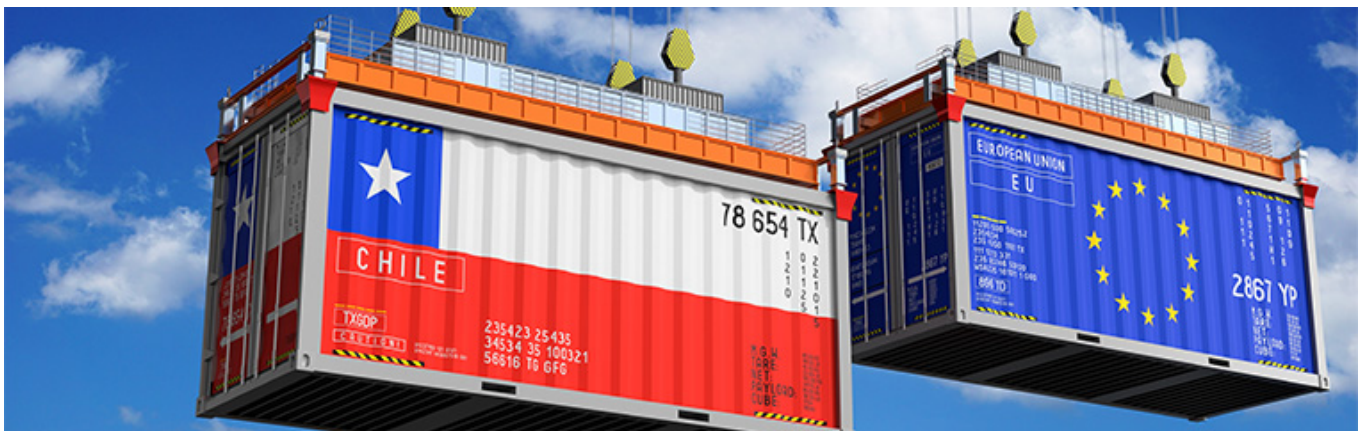
How does Chile's new notification system for chemical substances compare with REACH?

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DLA Piper senior associate Felipe Massardo examines the similarities, and differences, between Chile's first regulation on the management of hazardous substances and its European counterpart

- Chile
- GHS
- Chemical notification/ registration
- EU REACH
- Chemical management
- EU



Chile's first regulation on the management of hazardous chemical substances was published in 2021 by the Ministry of Health as Decree 57/2021, which approved the Regulation on Classification, Labelling and Notification of Chemical Substances and Hazardous Mixtures.

While this was some 15 years after the entry into force in 2007 of Europe's REACH regulation, both have a very similar content and purpose and we can reasonably expect that the Chilean regulation will follow a similar path in terms of its application and implementation.

REACH

REACH is an EU regulation, adopted to improve the protection of human health and the environment from the risks that may be posed by chemicals while enhancing the competitiveness of the EU chemicals industry. It works through a combination of mandatory requirements, incentives and facilitators.

In principle, REACH applies to all chemicals, not only those used in industrial processes. It therefore affects most companies in the EU. In fact, it is estimated that in 2017 its registration requirements affected around 60,000 substances in Europe, most of them substances that have been marketed on the continent for decades.

Under the slogan "no data, no market", this regulation places the burden of proof on companies that are responsible for identifying and managing the risks associated with the substances they manufacture or import into the EU.

Hence, registration becomes the most relevant part of the whole system. Simply put, after a certain period of time, unregistered substances and products containing them cannot be placed on the EU market, and even have to be withdrawn from circulation, regardless of their particular negative effects on health or the environment.

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

In Chile, the experience has been quite different. Most chemicals have run with very limited scrutiny by the authorities. The main mechanisms for control relate to the largest chemical producers and handlers in the context of their environmental assessment and the granting of sectoral permits for their operations. A renewed approach is long overdue, as recognised by the government of Chile in 2017 when issuing the national chemical safety policy.

The chemical sector in Chile is made up of approximately 300 companies that manufacture and distribute around 400 chemical substances for industrial use. In addition, sectors such as oil refining, iron and steel, pulp and paper, petrochemicals and copper mining, all use chemical products intensively.

The passing of the new decree has been a leap forward in term of chemicals control. Decree 57/2021 and its implementing resolution 777/2021, have created a local regime for registration of chemicals. The decree establishes deferred entry-into-force deadlines, ranging from one to six years from its publication (ie February 2021), depending on whether substances or mixtures are placed on the market, and on their use.

The notification deadline for industrial substances at the Ministry of the Environment's website is already available, and the authority has also made available an Instructions Guide for clarifying practical issues.

Like REACH, the decree establishes obligations regarding classification, registration and risk assessment of hazardous substances and mixtures with which manufacturers and importers must comply. It also establishes the criteria to which they must adapt, prior to marketing or use of the hazardous substances and mixtures.

GHS

The purpose of the decree is the regulatory development of the UN Globally Harmonized System (GHS) of classification and labelling of chemicals, although it does not implement the system in its entirety, excluding certain categories.

