RISK APPROACH IN THE INDUSTRIAL CHEMICALS MANAGEMENT SCHEME

INVENTORIES

Latin America Regulatory Cooperation Forum (LARCF)
International Council of Chemical Associations (ICCA)

Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America (VWG-SMC-LA)

LARCF
Foro de Cooperación Regulatoria de América Latina

Abril, 2022

This report was prepared by the Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America (VWG-SMC-LA), an initiative of the Latin America Regulatory Cooperation Forum (LARCF) with the support of the International Council of Chemical Associations (ICCA).

Its content is the result of a joint effort that involved government representatives, industry associations, industries and intergovernmental organizations.

Views represented here should not be regarded as ICCA's official position.

April 2022

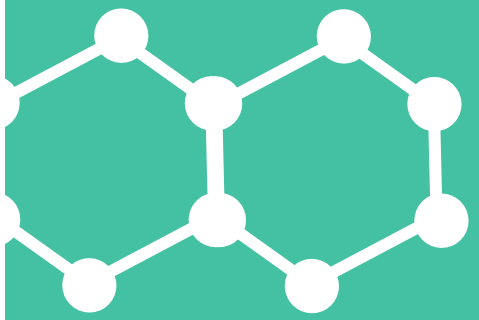
How to cite this document:

Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America (VWG-SMC-LA). (2023). Risk approach in the industrial chemicals management scheme. Phase 1: Inventories

Disclaimer:

The original document was prepared in Spanish. This is not an official translation.

CONTENTS



1. PURPOSE OF THE DOCUMENT

The aim of this document is to capture the key elements for the implementation of a risk management scheme for industrial chemicals (RMS-IC), with a focus on inventories, registries and other elements that are part of this process. The purpose is to promote debate among representatives of governments and industries in Latin America on the set of principles and technical concepts related to the development and implementation of regulations, not be interpreted as mandatory regulatory requirements.

2. FIRST STEPS WHEN STARTING THE DESIGN OF A RMS-IC [1] REGULATION

An important evidence-based policy-making element is the Regulatory Impact Assessment (RIA). Conducting an RIA helps governments to ensure that regulations are efficient and effective in a changing and complex world[2]. According to the Organization for Economic Co-operation and Development (OECD), "it is a systemic approach to critically assess the positive and negative effects of proposed and existing regulations and non-regulatory alternatives"[3].

In a simplified way, the following steps are recommended for the realization of a RIA[4]:

1. Definition of the problem.
2. Setting objectives.
3. Assessment of all viable management options, regulatory or non-regulatory.
4. Analysis of the impacts of these options.
5. Consultation with stakeholders[5].

Although in some countries of the region there are regulations that establish the realization of RIA (or at least, some of its steps)[6], it is noteworthy that there are very few cases where this evaluation was carried out in the context of elaboration of a regulation on the RMS-IC. It is important to note that resources for developing a RIA vary considerably depending on the level of detail required, and that countries must ensure that the requirements are consistent with their objectives.

According with the above, the first step at the beginning of the design of any public policy would be to clearly state the problem to be tackled before establishing its objectives. Without a clear definition of problems and objectives, efforts may not lead to the expected results.

In general, the **problem** is the **lack of information and/or the mechanisms for generating, collecting and transferring information** on substances in trade and use, necessary for making decisions aimed at reducing or eliminating risks and, therefore, to achieve the main goal of this type of regulation, which is to **protect human health and the environment**[7].

When starting the formulation of a policy for the RMS-IC, it is essential to analyse the initial context or "baseline" -both local and global- from which the design of a regulatory instrument in a country should begin. The

[1] It is also recommended to consult the "Roadmap for the sound management of industrial chemicals" VWG-SMC-LA (2021)
[2] It should be noted that RIA can be a complex and tedious process, especially when it comes to cost-benefit analysis. Extensive training and capacity building is required to ensure its successful implementation.
[3] Extracted from the official website of the OECD (2022). Available at: https://www.oecd.org/gov/regulatory-policy/ria.htm
[4] The APEC Chemical Dialogue Best Practice Principle Checklist for conducting a Regulatory Impact Assessment is a good reference for a RIA.
[5] In the context of the region, this step is also supported within the provisions of the Escazú Regional Agreement (Regional Agreement on Access to Information, Public Participation and Access to Justice in Environmental Matters in Latin America and the Caribbean) . Text in Spanish: http://repositorio.cepal.org/bitstream/handle/11362/43595/1/S1800429_es.pdf
[6] Some examples: Brazil ; Decree 10411 of June 30, 2020 regulates the RIA; Chile 1 and Chile 2; Colombia: Decree 1468 of 2020; Columbia 2; Columbia 3; Mexico .
[7] Likewise, these regulations cover secondary objectives such as providing security in commercial relations.

questions in Annex 1 function as a self-assessment tool, which could help perform this analysis. This tool has been developed by the VWG-SMC-LA based on OECD tools (Environmental Performance Review, or EPR[8]) and the documents quoted in *Bibliography*.

In many cases, after performing a baseline analysis, although most countries have information on the production and trade of some substances, it is concluded that the data is requested in a disaggregated manner by different authorities, and sometimes for purposes other than the protection of health and the environment (for example, for the control of narcotics, chemical weapons or customs movement). These schemes generate duplicated efforts, lead to increased times and unjustified costs for both the government sector and the industry.

ANNEX 1

See the **Baseline Self-Assessment Tool** developed by the VWG-SMC-LA based on OECD tools (such as the Environmental Performance Review) and other recognized sources detailed in the Bibliography section.

3. PURPOSE OF AN INDUSTRIAL CHEMICALS INVENTORY WITHIN A RISK MANAGEMENT SCHEME

While OECD emphasizes that it would be desirable to subject all chemicals to a detailed assessment, its instruments recognize that available resources are often limited and must be used selectively[9]. To this end, as a preliminary measure, it is necessary to have a system that makes it possible to define which substances to focus on and deepen the study. Hence the concept of **inventories of chemicals** subject to trade (imported, produced) and/or used in the country as the first phase of a collection system and analysis of information on substances.

The aim of an inventory is to know the production, import and use of chemicals present in a certain country and their basic necessary information to proceed with the identification and management of associated risks, in order to protect health and the environment. In countries with effective prior implementation of a hazard classification and labelling system, the inventory is the first step of a RMS-IC.[10]

> Inventories alone do not provide a mechanism to identify chemicals that may pose an unreasonable risk to citizens and the environment, but they are the necessary first step in implementing a risk management scheme.

The outline presented in the "Roadmap for the sound management of industrial chemicals" (VWG-SMC-LA, 2021) summarizes each phase of the RMS-IC, based on what was explained above. As may be understood, the need for resources by governments and industry increases progressively with each step from left to right.

[8]More information available at: https://www.oecd.org/environment/country-reviews/about-env-country-reviews.htm

[9]Original source (in English): OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT: "Although it would be desirable to subject all chemicals to detailed assessment for potential hazard, the limited resources available in terms of laboratories as well as expertise, must be employed selectively".

[10]It should be noted that the information obtained by the inventories is also essential to meet international obligations, such as compliance with the Rotterdam Convention.

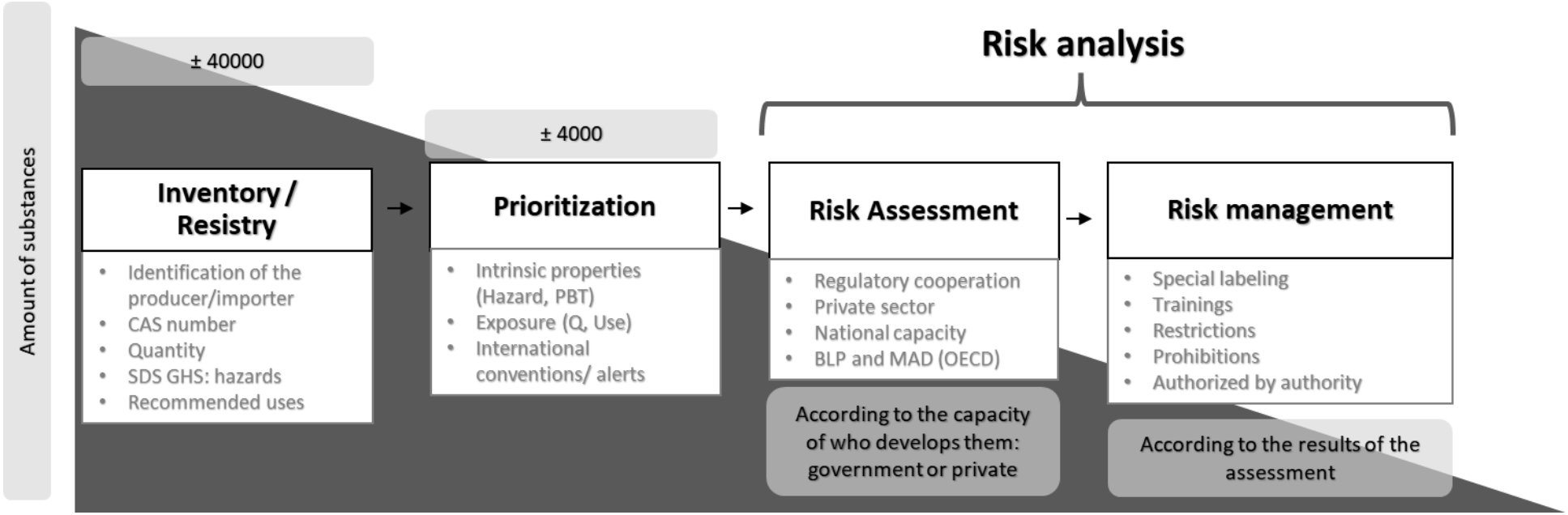


Figure 3: Common steps for the development of inventories/registers, prioritization, risk analysis, assessment and management regulations. Source: VWG-SMC-LA, 2021

1. **Inventory:** Essential basic information to proceed with the risk identification and management. Most of the existing systems require: the identification of the substance, volume/quantity imported and/or produced, recommended or identified uses, and hazards according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
2. **Prioritization of substances:** The inventoried/registered substances are submitted to a prioritization process based on their hazard classification and exposure conditions, which gives a preliminary indication of their risk level (potential or identified). The purpose of this stage is to identify those substances that may represent a greater risk to health and/or the environment, for which additional detailed information is required to establish safe conditions of use. The process is based on criteria such as the analysis of its intrinsic properties, uses recommended or identified, exposure scenarios, until their detection in monitoring programs.
3. **Risk analysis and evaluation:** The prioritized substances are studied through a detailed scientific evaluation, where risks to human health and the environment are identified, based on their hazardousness and exposure derived from manufacturing, fractionation, handling, distribution, storage, use, transportation and disposal. Risk assessment is a tool for making decisions about acceptable levels of risk related to the use of a substance. This step only depends on its hazardous properties for health and the environment, and the level of exposure, and is not related to socioeconomic benefits. In any case, this risk assessment would then be taken as an input to manage the risk.

4. **Risk management measures:** Risk management is a decision-making process based on information generated through risk assessment and socioeconomic assessment. This procedure involves establishing a qualitative or quantitative relationship between the risks associated with a chemical and its socioeconomic impacts, which means a complex weighting process. Its purpose is to develop, analyse and compare regulatory and non-regulatory mitigation and control options to be implemented by the different actors, which allow reducing the defined impact on health and the environment, and evaluating the benefits associated with the measures.

4. DIFFERENCES BETWEEN INVENTORY, NOTIFICATION AND REGISTRATION

The inventory of substances is sometimes referred to by other terms, the most common being the registration of substances. In the Roadmap, in order to simplify, both terms were used equivalently. However, it should be noted that in some jurisdictions they are considered differently. It is generally accepted that the former does not imply a license to market, while registration does imply the obligation and the granting of permission for marketing. In this way, registration systems are often combined with the preparation of inventories. In order to clarify the differences, the definitions of each term in the framework of the RSM-IC are detailed below:

DEFINITIONS

Inventory: Initial baseline database on imported and produced chemicals, which can contribute to regulatory decision-making.

(Source: ASEAN-based own development, 2019).

Notification: Formal requirement for the submission of specific chemical information for control and/or monitoring purposes by the competent authority.
(Source: ECHA adaptation. Available from: https://echa-term.echa.europa.eu/

Registration: Database with specific information on chemicals that is evaluated by the competent authority to grant, where appropriate, production, marketing and/or use permits.*

Registration is generally not recommended for the initial setup of an RSM-IC, especially in a context of scarce resource. This recommendation is based on the large number of chemicals in the market of a country (considering some 40,000 to 60,000 substances in use globally[11]) and the resources that would be needed to evaluate the granting of an authorization.

