INTERGOVERNMENTAL NETWORK ON CHEMICALS AND WASTE FOR LATIN AMERICA AND THE CARIBBEAN

Prioritization and Risk Assessment of Industrial Chemicals in Latin America and the Caribbean: Status of Trends and Regulatory and Institutional Frameworks

Technical Report Number 4 of the Intergovernmental Network of Chemicals and Waste for Latin America and the Caribbean

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EXECUTIVE SUMMARY

The United Nations Environment Programme (UNEP) is implementing the initiative **"Strengthening capacities and Regulatory Framework for the Sound Management of Chemicals and Waste in Latin American and Caribbean countries (LAC)"** with the support of the Swedish Chemicals Agency (KEMI), and through the Basel Convention Coordinating Centre - Stockholm Convention Regional Centre for Latin America and the Caribbean (BCCC-SCRC), headquartered in Uruguay. This initiative, in accordance with the priorities set forth in the **Work Programme 2021-2022** of the Intergovernmental Network of Chemicals and Waste for Latin America and the Caribbean (hereinafter referred to as "the Network"), seeks, among other goals, to create and share knowledge to support the decision-making on the regional management of chemicals and waste.

One of the main scopes of institutional strengthening defined by the Network is related to the **risk assessment of chemicals.** In this context, this report has the following objectives:

- Reviewing the regulatory frameworks, the institutional approaches and the practices related to the prioritization and risk assessment of industrial chemicals [1] in the countries of the LAC region where the identification of stakeholders and key actors are included;
- Identifying gaps and needs for the creation and strengthening of capacities based on global experience, starting with the analysis of elements in common;
- Designing the implementation of a regional training, taking into account the capacities gaps regarding the prioritization and risks assessment and the current initiatives.

Initially, for the preparation of this report, surveys and meetings were conducted with the governmental focal points of the Network and other relevant actors in order to outline the key actors and regulatory achievements, institutional arrangements and practices in place regarding the prioritization and risk assessment of industrial chemicals. Likewise, some cases were studied in countries that have since moved forward on this issue: Argentina, Brazil, Chile, Colombia, Costa Rica, and the Dominican Republic. Finally, the situation of the region was contrasted with those baseline countries and organizations to identify the region's best practices and applicable lessons.

Firstly, the report highlights that prioritization and risk assessment of industrial chemicals are usually included as the key elements of the general regulatory framework which involves other stages, such as the creation of inventories and registries, and risk management (Figure 1RE).

[1] This report focuses on industrial chemicals which are deemed herein as all those chemicals produced and/or traded in relevant quantities (greater than 100 kg per year) that are not regulated by specific standards (e.g., acitve ingredients in pesticides and pharmaceutical products, waste and natural chemical substances, among other substances regulated by specific standards). Source: UNEP, 2021 (adapted by the OECD).

Generation of basic information on industrial chemicals
Inventories Notification
(+ harmonized classification and labelling)

Prioritization in case additional information is needed
Prioritization

Generation of additional information
Risk Assessment

Decisions on industrial chemicals
Risk Management

While in other regions of the world, the regulation of industrial chemical risk under the described framework dates back several decades, LAC is still in its early stages of development. In accordance with the information obtained during the writing of this report, among the countries of the region, different levels of advancement can be identified (see Figure 2RE). These have been classified as: lack of advancements informed or identified (as per cited works), planning in progress (the country has a general legal framework that foresees the creation of specific industrial chemicals instruments), under development (current efforts are found such as drafts and/or agreed project of legal instruments, working plans of the intergovernmental committees, cross-sectors meetings, among others) and partial regulation (the country approved a regulation instrument for industrial chemicals, but its full regulation is pending). The greatest advances are identified in those countries that are members of the Organization for Economic Co-operation and Development (OECD), acknowledging the management of chemicals as the bedrock of their decisions and recommendations, or in those that have shown interest in becoming members.