Responsibility for classifying and labelling substances and mixtures lies with the manufacturers or importers. The main characteristics of this new scheme are as follows:

Hazards classification (Title II)

The Ministry of Health has issued a list of hazardous substances organised by class and category. With this information, manufacturers and importers must use the list to classify their products. If they do not agree with the list, they may submit background information to the Ministry of Health, proving another classification. If the substance is not present in the list, it must be classified according to the criteria of Decree 57/2021. This list shall be reviewed at least on a bi-annual basis.

Safety labelling of substances and mixtures (Title IV)

If factories have containers that store substances and mixtures classified as hazardous, they must have a safety label in accordance with the provisions of the decree. It is important to note that substances packaged for export or are imported for own use may be exempt, and the items on the label will be allowed in the work area.

Safety data sheet (Title V)

A safety data sheet will be provided to the final recipient for substances and mixtures that meet the criteria to be classified as hazardous.

Notification of substances and mixtures (Title VI)

Any manufacturer or importer of a substance individually considered and as part of a mixture classified as hazardous, in quantities equal to or greater than one tonne per year, must notify the corresponding information in the substance notification system through a portal run by the environmental authority. It is important to mention that, in the general provisions of the regulation, there is a list that establishes certain cases for which this decree does not apply.

The ministries of health and environment must issue a joint resolution with the criteria for defining the substances of interest that must undergo a risk assessment. The final objective of this process is to have an inventory of the substances used in the country. Then, the Ministry of the Environment will issue a Resolution with the substances notified as of 31 December of the year of the notification.

Parallels between REACH and Decree 57/2021

Scope of application

Both REACH and Decree 57/2021 aim to cover all sectors that manufacture, import, distribute or use chemicals as raw materials or finished products (ie not just the chemical industry), regardless of the size of the company, as long as it complies with the thresholds included in the relevant regulation (in both cases, one ton per year).

Note, however, that REACH sets forth differentiated information requirements that vary according to the annual amounts manufactured or imported (from one to 1,000 tonnes per year), and under REACH a chemical safety report is only required if the registrant manufactures or imports a substance in quantities equal to or greater than ten tonnes per year.

Registration

REACH requires companies using chemicals alone or in mixtures in the context of their industrial or professional activities to transmit this information to ECHA. Similarly, with the implementation of Decree 57/2021, and as stated in Article 291: "Every manufacturer or importer of a substance as such and every importer of a substance contained in a mixture, hereinafter the Notifier, who classifies as hazardous according to Title III of this regulation, in quantities equal to or greater than 1 tonne per year, must notify in the system indicated in the following article, the information indicated in this title."

Note that this notification is not a "pre-registration", but the only registration that shall apply under the Chilean regime. At this very initial stage, what the authorities want is to gather information about the substances being imported and/or manufactured in Chile, so as to be able to then prioritise and choose substances of interest for the purposes of risk assessment and subsequent obligations for manufacturers and importers. In other words, the Chilean regulation is more aimed at the creation of an inventory of chemicals imported to or manufactured in the country, rather than to restrict their immediate circulation in the Chilean market.

Authorisation

With the entry into force of the decree, all producers of hazardous substances in the country must have sanitary authorisation to manufacture such substances. The same occurs in the EU, where the use of hazardous substances is temporarily restricted to manufacturers until those substances obtain the relevant authorisations (although there are some excepted substances, as indicated below).

Note that, as per Decree 57/2021, in case of importation of new substances, the health authority will grant the respective import authorisation only if the notification process has been previously verified.

Labelling

Unlike REACH, the decree also deals with labelling issues. In this regard, it requires that substances or mixtures classified as hazardous have a label with information on product identifiers, hazard pictograms, signal words and hazard indicators, among others. In Europe, requirements on classification, labelling and data sheets are further regulated through the CLP regulation.

Exempted entities

Both REACH and Decree 57/2021 include exemptions for the purposes of the application of the registration obligation and requirements for chemical safety. While REACH considers total exemptions from registration and/or authorisation (eg radioactive substances, certain substances in temporary storage under customs supervision, or substances used in the interest of defence covered by specific national exemptions) and partial exemptions from registration and/or authorisation (eg substances used in scientific R&D, in food and feedstuffs,

in medicinal products, or occurring in nature, among others), Decree 57/2021 only provides for general exceptions from application of the decree (eg nuclear substances, certain pharmaceutical products, food and feedstuffs, cosmetic products, etc).

There is no doubt that Decree 57/2021 has been strongly influenced by REACH. Hence, Chile is expected to move towards a registration system, similar to the European one, in which importers and manufacturers will be required to notify the use of hazardous chemicals and take the necessary measures to protect the environment and human safety, beyond a mere notification process aimed at creating inventories of chemicals marketed in Chile.

Although the regulation has not yet fully entered into force, it is important that those affected by the decree begin to prepare themselves to be able to respond correctly to it. In particular, importers and manufacturers of chemicals shipping products to Chile will be required to notify, by August this year, the hazardous substances they handle in the context of their industrial use.

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