It is therefore recommended to start with an inventory phase, as countries with limited resources and/or experience would benefit from a notification scheme, based on the submission of a limited set of information, sufficient to support prioritization.

[11]Estimated total considering only chemicals for industrial use. Source: report by the United Nations Environment Program (UNEP) and the International Council of Chemical Associations (ICCA). United Nations Environment Program [UNEP], (2019). Global Chemicals Outlook II. From Legacies to Innovative Solutions: Implementing the 2030 Agenda for Sustainable Development.
https://www.unenvironment.org/resources/report/global-chemicals-outlook-ii-legacies-innovative-solutions
* Prepared with modifications based on ASEAN (2019). Original: "This is the baseline data of chemicals manufactured, imported, used in a country (e.g., all chemicals in commerce) and may form the basis for further regulatory evaluation (...)."
* According to the FAO definition, the register is "the process by which the appropriate national government or regional authority approves the sale and use (of a pesticide) after the assessment of comprehensive scientific data showing that the product is effective for its intended purpose and does not pose an unacceptable risk to human or animal health or the environment". (Source: LIRA GUIDE)

5. DEFINITIONS TO BE INCLUDED IN THE REGULATION

The use of adequate definitions is essential to avoid misunderstandings in the interpretation of the regulations. Ideally, they should be harmonized with international terms and definitions as far as possible. Some recommendations are presented in Annex 2.

6. CURRENT EXISTING MODELS AT A GLOBAL AND REGIONAL LEVEL

Among the good regulatory practices, it is recommended to conduct an analysis of different risk management schemes, and mainly of the approaches of the countries with greater ties at commercial level.

It is important to clarify that when studying an approach, its historical and political context must be considered, since the implementation of some of the most referenced schemes dates back more than 30 years. This indicates that, although they are now in force, they have previous legislation that must also be considered. On the other hand, there are the recently adopted schemes, which were created under a modern international framework, taking into account lessons learned and new data sources available.

To facilitate the study, the table in Annex 3 contains examples of inventories and records around the world, and their main characteristics. Although it is not exhaustive, it presents indicative information that can help to have a notion of global trends for each characteristic. A brief description of the most representative schemes in terms of chemical substance risk management is also included.

7. REGULATORY COOPERATION WHEN DEVELOPING NATIONAL INVENTORIES AND REGISTRIES

The development of individual and closed national inventories may not always be the most appropriate path, particularly if major trading partners have established inventories containing a substantially similar list of substances. To portray this situation, we can see in Figure 2, the large number of substances identified with a CAS number[12], which are listed in multiple inventories (in green).

[12]Identification of the Chemical Abstract Service.

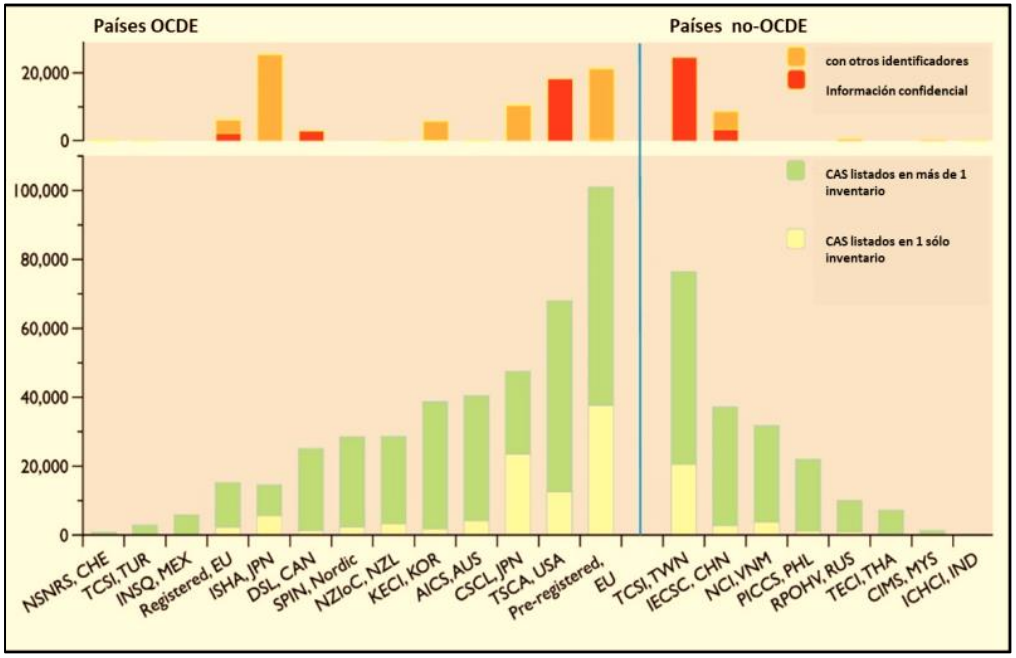


Figure 2: Chemicals with CAS Numbers Listed on Multiple Inventories.
Source: Zhanyun Wang et al. (2020), with modifications

Seeking to make efficient use of resources and avoid the duplication of data on the same substance in each territory, the OECD promotes the exchange of data between countries. This type of scheme is essential in economies with limited resources, and for this reason, the region is urged to consider its implementation at local level when designing its policies. For example, as the two cases below indicate, countries may establish a "Mutual Acceptance" scheme, accepting the information provided in the inventory of another country, or a combination of these two approaches.

Examples of schemes that apply external data acceptance

Philippines[13]

The Philippines has two types of chemical notification requirements. On one hand, for completely "new to the world" substances, complete information is required prior to import or manufacture, such as actual test results on physical-chemical properties, toxicological and environmental effects. On the other hand, the country has an abbreviated system, required for chemicals that have been included in the inventory of countries such as the United States, Europe, Canada, Australia, Japan or Korea. For this type of chemical, a summary statement on the physical-chemical properties and the toxicological and environmental effects of the chemical, among other requirements, is sufficient.

Canada[14]

Canada has two chemical inventories, namely: DSL (Domestic Substances List) for chemicals used in Canadian commerce and NDSL (Non-Domestic Substances List) for those listed on the United States inventory but not in Canada's DSL. If an importer or manufacturer plans to introduce a "new" chemical that is not on the DSL but is listed on the NDSL -except for those subjects to special restrictions/controls- then the importer or manufacturer may apply data requirements for a new substance, of a lower level. This significantly reduces the lead time for assessment and the cost of generating data for a chemical in the NDSL.

[13]ASEAN Guidance Document on Developing a Chemical Inventory. (2019) ASEAN.

[14]IDEM.

8. SUBSTANCES/GROUPS OF SUBSTANCES INCLUDED AND EXCLUDED FROM INVENTORIES

The OECD indicates that the scope should be restricted to substances (defined as chemical elements and their compounds as they are in their natural state or as produced by industry[15]) and that mixtures should be excluded from any systematic evaluation requirement. The large number of admixtures makes their inclusion extremely complex and demands high resources from government and industry. Instead, substances (sometimes only new ones) entering the country as a component of mixtures are usually reported individually[16].

On the other hand, some inventories consider two categories of substances: those that can be presented in the form of well-defined substances -including mono-constituent or multi-constituent substances-; and the "UVCB" for its acronym in English, i.e., with unknown or variable composition, complex reaction products and biological materials. The latter require additional description, such as the manufacturing process, and therefore provide additional complexity when configuring a chemicals inventory.

Efficient use of resources must be the basis of any regulation. Therefore, the development of inventories that include all substances should be evaluated against the availability of resources of each territory, especially in countries where they are scarce. Including all substances would be very complex, not only because of the quantity of substances, but because it is very difficult to identify non-hazardous substances contained in imported mixtures, as they are not generally reported in the GHS Safety Data Sheets (SDS). It is therefore recommended that the inventories include only those substances that qualify for a GHS hazard category. This decision is based on the fact that substances which are not classified as dangerous are less likely to fall into high priority levels in terms of the risk they may pose.[17] An alternative option, if non-hazardous substances are included, is for them to be delegated to a more advanced stage of the notification system established in the country.

Exclusions

The scope of a chemicals inventory should clearly define what is included and what is not. As indicated by the OECD, some substances may be exempted from these systems, either because they are intended for limited research purposes, or are exempted for specific reasons by national authorities.[18]

Other existing regulatory frameworks often cover specific chemical groups (e.g., food additives, pharmaceuticals, agrochemicals). To avoid duplication of efforts or potential conflicts, these substances are not included in inventories of industrial chemicals. However, it should be noted that not all existing registries and inventories have a health and environmental protection approach, aspect that should be taken into account when defining

[15]Original definition: " *Chemical elements and their compounds as they occur in the natural state or as produced by industry." (OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT)*

[16]Original text (in English): "Formulations should usually be excluded from any requirements for systematic assessment, except where a new chemical substance enters the country as a component of such formulations." *(OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT)*

[17] Also supported by the OECD. Original text (in English): "those substances which are least likely to create hazard and for which no further studies are deemed necessary at the time" (O ECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT)

[18]Original text (in English): "With a view to efficient use of the limited resources available, the assessment scheme is directed towards new substances which enter a country for the first time, through manufacture or import, with the exception of those intended for limited research purposes, or which may be exempted by national authorities for specific reasons." (OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT)

exceptions. The following are examples of commonly regulated uses of chemicals, which could justify their exclusion from inventories:

- **a)** Food and food additives (human and animal consumption).
- **b)** Products under customs supervision, which are in temporary storage, free zone, or customs warehouse, with the intent to be re-exported or in transit.
- **c)** Medical devices.
- **d)** Drugs, including human and veterinary drugs.
- **e)** Ammunition, gunpowder and pyrotechnics.
- **f)** Pesticides and fertilizers, including inert/inactive ingredients.
- **g)** Cosmetic products, personal hygiene and perfumes.
- **h)** Non-isolated intermediate products.

It should be clarified that this exception does not exclude that these same substances can be inventoried for other uses* under the industrial chemicals inventory, or after going through a prioritization process, be subject to risk assessments and adequate risk management measures.

Likewise, one option is to exempt certain categories of substances from notification when they offer very low exposure or there is sufficient information available to consider them as causing a negligible risk to human health and the environment. Examples include:

- **a)** Hydrates of substances notified or already regulated.
- **b)** Non-isolated intermediaries.
- **c)** Polymers, including the monomer units and additives that are part of the polymers. **
- **d)** Chemicals found in nature (non-hazardous, minerals, natural gas, liquefied petroleum gas, natural gas condensate, process gases and their components, crude oil, coal, coke).
- **e)** Substances considered as impurities, by-products and incidental reaction products.
- **f)** Substances in articles, except chemicals intentionally released from the article.
- **g)** Chemicals for exclusive use for research and development purposes.
- **h)** Chemicals to be used for analysis, property measurement or toxicity testing.[19]
- **i)** Chemicals that will be sold/used/marketed in quantities less than, for example, 1 tonne/year.
- **j)** Glass, frit, ceramic, ceramic raw material, steel, cement, metal alloy.

CLARIFICATIONS

* In case of multiple uses for a substance, it is advisable to notify only the quantities or volumes destined to industrial uses.

** Most chemical inventories include polymers, however, due to some factors, such as the large number of variations they present and - in general - their low level of risk, it is recommended to consider the exemption of their notification in inventories. It is important to consider that polymers may be covered by the following stages of the RMS-IC, from the monomers and reactants inventoried. This aspect, due to its technical complexity, can be addressed in future documents.

[19]NOTE: These would be excluded by setting a limit value in the volume of production/import for notifying to the inventory. If they were not excluded by volume, they should be included in the inventory as occupational exposure would be significant.

9. MULTIPLE INVENTORIES AND REGISTRIES AT NATIONAL LEVEL

Since many chemicals can have multiple uses, they may be listed in multiple national inventories and/or registries. In other words, inventories of industrial chemicals often have substantial overlays with those of substances and/or products of specific application. Several authorities may have the need to access inventory information to apply the law and impose compliance. For this reason, it is necessary to establish adequate coordination mechanisms and ensure access to shared databases.

In developing a national chemicals management information system, many countries are considering having a "centralized" system rather than a "decentralized" one. The evidence shows that no country, either developed or in development, has a completely centralized information system for the management of all types of substances and mixtures. Rather, countries have several institutions that collect and manage - the same or different - information from some group or type of chemicals.

Therefore, when designing a system, it is relevant to consider how to coordinate the decentralized elements and how to effectively organize the development, exchange and integration of information. An approach may be to establish an agency, committee or working group to coordinate these activities. Its creation may require formal endorsement in national legislation. Its responsibilities could include:

- Maintain a list of all members (with contact information, areas of activity and the data sets they have), guaranteeing representation of all the competent authorities involved in the management of chemicals;
- Strengthen cooperation among stakeholders through the development of a data access protocols;
- Promote the harmonization of data collection methods, formats, terminology and systems;
- Ensure financial support to enable stakeholders to fulfil their roles.

The OECD dictates that when new procedures are established for the evaluation of chemicals, an integrated approach should be sought ensuring that they are considered in terms of both human and environmental health, avoiding duplication of burden.

10. NEW AND PRE-EXISTING SUBSTANCES

In general, in line with international recommendations on progressivity, inventories allow a grace period of 2 to 3 years for the notification of substances, from the entry into force of the new regulatory framework and the systems required for its operation. Substances notified during this period are identified as "pre-existing" substances within the framework of this document[20]. On the other hand, substances notified for the first time after this period has expired are identified as "new". This process is illustrated in Figure 3.

[20]It should be noted that pre-existing substances will always maintain that character, unless there is a change in any of the minimum data presented.

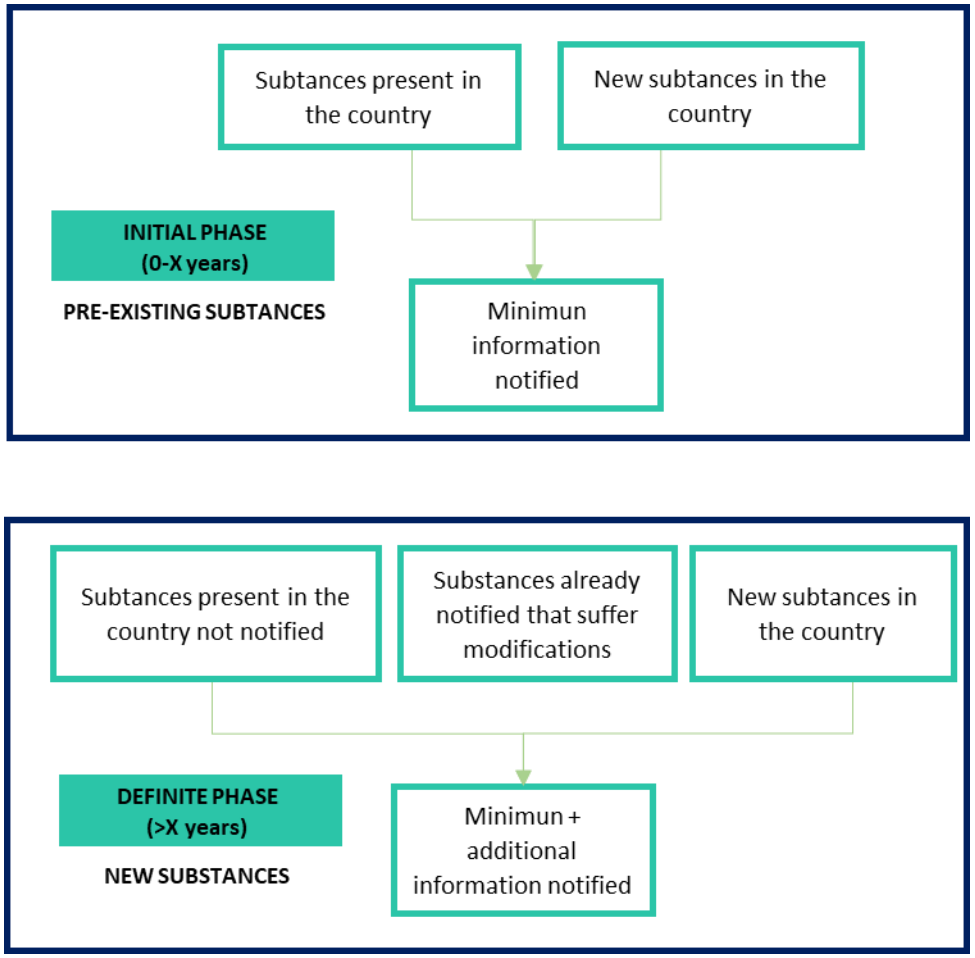


Figure 3: RMS-IC: Inventory and registry implementation in phases. Source: VWG-SMC-LA

The notification of "new" substances usually involves increased reporting requirements that should be aligned with the requirements established by other jurisdictions, as it is not recommended to require additional information to those required in international schemes. Likewise, for new substances an approval for commercialization is usually linked to the provision of the requested information.

It is recommended to clearly establish the set of minimum information requirements for the introduction of new substances. According to the OECD, these data could be: (a) chemical identification data; (b) production, use, transportation and waste management data; (c) precautions and contingency measures; (d) physical and chemical properties; and (e) acute toxicity, chronic toxicity, mutagenicity, ecotoxicity, degradability, and bioaccumulation data[21].

The request for additional data must be based on predefined criteria related to conditions that may lead to risks. If the request of additional data concerns to new substances, it should be addressed directly to the notifier/registrant as a measure to protect confidential data. In the case of existing substances, it is recommended to publish a public announcement, allowing voluntary contribution of information. If it is not provided voluntarily, it can be requested directly from the notifier/registrant.

11. RESPONSIBILITIES

It is important to note that the implementation of chemical inventories/registries involves a large number of tasks for which it is necessary to have pre-established responsibilities and roles in the regulations.

In general, the OECD defines that the responsibility of generating and evaluating the necessary data to determine potential effects and the safe use of substances with respect to human health and the environment should be the responsibility and part of the functions of the industry.[22] It also clarifies

[21]Decision on the Minimum Pre-marketing set of Data in the Assessment of Chemicals [C(82)196/Final]. https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0199

[22] Original text: " Responsibility for generating and assessing the data necessary to determine the potential effects and the safe use of substances with respect to man and the environment must be part of the overall

that, when new procedures are established for the assessment of substances, an integrated approach should be sought. Several authorities may have responsibility for treating notifications, declarations and dossiers required under different laws or schemes for the control of chemicals in a country. Arrangements should be made for optimum co-ordination of such activities.[23] The responsibilities of the authorities will vary according to the scheme chosen (new inventory or inventory integrated with other databases).

Additionally, governments should ensure that information is received in a properly functioning IT system and that it is subject to a review process. Also, they must ensure that confidential information is pre-defined and protected.

In general, the countries assign the faculties for the development of this type of tools to their portfolios of environment, health, production, and labour. There is a tendency for inventories/registries to be managed by environmental agencies (as Competent Authority), due to their responsibility before international treaties, their representativeness before agencies such as the OECD, and the delegation of powers through national regulations aimed at protecting human health and the environment.

It is recommended that, although it is a process that requires time and resources, governments evaluate the possibility of accepting information available in regulatory systems of other jurisdictions or scientific databases. [24] If so, the regulation must clearly define what information must be generated in the country and what information may be obtained from external sources, clarifying the type of acceptable sources and the criteria to be used to validate the extrapolation of information to local conditions. Some sources available are:

- OECD eChemPortal
- ICCA/UNEP Report 'Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals'
- IPCS INCHEM
- German MAK commission
- ECHA Dissemination website
- ECHA Chem
- US ATSDR tox profiles
- PUBMED
- EFSA Scientific Opinions
- IRIS Risk Assessment
- NICNAS Risk Assessments

12. PRELIMINARY STAGE FOR THE NOTIFICATION OF PRE-EXISTING SUBSTANCES

All information required in the inventory must meet the criteria that have been decided for the prioritization stage. The data set described below not only responds to the inventory models already installed at international level but is also in line with requirements and recommendations of international organizations and conventions, including the Stockholm, Rotterdam and Minamata Conventions and the Escazu Agreement [25].

function and liability of industry". (OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT)
[23] OECD-LEGAL-0154 - ANNEX I - GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT

[24] It is recommended to use data obtained from studies conducted using recognized protocols. In any case, a study may not have been conducted under an OECD protocol, and still have information that can help in the process of evaluating the weight of the evidence.
[25] Chemical data collection has been on the international agenda since 1972. Most international and regional conventions and initiatives on substances and products involve reporting. For example, the national report for

Therefore, the development of an efficiently designed inventory, with adequate data requirements, may imply reduction in efforts and resources to respond to the country's commitments.

Details about the producer/importer

Covers the contact information necessary to link the substance with the subject bound by the regulation. It should be ensured that only authorized persons can notify on behalf of the company.

Substance identity

Due to the complexity of chemicals[26], a clear methodology is needed for their identification to:

- Avoid ambiguity in its identification.
- Verify that it is within the scope of the chemical inventory.
- Facilitate additional necessary actions (e.g., prioritization of chemicals, risk management measures).

The most appropriate reference to identify a chemical substance is the CAS number and it/s name/s (for example, CAS[27]and/or IUPAC[28] name). In their absence, alternative chemical identities may be required, for example, the INCI[29] name or the HSPA[30] name.

It should be noted that substances may have a CAS name, but not all substances will have a CAS number assigned. This may apply to substances at a research and development stage or those that are subject to a trade secret. UVCBs, due to their complex nature, can often have different CAS number assignments, although they may, from a hazard and risk management point of view, be captured under a group or a single definition. Other technical challenges related to the use of numerical identifiers were identified by Zhanyun Wang et al. (2019), based on a systematic search of 22 inventories from 19 countries.

Quantity imported or produced

There are different approaches on this matter. Some jurisdictions prefer to request accurate information, while in others an average is requested –generally of the past three years-. This period is recommended since it is considered sufficient for the purpose of inventories.

Quantity data can be reported in the format of ranges pre-established by the authority. The reporting of exact amounts may require the use of unnecessary resources for the purposes pursued by the regulations. However, exact amounts could be requested if deemed relevant by the authority and in accordance with the provisions relating to the protection of confidential business information.

Threshold for notification

Based on a phased approach, notification may be required only if a chemical is imported or manufactured above a certain threshold. The quantity of substances imported/produced annually is usually a commonly used criterion because it is not only related to the potential exposure, but also related to the size of the companies that import/manufacture them. The

the Stockholm Convention includes -on certain persistent organic pollutants- the following data: volume (kg/year) of production, import, export and use; and location and conditions of stocks. Within the framework of the Rotterdam Convention, for prohibited or severely restricted products, the following is requested: common name, chemical name according to internationally recognized rules (for example IUPAC), trade name, codes (CAS number, customs classification, among others), hazard classification, uses, physicochemical, toxicological, ecotoxicological properties.

[26]In most inventories the term "substance" refers to *a chemical element and its compounds in its natural state or obtained by any manufacturing process, including any additives necessary to preserve its stability and any impurity derived from the process used, but excluding any solvent that can be removed without affecting the stability of the substance or changing its composition* . Its identification is derived from this definition.

[27]All substances registered in CAS receive a *Chemical Abstracts (CA) index name* (CAS name). Although the registry includes other common denominations, this is the "official" name that is assigned following a series of nomenclature rules, typical of the American Chemical Society (ACC) (https://www.cas .org/sites/default/files/documents/indexguideapp.pdf). Its nomenclature follows -in general- the rules published by the IUPAC.

[28] International Union of Pure and Applied Chemistry

[29] International Nomenclature of Cosmetic Ingredients

[30] Hydrocarbon Solvent Manufacturers Association

threshold should allow to assess as many as substances as possible present in the territory and to obtain total quantities notified that are representative to carry out the prioritization process, without losing sight of the efficiency in the use of resources.

In most current inventories, information is requested from the producers or importers of the substances, generally when their average annual import or production exceeds a certain amount. Examples are: 100kg in Australia, Canada for new substances, South Korea and Sweden, among others; 1000kg in Canada, for pre-existing substances, China, the Philippines, Japan, and the European Union, through REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)[31], among others.

To date, the authors of this document have found no justifications regarding the reporting threshold in the literature. However, it is relevant that countries understand that deciding between thresholds with one or more orders of difference can severely impact the amounts of resources affected. That is why a threshold of 1 ton is recommended, as long as a previous analysis indicates that this value meets the conditions of representativeness and relevance at the local level mentioned above.

It is pertinent to note that some schemes consider the possibility of requiring the notification of high-risk substances, even if they are produced or imported in quantities below the specified threshold. Other schemes also offer the possibility of notifying substances voluntarily, even if their quantity does not exceed the threshold.

Applications

It is usually referred to as "recommended uses", "suggested uses", "expected uses", "intended uses", "identified uses". Based on the GHS, it is considered to be *the use for which the substance or mixture is intended for or recommended*. Within this document, the preferred terms are "recommended or identified uses".[32]

Ultimately, the use should provide useful information to characterize possible exposure scenarios (e.g., consumer, workplace, intermediate products). To contribute to the discussions between countries and achieve a harmonized definition, the OECD has developed a document in 2017 that compiles 107 functional uses extracted from 10 data systems[33]. The report notes that it is important to establish how broadly or specifically use categories should be defined, considering the intended purpose and audience of the information, and the chemicals associated with each use category. Both approaches (broad and specific) have advantages and shortcomings. Broad categorization results in a larger number of chemicals covered by a given category. Restricted definitions offer the benefit of grouping chemicals in a more refined manner. However, a high level of specificity could limit cross-country data, and make reporting more difficult. Table 2 below illustrates examples of some common uses:

Table 2. Examples of the most common potential functional uses according to chemical class. Font: OECD (2017).

Chemical class	Potential functional use
alcohols	Fuel, Solvent
ethers	Propellant, blowing agent, Coolant, Solvent
Organic acids	Preservative, pH regulator
alkali acids	Cleaning agent, Surfactant, pH regulator
Phthalates	plasticizer

Communication throughout the supply chain becomes essential when it comes to identifying the uses of a substance. It is desirable that the regulations provide for the establishment of obligations for users in such a way that new uses are reported, either to their supplier or to the system. In this case, producers and importers should evaluate the new suggested use

[31]It should be noted that the European Union has adopted a gradual reduction approach to the threshold, which is described in more detail in Annex 3.
[32]Among the particular cases, we can mention the situation of companies that import directly for their industry. In such a case, the declared use will be known and specific.
[33]Source: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2017)14&doclanguage=en

and make a decision on whether to include it -or not- as a new identified/recommended use in the corresponding notification and conduct the subsequent risk analysis, if applicable. The regulation should consider the way forward if the producer or importer does not recommend such use. The user could be held responsible in terms of reporting and conducting out the relevant risk assessment, in order to promote safe use of the substance. Likewise, as a control measure, the schemes could contemplate the prohibition of giving a substance an unreported use in the inventory.

Hazards

In order to promote the implementation of a harmonized and internationally recognized system, information on the hazards of the substance should be submitted following the GHS[34].

Additional Information

If additional information is required, it should be clearly defined and related to the hazardous characteristics of the substance and its exposure scenario (in cases of high reported quantities or uses with higher risks).

Progressive approach

Another approach is proposed in the LIRA Guidance[35] (p. 40) of the United Nations Environment Program (UNEP):

1. *Inventory of primary suppliers of chemicals in the country (importers and manufacturers)*
2. *Inventory of data on import and manufacture of pure substances (technical quality) of particular interest for a country (possibly including volume data/classification)*
3. *Inventory of import and manufacture of mixtures in certain groups of chemicals (lubricants, paints, glues etc.) of particular interest for a country (possibly incl. volume data/classification)*
4. *Inventory of hazardous components in classified mixtures (in certain groups, group by group, possibly percentages of components, etc.)*

The guidance indicates that establishing a simple inventory of primary suppliers (i.e., importers and manufacturers) can be considered as a first step on which to base planning and inspection. Depending on the availability of resources, the inventory can be refined by adding information on the types and uses of chemicals placed in the market by the primary suppliers registered in the inventory. This could provide an overview of flows in the national market and generate useful information for the adoption and application of decisions.

13. FREQUENCY OF UPDATE OF INVENTORY INFORMATION

In its instruments, the OECD states that a systematic approach for assessing existing substances can be applied, with a defined periodicity or when a relevant change occurs, such as a new recommended/identified use[36], a significant increase in the quantities produced and/or or imported,

[34] It is important to note that while persistence, degradability and bioaccumulation potential are part of the criteria for classifying substances as hazardous to the aquatic environment under GHS, these properties are not considered hazard classifications per se and for that reason in some jurisdictions it is usually included in the list of minimum requirements, because they tend to be a prioritization criterion in subsequent steps. It should be clarified that this information should be provided in the Safety Data Sheet (point 12: ecotoxicological information).

[35] https://wedocs.unep.org/bitstream/handle/20.500.11822/12224/LIRA_Guidance%20Report_PRESS.pdf?sequence=1&isAllowed=y

[36] Some regulations have considered defining obligations for users of substances to report a new use to producers/importers.

for such notification will depend on available resources, and usually varies between one and four years.

14. CONFIDENTIALITY OF INFORMATION

Protecting confidential business information is an often-overlooked area, but it is extremely important to the industry, where many knowledge and competitive advantage have been developed over the years. Under some existing regulatory models, companies are allowed to request non-disclosure of certain information (called confidential business information, CBI) that they share with public authorities for inventories, registrations, licensing, or other purposes. This request is based on avoiding substantial commercial damage to the owner of the information (the companies).

However, the need for confidentiality must be balanced with the right of the people to be informed about the identity of the substance and the hazards and risks to health and the environment. Therefore, the regulations need to clearly specify the data that would be outside the scope of the confidentiality request, as well as the type of information that can be made confidential and under what conditions. Furthermore, it should be clarified that confidentiality refers to the reservation of data from the general public, whereas public authorities should have full access to such information.

It is important to define in the regulations what information is considered confidential and what is considered to be of public interest, the correct way to keep and store confidential records, and the persons and entities that must have access to those records.[37] Government officials should be assigned with legal authority to collect data and protect confidential business information. The CBI should be made available only to authorized persons, and the public should only have access to information deemed relevant to health and environmental safety. However, the scheme should ensure that all submissions are safe and secure, not just those containing confidential information.

Typically, confidentiality requirements and rules are defined in specific national legislation, often in accordance with rules established by the World Trade Organization (WTO)[38]. However, existing instruments in the region tend to regulate in a general way, leaving a legal vacuum for specific issues related to the management of substances and products. It is therefore recommended that inventory regulations reserve a section for confidentiality issues. For its development, although the schemes are not identical, models can be taken from the pesticide registries that exist in the region, as well as the guidelines of the United Nations Food and Agriculture Organization (FAO) related to pesticide records[39]. The models adopted by other countries can also be taken into account (see Annex 3 and Annex 4), as well as recommendations 0203, 0204 and 0205 of the OECD.

The VWG-SMC-LA suggests the following examples of information that could be considered confidential:

- Detailed usage information.
- Exact quantities of manufacture or import.
- Complete reports of toxicological/ecotoxicological studies.

In addition, the following information could be considered confidential under certain conditions defined by the country's authorities[40].

- Unique chemical name and/or identifier (e.g., CAS number, CAS name, chemical name)

[37]LIRA Guide, UNEP.
[38]For WTO members, the protection of undisclosed information is mandatory under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is contained in Annex 1C of the Agreement establishing the WTO. More information available at: https://www.wto.org/spanish/tratop_s/trips_s/trips_s.htm

[39]Source: https://www.fao.org/pesticide-registration-toolkit/registration-tools/registration-process/data-protection-and-confidentiality/es/
[40]For example, if the substance is not classified in any hazard category and there is a reason to justify a relevant commercial injury (for example, disclosure reveals a formulation).

- Name of the notifier.

It is noted that most of the existing models the authorities reserve the right to disclose information that is normally considered confidential in cases that require urgent action to protect human health, safety or the environment (such as, for example, in emergency situations).

As regards to non-confidential information, among the GHS CBI protection principles (section 1.4.8.3) it is highlighted that confidentiality claims in SDS should be limited to the names of the substances and their concentrations in mixtures, and that all other label and SDS information should be disclosed. According to OECD Recommendation 0205, the following information on substances should be considered non-confidential[41]:

- Trade names or names in common use;
- General data on uses;
- Handling precautions to be taken during the manufacture, storage, transport and use of substances and mixtures;
- Recommended methods for waste disposal and management;
- Accident safety measures;
- Physical and chemical data, with the exception of data that reveals the identity of chemicals (for example, spectrometry). If the physical and chemical data allow the identity of the chemical substance to be deduced from them, only ranges of values can be given;
- Summaries of health, safety and environmental data, including accurate figures and interpretations (the submitter of health, safety and environmental data should be involved in the preparation of summaries).

[41]In this context, "non-confidential" means that no restrictions should be placed on the exchange of data between governments or on disclosure to the public. OECD considers that property rights over the data would not be affected.
[42]Among them: China, South Korea, Costa Rica, those belonging to the European Economic Area, Switzerland, Turkey.

15. EXCLUSIVE REPRESENTATIVE FIGURE

Some countries[42] include in their schemes the figure of exclusive representative, that is, a resident of the country designated by the producing companies located abroad who assumes the tasks and responsibilities of the importing companies required to notify their substances in the local inventories. This practice simplifies the access of products to the national market, facilitates the supply and protects the confidentiality of information, limits importers' responsibilities by removing unnecessary burdens on them as a way to protect small and medium-sized companies, and is a mechanism that provides efficiency to the regulatory system.

In some existing international systems, in order to obtain the figure of exclusive representative it is necessary to comply with certain conditions, such as: being a natural or legal person physically established in the country, being designated by mutual agreement between the importer and the producer abroad, be responsible for complying with the legal requirements for importers and additional requirements specific to their role as exclusive representative, have sufficient knowledge in the practical handling of substances and related information[43, 44].

The scope of the responsibilities of the exclusive representative should be clearly established in the regulations, and differentiated from those of the producer/importer, so that the authorities can determine which subject would be penalized when cases such as failure to notify or false information arise.

[43]Under the European Union's REACH scheme, it is not considered an exclusive representative in the following cases: when the non-European Economic Area supplier is a distributor, or if its only function is to act as a third-party representative in the REACH data sharing process. More information available here
[44]While this is a condition established in the regulations, there are no detailed criteria or requirements on what is considered "sufficient knowledge in the practical handling of substances and information related to them". Source: https://echa.europa.eu/es/support/qas-support/browse/-/qa/70Qx/view/scope/reach/Only+Representative+of+non-EU+manufacturer

16. REVIEW BY THE AUTHORITIES OF THE INFORMATION PROVIDED

The establishment of a notification scheme implies that, at a minimum, the authorities certify that it complies with all the requirements of the regulations. That is, that the information provided is complete.

Regarding the quality of the information provided, the review of the data can be complex and consume many resources, due to the large number of substances in the market. However, it is recommended that the authorities monitor the quality of the data, at least on a random basis[45]. The control of the information ensures equal conditions among all the subjects bound by the regulations.

It is worth mentioning that, at this stage, given the diversity of possible hazard classifications for the same substance, a harmonization process might be necessary, that is, that the authorities put forward official lists of harmonized minimum classifications at the national level[46].

17. ASPECTS TO ENSURE COMPLIANCE[47]

Oversight activities must be applied in a legal, fair, predictable, transparent and consistent manner[48]. For this, it requires an analysis of which civil service officials will be part of the monitoring tasks, what mechanisms will be used and what resources will be required. Likewise, the corresponding qualifications and training should be planned. Coordination between different authorities for joint inspections is also a recommended technique for monitoring.

Sanctions and penalties are valid tools to ensure compliance and strengthen control actions. Other instruments include, for example, public reports of non-compliance and complaints. Potential non-conformities should be subject to detailed investigation, and repeated non-conformities may lead to more severe penalties.

Measures that voluntarily stimulate more challenging proactive initiatives can also be adopted, for example, through public listings of companies with satisfactory behaviour and the reduction of fees.

Likewise, in view of the introduction of new legal requirements, it is necessary to carry out outreach activities to inform the regulated entities of the purpose of the regulations and the requirements to be met. These organizations are more likely to adopt the measures if they understand them. Therefore, a cost-effective way to promote compliance is to ensure transparency and communication throughout the process. Public awareness

[45] Another possible approach -taking into account the lack of financial and human resources of the governments- is for a preliminary data review phase to be conducted by a computerized system. There are even schemes with a more complex second random review using artificial intelligence. Once that process has been completed, the competent authority could assess the most pressing cases.

[46] Among others, the European Union has a harmonized list that was recently adopted by Chile.

[47] There is a wide range of guides and reference material developed by international authorities and organizations, which the VWG-SMC-LA recommends. These include: OSHA Guide on inspections focused on the hazard communication standard (access), KEMI Guide on the control of instruments on substances in the market (access), Canada Guide on GHS compliance (access) .

[48] For the purposes of this document, the VWG understands the following definitions: *"Fair"* means that the same rules exist for all auditees, and that the process allows all interested parties the opportunity to defend/justify. " *Predictable and transparent* " refers to minimizing the need for individual interpretations by the inspectors and avoiding ambiguities, achieving, for example, clarity in the elements that will be inspected, and in sanctions. *"Consistent"* relates to coordination with federal statutes and regulations, ensuring that there are no inconsistencies. Likewise, that efforts be focused with priority on cases of greatest risk to human health and/or the environment.

of the risks of chemicals and products and existing safety measures, including the development and updating of labels and SDS, is also important to promote compliance.

18. RESOURCES REQUIRED FROM GOVERNMENTS AND INDUSTRIES FOR THE CREATION OF THE INVENTORY

Each element presented in Table 3 (next page) will depend on the responsibilities assigned to both the industry and the government (above all, the definition of responsibility for the generation and updating of information is key).

19. OPTIONS TO FUND THE SYSTEMS CREATED FOR THESE REGULATIONS[49]

In the first place, an analysis of the costs of proposed initiatives and sources of funding is essential for sustainable infrastructure financing.

It should be noted that it is necessary to consider both the initial capital cost to launch the system and make the necessary updates, as well as the cost of its operation over the years. This analysis serves as a fundamental argument to demonstrate the viability of the proposals and the advantages of investing in the management of industrial chemicals for the development of the country.

There are different financing options both at the national (for example, budget and fees) and international level (international capacity-building programs, for example, through the UNEP Quick Start Program[50] or the Global Environment Facility - *GEF*-[51] or bilateral agreements). Joint financing (international-national) can be one of the most important sources of financial and technical capacity, as long as it is linked to centralized decision-making structures at the national level.

[49] Section made based on the UNEP LIRA Guide.
[50] It is important to note that the Quick Start Program funds are limited to two years and, in general, try to be distributed among several countries.
[51] GEF funding is limited to specific topics that do not cover the full range of chemicals management concerns that developing countries and countries with economies in transition may face.

Table 3. Elements and resources required for the creation, operation and maintenance of inventories of industrial chemicals

Element/ resource	Governments	Industries
Budget	A budget would need to be allocated and, depending on the existing national approval process, may take time to prepare and reach consensus. Keep in mind that, once in operation, aspects of inventory improvement will be identified. Therefore, budget allocation becomes necessary both during the execution phase and during the maintenance phase.	It is important for the industry to provide information on the projected costs for the sector associated with the implementation of the system. These may be taken into consideration for the Regulatory Impact Analysis.
Staff	Personnel with various skills will be required for the different phases of the project: initial phase, preparation phase, implementation phase and maintenance. Additional staff may need to manage the project, set up an IT system and handle the numerous notifications during the implementation period. For staff resources, an approximate general estimate, based on existing work in some of the ASEAN countries, would be about 20 full-time employees, including system development. Staff can be reduced once the project has reached full implementation and moved into a maintenance mode. This number highly depends on defined objectives and is for inventory purposes only, not for any further evaluation work. For comparison, developed economies such as Australia, Canada, the EU and the US require resources ranging from 60 to 600+ employees, but cover a broader scope of activities. SKILLS: Those needed during project setup will be IT personnel, qualified personnel with chemical backgrounds, who have a good knowledge of chemical nomenclature, industry subject matter experts and dedicated legal/departmental personnel.	The number of staff currently available, which could be related to the tasks necessary to fulfil the obligations, should be identified. In the case of companies with differentiated departments, some related employees will belong to the regulatory compliance area, while others will be technicians capable of identifying substances, their dangers -among other data-, managing databases and computer systems. Some companies -especially small and medium-sized ones- do not have many employees or specialized departments, so they may delegate the fulfilment of their obligations to third parties (for example, specialized consulting companies)[52]. SKILLS: IT personnel, qualified personnel with experience in chemistry, who have a good knowledge of chemical nomenclature, industry subject matter experts and dedicated legal/departmental personnel. It is important that industries have previously implemented a hazard classification system in order to notify substances

[52]Regarding the context of SMEs, it is suggested to consult guides such as OSHA's "HAZARD COMMUNICATION Small Entity Compliance Guide for Employers That Use Hazardous Chemicals" (access).

Element/ resource	Governments	Industries
	The government must invest time and part of its budget in continuous training of its personnel, both for the stages of preparing policy instruments and for their execution.	
Computer administrative system	All information should be collected in a centralized and electronic system for data submission and reporting. The stored information should be made available to interested parties so that they can fully participate in the management plan. Government departments should have access to all stored information necessary for their work. A robust, well thought out and tested system with high specifications regarding integrity, stability and especially security for the storage of confidential information is essential to handle the numerous and high accesses of notifiers, particularly close to deadlines. It is a good option to evaluate starting with an existing system and generating a common platform that is already in use and that has proven its good functioning, avoiding having to go through the first errors of the system. Furthermore, a harmonized tool can be advantageous if it is used in all member states. Some technical considerations: - The system should be easy to operate, intuitive and user friendly. - Ensuring that information is provided in a digital format with "exploitable data". - Include a mechanism to take data from previous notifications, for the development of very similar notifications. - Provide a user manual, guides, clear answers to frequently asked questions, a help desk and training. - To avoid typing errors, minimize the possibilities of free text. For example, through an automatic filling system, the possibility of linking the administrator's data with existing information (for example, from fiscal data), inclusion of menus with lists to select from.	Companies must find a way to manage their data, which allows them to relate those to be provided to the users of their products, those that must be provided to the authorities, confidential and specific to the operation of the industry. Industries will need to be involved in the development of the information system, with active participation, such as in the tests and pilot systems. Likewise, it will be important to report system errors when the system is in operation.

Element/ resource	Governments	Industries
Access to data and information	Need to have databases and information to verify the information provided. Ensure sufficient resources for laboratory tests and analyses that will be necessary to classify substances and verify information, in case of doubt. Some of these costs can be reduced by regulatory cooperation and the use of public databases.	Testing for identification of substances and identification of associated hazards. Some of these costs can be reduced by regulatory cooperation and by the use of public databases.
Communication and training	Training courses to prepare the private sector. Websites, guidelines and other types of information material may also facilitate regulated entities' access to requirements and thus promote compliance. As mentioned above, it is part of the government's responsibilities to invest time and part of its budget in continuous training of its personnel.	The staff of private companies will need to have expertise to perform proper chemical management (correct labelling, safe handling, making the right decisions about the substances and products that they commercialize, etc.)

BIBLIOGRAPHY

European Agency for Substances and Mixtures. (2021). ECHA- *term terminology database* . Official Web site. https://echa-term.echa.europa.eu/

ASEAN. *(* 2019). *ASEAN Guidance Document on Developing a Chemical Inventory*

Acosta A., Schlezak S. (2021). *Report on legal and institutional frameworks for the integrated management of chemicals in Latin American and Caribbean countries.* Intergovernmental Chemical and Waste Network for Latin America and the Caribbean.

Plant Health Committee of the Southern Cone (COSAVE). (1996). *Regional Standard on Phytosanitary Protection. Glossary of terms related to the Registry of Phytosanitary Products v.1.2.* Official Web site. http://www.cosave.org/sites/default/files/erpfs/st20700v000102_esp.html

Derbenev A. (2020). *Survey for Review of Chemical Management Regulatory Systems Worldwide – Summary* . APEC Committee on Trade and Investment. Chemical Dialogue

Australian Government . Health Department. (2021). *Industrial Chemicals: Who we are and what we do.* Official Web site. https://www.industrialchemicals.gov.au/about-us/who-we-are-and-what-we-do)

Government of the Republic of the Philippines. Control Body for the Management of Substances. Official Web site. https://chemical.emb.gov.ph/?page_id=44

ICCA Virtual Working Group for the management of industrial substances in Latin America. *(2021). Roadmap for the management of industrial substances and products.*

IOMC. (2019). *IOMC Toolbox* . Official Website . _ https://iomctoolbox.org/

OECD. (1977). OECD-LEGAL-0154-en_Anticipating effects of chemicals

OECD. (1982). OECD-LEGAL-0199-en_Pre-Marketing Set of data

OECD (2017). Internationally harmonized functional, product and article use categories. ENV/JM/ MONO(2017)14. OECD Environment, Health and Safety Publications Series on Testing & Assessment No. 262.

World Health Organization. (2018). *National chemicals registers and inventories: benefits and approaches to development.*

UNEP. (2015). *UNEP LIRA Guide On the development of legal and institutional infrastructure and measures to recover the costs of the National Administration in the sound management of chemicals.*

UNEP, ICCA. (2019). *Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals.*

Zhanyun Wang et al. (2020). *Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories.* Environmental Science & Technology 54 (5), 2575-2584. DOI: 10.1021/acs.est.9b06379.

ACRONYMS

ASEAN	Association of Southeast Asian Nations
CAS	Chemical Abstract Service
CBI	Confidential Business Information
DSL	Canada´s Domestic Substance List
EPR	Environmental Performance Review
FAO	Food and Agriculture Organization of the United Nations
SDS	GHS Safety Data Sheets
GEF	Global Environment Facility
HSPA	Association of Manufacturers of Hydrocarbon Solvents
INCI	International nomenclature of ingredients
IUPAC	International Union of Pure and Applied Chemistry
NDSL	Canada´s Non-Domestic Substances List
OECD	Organization for Economic Co-operation and Development
WTO	World Trade Organization
UNEP	United Nations Environment Program
REACH	Registration, evaluation, authorization and restriction of chemicals - European Union
RIA	Regulatory Impact Assessment
RMS-IC	Risk management scheme for industrial chemicals
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
UVCB	Substances with unknown or variable composition, complex reaction products and biological materials
VWG-SMC-LA	Virtual working group for the sound management of chemicals in Latin America

ANNEX 1. SELF-ASSESSMENT TOOL FOR THE CONFORMATION OF THE BASE LINE

- What motivates the development of regulations on RMS-IC? What are the objectives pursued?
- What is the existing regulatory framework on chemicals both at the national and local levels?[53]
    - What is the degree of progress in the implementation of GHS? [54] What is the regulatory situation regarding the Stockholm, Minamata and Rotterdam conventions? What provisions regarding illegal trade currently exist?
    - Which types of chemicals are currently subject to monitoring/notification? Who has authority over each chemicals group and what are their powers, nationally and locally?
    - Who controls compliance with regulations?
    - Are there bilateral or regional cooperation agreements in relation to chemicals ?
    - Are there regulations that establish a regulatory impact assessment/analysis process? What steps should be taken once a normative project has been generated?
    - What are the existing cost recovery mechanisms for the implementation of chemicals management schemes?
- How is the management of chemicals coordinated between the different authorities? How is the flow of information between local and national governments? How is confidential information handled?
- Is there information available -commercial, statistical, regulatory or other characteristics- about industrial chemicals in the country? How is it collected? Who has it?
- How is information on chemical safety communicated to the population? What data is publicly accessible?
- How is the local market characterized (mostly import/production/mixed)? What is the profile of the companies that comprise it? What proportion is represented by industry associations?
- What is the participation of the industrial sector in the management of chemicals? And of the academy and social organizations? How does the government coordinate activities with each sector? Are there instances of public consultation during the development of a regulation?
- What human, administrative, technological and financial resources are available at the national level[55] related to the management of chemicals?

[53] Consider, to the extent possible, both environmental regulations and other non-tariff measures on the chemical sector.

[54] Character of the measure (voluntary, mandatory); regulated domains (e.g. labour, consumer products, agricultural sector); stage in the implementation (some schemes do it progressively); regulated items (e.g., label, safety data sheet); evaluation of national adaptations (e.g., implementation of modules); degree of compliance, control and supervision.

[55] For this analysis, consider the resources of all the sectors involved: government, industry, academia.

ANNEX 2. RECOMMENDED DEFINITIONS TO BE INCLUDED IN THE REGULATION

Term	Definition
Additive	Compound that has been intentionally added during the manufacturing process to stabilise the substance. *Source: ECHA-term*
Alloy	A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. *Source: ECHA-term*
Article	a manufactured object formed to a specific shape or design relevant to its function. An article undergoes no change of chemical composition or form during its use, other than that which is incidental to its use, that which is an intrinsic part of its use, or that which has no commercial purpose separate from that of the article. *Source OECD: ENV/JM/MONO(2007)13*
By-product	Substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture. *Source: TSCA*
Chemical / Chemical product	Substance and/or mixture of substances with certain percentages or percentage ranges of the chemical. Note: The term product is sometimes used to refer to chemicals, mixtures and articles. *Source: IOMC toolbox*
Composition	Composition (chemical) means typical concentrations and concentration ranges (minimum and maximum values) for all known constituents of a given substance or mixture. NOTE: It must be considered that the concentration ranges are reasonable, that is, that they are not too wide and reflect reality. They must be consistent with the declared hazard classification (the classification must be valid when the maximum values of the indicated concentration ranges are considered). *Source: OECD and GHS (modified)*
Confidential Business Information	Information which concerns or relates to the trade secrets, processes, operations, style of works, or apparatus, or to the production, sales, shipments, purchases, transfers, identification of customers, inventories, or amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or other organization, or other information of commercial value, the disclosure of which is likely to have the effect of either impairing the [authority´s] ability to obtain such information as is necessary to perform its statutory functions, or causing substantial harm to the competitive position of the person, firm, partnership, corporation, or other organization from which the information was obtained, unless the [authority] is required by law to disclose such information. The term "confidential business information" includes "proprietary information. *Source: US: 19 CFR 201.6 - Confidential business information*
Constituent	Any single species present in a substance that can be characterised by its unique chemical identity. *Source: ECHA-term*
Exclusive	A natural or legal person established outside the country

Term	Definition
representative	who manufactures a substance on its own or in preparations, formulates a preparation or produces an article imported into the country, may by mutual agreement appoint a natural or legal person established in the country to fulfil, as his only representative, the obligations on importers regarding the notification of substances. The only representative shall also comply with all other obligations of importers under the regulation. The foreign country exporter must inform the importer(s) within the same supply chain of the appointment. These importers are regarded as downstream users for the purposes of the regulation. *Source: adapted from ECHA-term– Only representative*
fractionator	Any natural or legal person established in the jurisdiction that transfers chemicals from one container to another more suitable for sale. *Source: PLANT HEALTH COMMITTEE OF THE SOUTHERN CONE (COSAVE) (modified)*
Hazard	Inherent property of a chemical of causing adverse effects when an organism, system or (sub)population is exposed to it. *Source: IOMC toolbox*
Importer	Any natural or legal person established within the country who is responsible for import. *Source: adapted from ECHA-term*
Impurity	An impurity is an unintended constituent present in a substance as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present along with the final substance it was not intentionally added, nor does it enhance the commercial value of that substance. *Source: OECD: ENV/JM/MONO(2007)13*

Term	Definition
Incidental reaction products	Substances produced when a substance undergoes a chemical reaction that is consequent to the use to which the substance is put or that results from storage or from environmental factors. *Source: OECD: ENV/JM/MONO(2007)13*
Industrial Chemicals	Any chemicals that are NOT managed through legislations dedicated to specific uses, such as pharmaceuticals, pesticides, biocides, etc. *Source: Adaptation of OECD ENV/JM/MONO(2007)13*
Intermediate	A substance produced and consumed in the course of the manufacture of another substance. *Source: OECD: ENV/JM/MONO(2007)13*
Isolated intermediary	A substance that is manufactured for the purpose of being transformed into another substance in a subsequent step. *Source: ECHA-term*
Non-Isolated Intermediary	An intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture. *Source: ECHA-term*
Mixture	Mixture or a solution composed of two or more chemicals /substances in which they do not react. The term preparation is synonymous to mixture. *Source: IOMC toolbox*
Monomer	A substance which is capable of forming covalent bonds

Term	Definition
	with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process. *Source:* ECHA-term
Mono-constituent Substance	As a general rule, a substance, defined by its composition, in which one main constituent is present to at least 80% (w/w). *Source:* ECHA-term
Multi-Constituent Substance	As a general rule, a substance, defined by its composition, in which more than one main constituent is present in a concentration ≥ 10% (w/w) and < 80% (w/w). *The difference between mixture and multi-constituent substance is that a mixture is obtained by combining two or more substances without chemical reaction. A multi-constituent substance is the result of a chemical reaction. *Source:* ECHA-term
Polymer	A substance consisting of: 1) Molecules characterized by the sequence of one or more types of monomers units; 2) A simple weight majority of molecules containing at least three monomer units that are covalently bound to at least one other monomer unit or reactant; 3) Less than a simple weight majority of molecules of the same molecular weight; and 4) Molecules distributed over a range of molecular weights wherein differences in the molecular weights are primarily attributable to differences in the number of monomer units. *Source: OECD:* ENV/JM/MONO(2007)13
Producer	Any natural or legal person who makes or assembles an article within the country.

Term	Definition
	Source: adapted from ECHA-term
Sound management of chemicals (SMC)	Adoption of all possible measures to ensure that chemicals are handled in such a way that the environment and human health are protected against the harmful effects that may result from them throughout their life cycle. Note: Other possible terms for "sound" are "integrated" or "safe". *Source: adapted from Basel Convention.*
Substance	Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. *Source:* GHS
Substance for research and development	A substance that is undergoing systematic investigation or research, by means of experimentation or analysis, other than test marketing, the primary objective of which is: 1) to create or improve a product or process; or 2) to determine the technical viability or performance characteristics of a product or process; or 3) to evaluate a substance prior to its commercialization, which includes pilot plant trials, production trials other than marketing, in order to modify the technical specifications in response to the performance requirements of potential customers. *Source: OECD:* ENV/JM/MONO(2007)13
Substances occurring in nature	substances that are unprocessed, processed only by manual, gravitational, or mechanical means, or by dissolution in water, or by flotation, or by heating solely to remove water, or are extracted from air by any means, without chemical change in the substance.

Term	Definition
	Source: OECD: ENV/JM/MONO(2007)13
User	End user: Person or body using substances or preparations in an industrial or professional activity (e.g., not a consumer or distributor) who does not supply it further downstream. Downstream user: Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. Industrial user: End user using substances/preparations which do not remain in the product (e.g., is applied as a processing aid) in the context of an industrial process. *Source: ECHA-term*
UVCB	Substance of unknown or variable composition, complex reaction products or biological materials *Source: ECHA-term*
Waste	Substances or objects which are disposed of or are intended to be disposed of or are required to be disposed of by the provisions of national law. Source: Basel Convention

ANNEX 3. INTERNATIONAL CHEMICAL RISK MANAGEMENT SCHEMES

Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), European Union

In 2007, the European Union enacted the Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). Its creation was encouraged by the diversity and complexity of the pre-existing European regulations [56], deficiencies in the functioning of the internal market and a growing social concern on the subject. To ensure efficient management at a technical, scientific and administrative level, the European Chemicals Agency (ECHA) was created, the authority in charge of managing legislation and coordinating with national authorities.

European legislation considers that there is no "innocent" chemical substance in terms of its environmental danger and possible risks. It also applies to all industry sectors dealing with these products and to the entire supply chain. First of all, it orders the mandatory registration of all substances sold in more than one ton and categorizes them into five divisions, each with different information requirements, which accumulate as the amount of the chemical substance sold increases. In quantities greater than 1 ton per manufacturer or importer, a set of physicochemical properties must be included. In addition, a safety data sheet must be provided. For substances with production or import volumes greater than 10 tons/year/company, a Chemical Safety Report must be submitted for registration purposes, containing more detailed information on the type and quality of the effect data used in the classification and evaluation of substances. risks. A third report must also be prepared for substances that exceed 10 tons/year/company, which will remain in the possession of the company (it is not submitted to the registration evaluation agency) but must be available to the authority during sudden events or unexpected situations.

ECHA has an infrastructure and human resources of more than 500 people, however, it is a limited number given the large amount of information submitted by companies to assess the quality of the registration dossiers and clarify whether the substance in question represents a risk for human health or the environment.

Treatment of confidentiality[57]

Under Article 119, paragraphs 1 and 2 of the REACH Regulation, the European Chemicals Agency (ECHA) is obliged to publish on the Internet, free of charge, the information it has on registered substances (by themselves, in mixtures or in products). However, in some cases it is possible to prevent the publication of the information, provided that the registrant indicates that he wishes to keep it confidential, together with a reason why its publication could be detrimental to his commercial interests or those of other parties. If ECHA validates the justifications, the information they refer to will not be published. In cases requiring urgent action to protect human health, safety or the environment, such as emergency situations, the authority reserves the right to disclose information normally considered confidential.

Canadian Environmental Protection Act (CEPA), Canada[58]

For the management of substances, Canada has been another international pillar, with a scheme different from REACH, but which is

[56]It is important to clarify that at the time of the creation of REACH, the European Union already had an inventory of existing substances. Based on this information, it was decided to create three groups of substances to define the information requirements: 1. Substances in transitory phase; 2. Substances outside the transitory phase and 3. Substances in transitory phase that do not comply with certain dangerous characteristics.

[57]More information available at: https://echa.europa.eu/documents/10162/22308542/manual_dissemination_es.pdf/ae6a9a88-126c-475b-904a-ee61f2a91775

[58]More information at: https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/substances-list.html

essentially guided by the principles of prevention and protection of health and the environment. Although the Canadian Environmental Protection Act was enacted in 1988, the legal framework on the subject was strongly strengthened at the beginning of the year 2000, when it was updated.

Under the different CEPA concepts, understanding and risk reduction must be done for both new and existing substances. In this context, an existing substance is one that is being or has been used in Canada as a commercial substance or product, or has been released into the Canadian environment, either as a single substance, in effluent, mixture, or as pollutant. The Domestic Substances List (DSL) is a list of those substances that between January 1, 1984 and December 31, 1986 were in commerce in Canada, either manufactured or imported in a quantity of 100 kilograms or more per year. While a new substance is one that is simply not on the DSL. CEPA required that all substances in the DSL that had not been subject to evaluation, such as new substances, be classified within seven years from the publication of the Royal Penalty Law, which took place on September 14 1999. Classification was completed on September 14, 2006. Critical to understanding CEPA is understanding the categorization process, which involves identifying substances on the DSL that should be subjected to an even more detailed risk assessment than previous. This includes substances that are inherently toxic, persistent or bioaccumulative; or that represent the greatest exposure potential for individuals.

In the case of new substances, there is a special program in Canada, which is responsible for administering the regulations on the notification of new substances (chemicals, polymers and biotechnology products). When Environment Canada receives a notification from a company or person proposing to import or manufacture a new substance, it conducts a joint assessment with the Ministry of Health to determine if the substance has the potential to cause adverse effects in the environment. environment and human health. This evaluation requires that specific administrative and technical data be provided prior to its manufacture or importation.

Treatment of confidentiality

Under CEPA, any information provided to the Minister of Environment and Climate Change can be claimed as confidential. For example, CEPA allows confidential substances to be published on the DSL with a masked name and a confidential substance identity number, also known as a confidential access number (CAN), assigned by authorities. Confidentiality requests may only be based on any of the following reasons: (a) the information constitutes a trade secret; (b) disclosure of the information would likely cause a material financial loss or detriment to the competitive position of the person providing the information or on whose behalf it is provided; and (c) disclosure of the information would likely interfere with contractual or other negotiations being conducted by the person providing the information or on whose behalf it is provided.

Toxic Substances Control Act (TSCA), United States

The United States Toxic Substances Control Act (TSCA) was enacted in 1976 to ensure that chemicals present in U.S. commerce do not pose an unacceptable risk to human health and the environment. the Environmental Protection Agency (EPA) is responsible for its implementation.

Substances listed on the inventory are considered to be existing chemicals in commerce in the United States, therefore those that are not listed are considered new. In this case, the manufacturer or importer is required to submit a Pre-manufacturing Notification 90 days before the substance is manufactured, accompanied by the results of the tests stipulated in section 4 of the TSCA, which requires manufacturers and distributors of chemicals testing and collecting data on product hazards. Once the review of the Pre-manufacturing Notification has been completed, the company must submit a "Notice of Start of Manufacturing or Importation" to the EPA within 30 calendar days of the date the substance is manufactured or are imported for commercial purposes. Upon receipt of this notice by EPA, a substance is considered to be on the inventory. EPA receives between 500 and 1,000 such notices each year, so the TSCA inventory changes daily.

TSCA also contains various reporting and recordkeeping requirements. Certain producers, importers, or processors are required to provide specific information related to the production, processing, waste treatment, and exposure of a long list of chemicals under a standardized system known as the Comprehensive Assessment Information Standard. In addition, it requires a one-time report on the production, use, and exposure of listed chemicals.

In 2016, the regulations were updated through the *Frank R. Lautenberg Chemical Safety for the 21st Century Act* , which, in addition to delegating to the EPA the designation of two groups of existing substances on the TSCA Inventory: "active" and "inactive". According to its commercial situation in the United States, it introduced -among others- the following changes [59]:

Existing Substances (on the TSCA Inventory)

- EPA must establish a risk-based process for determining high or low priority substances. Those of low priority will not require further action but could be reclassified based on new information. Those of high priority (that is, those that may present an "unreasonable risk" for health, or the environment based on the hazards and route of exposure) will be evaluated by the Agency within previously established periods (in the first 180 days 10 evaluations of risk, and in 3.5 years, 20).
- The evaluations will be based on new security standards, which exclude the consideration of costs and other factors not related to risk. They must consider vulnerable and highly exposed populations. For its realization, greater authority is granted to EPA to request additional information. In the case of persistent, potentially bioaccumulative or toxic substances, the process is faster and risk assessment is not necessary (only use and exposure).
- Upon determining unreasonable risks, EPA must take management action within 2 years (up to 4, if necessary). Costs and availability of alternatives will be considered in determining management actions (including prohibitions and restrictions).

New Substances: EPA must affirm the safety of a new substance or new use before it is placed on the market.

Management of Confidential Information: Establishes new requirements for certain confidentiality requests and states that EPA must review old confidentiality requests on the identity of the substance to determine its current validity.

System maintenance: EPA will support its new responsibilities through fees applied for data review, Pre-manufacturing order, Notification of new use, development of risk assessment.

Relationship between federal and local government : Allows the States to act on particular uses or substances that the EPA has not analysed and preserves the autonomy of the States over air, water, waste treatment and disposal. It allows the co-management of identical regulations between States and the federal government.

Health and safety information

Under TSCA, EPA collects a variety of information, including health and safety studies on chemicals, and in some cases the law allows some of it to be declared confidential. Health and safety studies, health and safety study information, and certain other information may not be protected under TSCA. However, section 14(b) of the act prevents EPA from disclosing "information that discloses the processes used in the manufacture or processing of a chemical or mixture or, in the case of a mixture, the portion of the mixture that comprises any of the chemicals in the mixture."

[59]Additional information available at: https://www.epa.gov/tsca-inventory/tsca-inventory-notification-active-inactive-rule and https://www.epa.gov/assessing-and-managing-chemicals-under -tsca/highlights-key-provisions-frank-r-lautenberg-chemical

EPA uses the chemical information it has received under TSCA to conduct activities such as prioritizing chemicals for review, conducting risk assessments, and taking risk management actions as necessary. Information collected under TSCA is also used by a variety of entities, both inside and outside of government, for public health and environmental protection purposes.

Australian Introduction of Industrial Chemicals Scheme (AICIS –former NICNAS-), Australia

In Australia, chemicals are regulated by both local and national laws. At the national level, they are regulated according to their use. For their part, local authorities regulate and enforce the use, storage and disposal of appropriate chemicals.

There are 4 main authorities for chemicals, each focusing on a particular type of use: 1. Industrial (such as paints, adhesives, inks, plastics, glues, solvents, soaps, and cosmetic ingredients); 2. Agricultural and veterinary chemicals; 3. Therapeutic Products, drugs and products marketed with therapeutic effects; 4. Food ingredients and food additives for human consumption.

The Industrial Chemicals Act 2019 establishes the Australian Industrial Chemicals Introduction Scheme (AICIS) to regulate the import and manufacture (introduction) of industrial chemicals into Australia. AICIS replaced the National Industrial Chemicals Assessment and Notification Scheme (NICNAS) on July 1, 2020.

Under this regulation, chemicals (including polymers) introduced for industrial use are regulated, such as in inks, paints, adhesives, solvents, cosmetics and personal care products, cleaning products, as well as in manufacturing, construction and mining applications. . Australia defines industrial use by exclusion [60].

The competent authority assesses the risks of industrial chemicals to human health and the environment through the scientific interpretation of information on chemicals provided by industry (or obtained from other sources) in the context of the intended use of the chemical. In addition, among others, it has the following responsibilities:

- Maintain the Australian Inventory of Industrial Chemicals (the Inventory);
- Issue certificates and authorizations for the introduction of industrial chemicals in Australia;
- Make risk management recommendations to protect human health and the environment for consideration by other Australian state, territory or government agencies under their laws, regulations and standards;
- Establish and maintain the Guidelines for the categorization of industrial chemicals;
- Maintain the Registry of Introducers of Industrial Chemicals.

The categories assigned to chemicals under the Australian system are:

- Lower risk (exempt and reported presentations) can be made without being evaluated. However, record keeping and reporting obligations apply.
- Medium to high risk: they require an evaluation certificate issued by the Competent Authority and must comply with the terms of the certificate. These are listed on the Australian Inventory of Industrial Chemicals after 5 years. Any registered person can market an industrial chemical substance from the Inventory, and must comply with the requirements established therein.

[60]Where a chemical has multiple types of uses, in Australia the regulations of each responsible regulator must be followed in Australia for each use.

cost recovery

The full cost of administering AICIS is recovered through fees and charges paid by importers and manufacturers (introducers) of industrial chemicals.

Treatment of confidential information

Under AICIS, you can request to have the following types of information protected as CBI:

- The identity of the chemical
- Details of chemical introduction (e.g., exact function of a chemical in a product (use), exact concentrations, exact volumes of introduction, customers)

The Australian Government uses legal criteria to decide on applications for CBI protection. If they grant the protection, they do not publish certain commercially sensitive information. In order for the confidentiality request to be successful, the registrant must be able to demonstrate to us that: 1) It has a business interest, and it is reasonable to expect that by posting certain information, its business interests could be substantially harmed; 2) This commercial bias outweighs the public interest in having access to this information. Detailed information on how to test these two conditions is described on the official website of the country.[61]

Substances Management System, Philippines

The Philippine System for the management of substances is framed in Regulation RA 6969. It is made up of the following control elements:

The Philippine Inventory of Substances and Chemicals (PICCS)

It is a list of all new and existing chemicals that are used, imported, distributed, processed, manufactured, stored, exported, treated, or transported in the Philippines. The first PICCS was published in 1995, and subsequent PICCS updates were published in 2000, 2002, 2005, 2008, 2011, 2013, 2015, 2017, and 2020. The inventory contains the following information: Chemical Name and CAS, Part No. unique identification assigned to a particular chemical or chemical substance, CAS name and common name -if different from the CAS name-. Its purpose is to provide government, industry, and the public with a basic inventory of all chemicals and substances in the country. Chemicals and non-PICCS chemicals cannot be manufactured or imported unless the proponent follows an evaluation process.

Prefabrication and Pre-Import Notification (PMPIN)

Manufacturers and importers (proposers) of a new chemical or chemical substance must notify the authority of their intention to manufacture or import between 180 days before and 90 days after. Along with this notification, the proponent submits the corresponding PMPIN forms. A new chemical is defined as any chemical that is not listed on the PICCS. The PMPIN assessment process aims to screen for harmful substances before they enter Philippine commerce and, where appropriate, prevent the manufacture or importation into the country of new chemicals that pose an unreasonable risk to human health and the environment. , or control and/or restrict them to limit possible emissions. There are two types of PMPIN forms for notification. One, in short form, is used when a new chemical or chemical is being used in a country with a review process developed and/or similar to that of the Philippines. The notifier must submit sufficient information to clearly demonstrate that the chemical/chemical does not pose an unreasonable risk. The detailed form, on the other hand, is used when the new chemical substance that is manufactured or imported is not yet included

[61] https://www.industrialchemicals.gov.au/business/apply-confidentiality-data-and-information/statutory-test

in the list of any country, or when the authority determines that the information sent for the new chemical substance does not contain sufficient documentation.

Once the competent authority has evaluated and approved a new chemical for import and manufacture, it grants the notifier an authorization to import and manufacture. The registrant must submit a Notice of Commencement of Import or Manufacture form, along with the requirements set forth in the form. Once the form is submitted, the new chemical is added to the PICCS.

Treatment of confidentiality

Chemicals can be added to the public version of PICCS or to the confidential version. This is dependent on the filing of a Confidentiality Notice by the producer/importer.

ANNEX 4. EXISTING CHEMICAL INVENTORIES WORLDWIDE AND THEIR MAIN CHARACTERISTICS

It is recalled that this list is not exhaustive and is subject to revision. This list has been prepared based on the work of Zhanyun Wang et al. (2020), "Toward a Global Understanding of Chemical Pollution: A First Comprehensive Analysis of National and Regional Chemical Inventories. Environmental Science & Technology" 54 (5), 2575-2584. DOI: 10.1021/acs.est.9b06379.

Region and Country	Name of the Chemicals Risk Management Scheme	Scope	Threshold for reporting	Exceptions	Basic information required	Entity responsible for risk assessment	Associated fees/taxes
Asian/Chinese	**Inventory of Existing Chemical Substances Produced or Imported in China (IECSC)** Access	Substances produced or imported	≥1 ton per year (after 5 years of producing/importing)	Medicines for human or veterinary use, pesticides, cosmetics, food, food additives and feed	Identification numbers (CAS or other); Chemical name; Additional information on the molecular formula for certain substances	Industry	1) Administrative: They do not exist, only to check if a new substance category applies or not, 2) Analysis: the assessment must be carried out in certified laboratories 3) Management (in the case of exclusive representatives) Source: https://chemical.chemlinked.com/chempedia/china-reach
Asia /Taiwan	**Taiwan Chemical Substance Inventory (TCSI)** Access	Substances produced or imported (1993-2014)	≥0.1 ton per year (basic information)	Substances that exist in nature, substances in testing equipment, intermediates that cannot be isolated, substances for national security or defence, substances under customs supervision, residues of industrial processes, by-products or non-commercial impurities, mixtures as such, articles, polymers that comply with the 2% rule (according to the OECD definition). For new substances, the following are not included: pesticides, food and food additives, fertilizers, veterinary and human medicines, regulated drugs, cosmetics, feed, food containers, tobacco, alcohol, radioactive materials, industrial explosives, substances under the Montreal Protocol , environmental agents, and toxic substances determined by regulation.	Low volume: Identification numbers (CAS or other); use. Simplified: +SGA classification, uses, physicochemical properties Standard: + Toxicological information, ecotoxicological information, Hazard and exposure assessment (≥10 tons per year)	Industry	There are fees for all administrative steps: permits, registrations, approvals, application requests. Source: https://oaout.epa.gov.tw/law/EngLawContent.aspx?lan=E&id=261&kwStr =
Asia /Japan	**List of existing and new chemical substances under the Chemical Substance Control Law (CSCL)** Access	Substances produced or imported	≥1 ton per year (by approval)	Reagents for research or analysis; low concern polymers; Specific substances determined by the authority: Intermediaries, used in closed processes or subject to export only.	Identification numbers (CAS or other); Chemical name	Industry and Government	Permit fees: for production of class 1 substances, change of substance information, import of class 1 substances. Source: http://www.japaneselawtranslation.go.jp/law/detail/?id=3350&vm=02&re=01

Asia /Philippines	**Philippine Inventory of Chemicals and Substances (PICCS)** Access	All existing, used, imported, distributed, processed, produced, stored, exported, handled and transported substances	≥1 ton per year (case of substances for research and analysis)	Substances existing in nature, mixtures, radioactive substances, pesticides, drugs, food and consumer products regulated by other regulations, by-products, substances produced or distributed (not imported) for testing and research in quantities less than 1 ton	Identification numbers (CAS or other); Chemical name	Government	There are fees for all administrative instances: Notification (abbreviated or complete), Renewal of registration, import, etc. Some are by company (e.g., notification), and others by chemical (e.g. import request). Source: https://chemical.emb.gov.ph/wp-content/uploads/2017/03/DAO-2016-28-Payment.pdf
Asia / Republic of Korea	**Korea Existing Chemicals Inventory (KECI)** Access		≥0.1 ton per year (for new substances as of 2020)	Chemical substance contained in an imported machine; chemical substance contained in a product that performs a certain function in a specific solid form, which is not leachable in the process of using the product; Publicly Notified Designated Very Low Risk Chemical; chemical manufactured or imported exclusively for export.	Identification numbers (CAS or other); Chemical name; Additional information (such as regulatory status in the country)	Industry (≥10 tons per year) and Government	Fees for registration, notification, approval, confirmation of exemption. Source : https://www.kcma.or.kr/eng/sub4/4_1.asp
Asia/Thailand	**Thailand existing Chemicals Inventory (TECI)** and **Hazardous substance List – (In 2021 they are developing a Substances Regulation to replace the existing one)** Access	Hazardous substances: 1. Low hazard. Notification required for +1 annual ton. 2. With registration, control and monitoring requirements. 3. High risk: registration and authorization required 4. Very risky, prohibited	≥1 ton per year	The list of dangerous substances includes: (1) explosives; (2) flammable substances; (3) oxidizing agents and peroxides; (4) toxic substances; (5) infectious substances; (6) radioactive substances; (7) mutagens; (8) corrosive substances; (9) irritating substances; (10) other substances, whether chemical or not, that may be harmful to people, animals, plants, property or the environment.	Identification numbers (CAS or other); Chemical name; Additional information (such as regulatory status in the country, customs code, volume)	Government (existing) and industry	Fees for registration, production permit, import and export, renewal and changes in permits. Source: https://www.chemsafetypro.com/Topics/Thailand/Thailand_Hazardous_Substance_Act_BE_2535.pdf
Asian / Vietnam	**National Chemical Inventory (NCI)** Access	Substances notified to the Substances Agency, (from different regulations and foreign inventories, databases)		Chemicals that are manufactured or imported in the service of national defence and security, responding to natural disasters and emergency epidemics; drug precursors, explosive precursors, industrial explosives and those authorized for their production or importation; imported less than 10 kg; raw materials for the production of medicines; raw materials for the production of phytosanitary drugs;	Identification numbers (CAS or other); Chemical name; Additional information (such as regulatory status in the country)	Industry	Fees for registration request, marketing permits, extension or amendment of certificates. Source: https://www.chemsafetypro.com/Topics/Vietnam/vietnam-chemical-law.pdf
Asia/Malaysia	**Chemical Information Management System (CIMS)** Access	Dangerous substances imported or commercialized (dangerous according to the classification of the Code of Industrial Conduct)	≥1 ton per year	Radioactive material, waste, cosmetics, pharmaceuticals, pesticides, chemicals for research and development (less than 5 kg); substances in transit for export, articles that do not contain substances that can be released	Identification numbers (CAS or other); chemical name ; amounts	.	There are no fees for loading into inventory. Source: https://www.dosh.gov.my/index.php/list-of-documents/osh-info/chemical-management-1/3694-faq-cims/file

Asian/Indian	**Inventory of Hazardous Chemicals Import in India (ICHCI) – In 2021 they are working on a new regulation.** Access	Hazardous chemicals that are imported	≥1 ton per year	Radioactive substances; Substances under customs supervision, which are not placed in Indian Territory; Substances stored in customs free zones with the aim of re-exporting; Waste, as defined in the Hazardous Waste Management Rules of 2016; Substances used for defence purposes; Substances used as human or animal food, including human or animal nutrition; Specific substances, established in Annex IV.	Chemical names; imported quantity	Industry and Government	Notification fees are adjusted to tons produced/imported. There are also joint notification fees. Source : https://indianchemicalregulation.com/icmsr/feespenalty/ _ _ _ _
Central America / Mexico	**National Inventory of Substances of Mexico (INSQ)** Access	individual substances		Mixtures, minerals, inks, packaging material, generic names	Identification numbers (CAS or other); Chemical name; quantities; molecular formula; TSCA listing; chemical group; quantities produced/imported; ecotoxicological data; persistence in the environment; bioaccumulation; Alternative or previous CAS	Does not apply	Does not apply
Europe / European Union	**registered substances** Access	Substances produced or imported	≥1 ton per year	Non-isolated intermediates, substances used in medicines for humans or for veterinary use, among others.	Identification numbers (CAS or other); Chemical name; additional information according to the type of registration, total quantity, production, use, dangerousness, etc.	Industry	Registration fees apply. There are possibilities of reduced rates for small and medium-sized companies. Source: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02008R0340-20150625
Europe / Switzerland	**List of new substances notified or registered in Switzerland (NSNRS)** Access	New substances (substances not listed in EINECS)	≥1 ton per year	Substances in transit, medicines, feed, weapons, waste; polymers (2% rule); substances not listed on the NPL list; new substances with volume less than 1t/y; substances for research and development; substances used exclusively as active ingredients or additives in food, therapeutic products and animal feed; Substances used exclusively as active ingredient in for agrochemicals and biocides; substances purchased in Switzerland; intermediates, if they are not monomers; substances in annex V of REACH (by-products, substances present in nature, impurities, etc.); substances for PPORD purposes (**)	Identification numbers (CAS or other); Chemical name	Industry	Substance notification fees apply, which vary according to the quantity produced/imported. Source: https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/wegleitung-anmeldungen-meldungen-mitteilungen-neuer-stoffe-chemv-schweiz.pdf.download.pdf/Wegleitung_NS_EN.pdf
Europe /Turkey	**Former Turkish Chemical Substance Inventory (TCSI)** Access	Substances produced or imported under the former ICRC, and substances produced or imported in quantities	≥1 ton per year	radioactive substances, substances subject to customs control, substances for use in national defence, waste, non-isolated intermediates, transport of dangerous substances by rail, road, inland waterways, sea or air. food or feed, medicines, substances included in annex IV, substances included in annex V, registered substances from the recovery process, registered	Identification numbers (CAS or other); Chemical name	Industry	Pending for approval. Registration fees will be established according to the range of tons produced/imported. Source: https://www.crad.com.tr/eng/1755/TURKISH%20KKDIK%200FFICIAL%20FEE

		greater than or equal to 1 ton per year		substances that are re-imported, polymers (monomers and other reagents must be registered).			S%20ANNOUNCED%20AS%20A%20DRAFT/#.YVIto7hKjlU
Europe/Asia/Russia	**Russian Register of Potentially Hazardous Chemicals and Biological Substances (RPOHV)** Access	Individual substances and biological compounds produced and/or imported, including those used as ingredients in products; by-products		State registration is subject to: for the first time introduced into production and previously unused chemical, biological substances and preparations made from them (hereinafter referred to as substances), potentially dangerous to humans; certain types of products that pose a potential danger to humans; certain types of products, including food products, imported into the territory of the Russian Federation for the first time.	Identification numbers (CAS or other); Chemical name in Russian; molecular formula; registrant information	Government	Does not apply
North America/ Canada	**Domestic Substances List (DSL)** Access	Substances produced, imported or used. Includes polymers, organisms, and enzymes		Pesticides, food packaging, cosmetics	Identification numbers (CAS or other); Chemical name; additional information such as regulatory status in Canada	Government	There are fees for notification of new substances, according to the annual sales of the companies. Source: https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/notifications/new-substances-notification-fees.html
North America/ United States	**Toxic Substances Control Act (TSCA) Chemical Substance Inventory** Access	Substances produced, processed or imported that do not qualify as excluded by TSCA. Includes organic, inorganic substances, polymers and UVCBs		Pesticides, food and food additives, drugs, cosmetics, tobacco and tobacco products, nuclear materials, ammunition. Low volume exceptions, low level releases/exposures, test kit, research and development, polymers that comply with the 1995 polymer exception rule	Identification numbers (CAS or other); Chemical name; additional information such as UVCB, regulatory status, commercial status (active/non-active)	Government	Fees apply for notification, tests, risk analysis, among others. There is the possibility of reducing rates due to the size of the company. Also, multiple entities can be associated for the payment of fees. Font: https://www.epa.gov/tsca-fees
Oceania / Australia	**Australian Inventory of Chemical Substances (AICS)** Access	Substances available for industrial use		Substance in small quantities (≤100 kg/year) for research, development, analysis or for non-cosmetic use. Used in cosmetics with a concentration of less than 1%	Identification numbers (CAS or other); Chemical name; additional information such as molecular formula, notification condition, conditions of use	Industry	For registration, rates apply according to earnings. Fees are also applied for production permits, analysis, among others. Source : https://www.industrialchemicals.gov.au/fees
Oceania/ New Zealand	**New Zealand Inventory of Chemicals (NZIoC)** Access	Hazardous substances produced and/or imported		impurities and by-products. Articles containing a dangerous substance (Other than explosives)	Identification numbers (CAS or other); Chemical name; approval status	Government	There are no fees associated with the notification of new chemicals for the NZIoC . Source: https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/New-Zealand-Inventory-of-Chemicals-NZIoC-Guidance.pdf

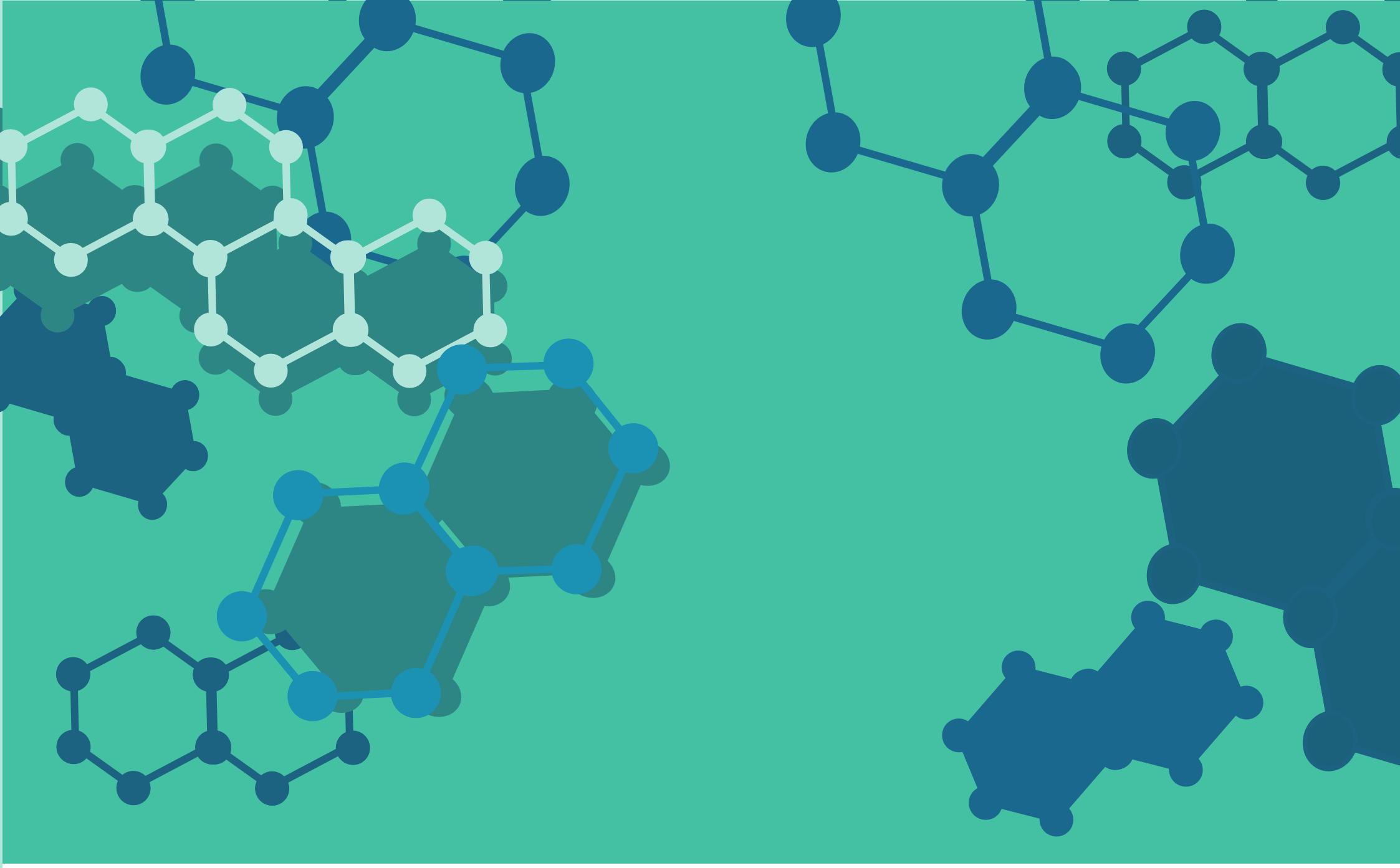
South America /Chile	**Substance Notification System** Access	Hazardous substances produced and/or imported	≥1 ton per year	nuclear substances. Pharmaceutical products (except raw materials). Pharmaceutical products for veterinary use (except for additives and raw materials used for their manufacture or preparation). Foodstuffs for human consumption (except for food additives and raw materials used for the manufacture or preparation of food products. Foodstuffs for animal consumption (except for additives and raw materials used for its manufacture or preparation. Cosmetic products. Pesticide residues in food. Hazardous waste. Articles containing dangerous substances or mixtures, except explosive articles. Substances and mixtures subject to customs supervision, provided that they are not subject to of any type of treatment or transformation, and that are kept in temporary storage in order to be exported or in transit Substances and mixtures intended for research and scientific development, not commercialized, provided that they are used under controlled conditions in accordance with the Normative in force. Non-isolated intermediates. Medical devices. Minerals of natural origin, whose composition has not undergone chemical modifications, extracted mechanically and that are transported directly to where they will be processed, provided that their extraction does not exceed 5,000 Dry Metric Tons of mineral per month. Fertilizers.	Data of the notifier and legal representative; Identity of the substance(s) (IUPAC nomenclature name(s) or other name(s); CAS number; hazard classification of the substance; Amount of the substance manufactured or imported per year, expressed in mass ranges; Intended uses. Substances contained in mixtures: use of the mixture; safety data sheet of the substance in case of substances as such.)	Government	Not reported in the standard.

ACKNOWLEDGMENT

This document was made possible thanks to the participation of members and observers of the VWG-SMC-LA.

We also thank all those who have participated in the VWG-SMC-LA meetings as observers and have greatly contributed to the discussions that led to the development of this document.

Finally, we thank the Latin American Regulatory Cooperation Forum (LARCF) and the support of the International Council of Chemical Associations (ICCA).



LARCF
Foro de Cooperación Regulatoria
de América Latina