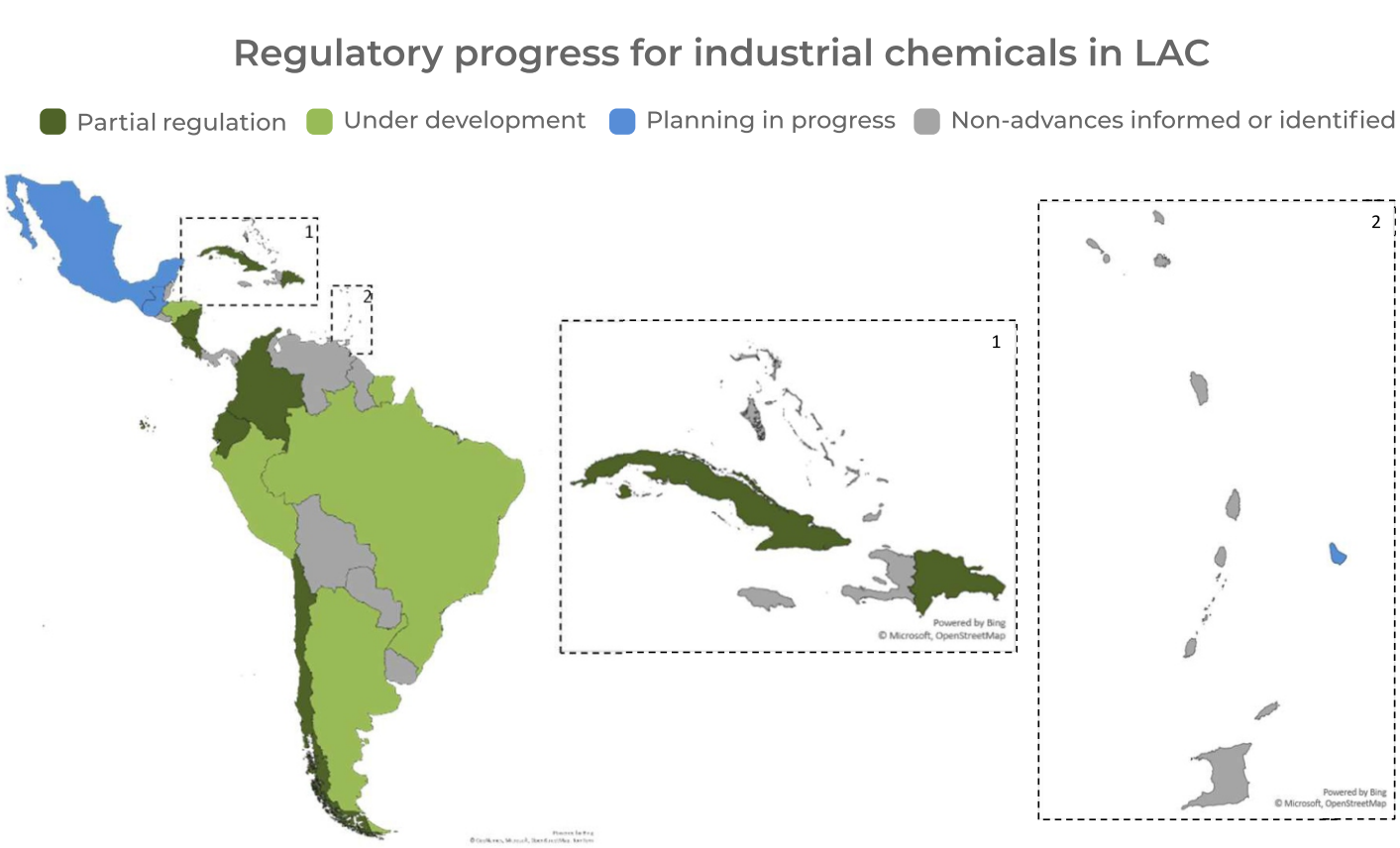

Figure 2RE. Scenario map regarding the regulatory frameworks of industrial chemicals in LAC. Source: Own compilation based on surveys and interviews with focal points of the Network. [2]

[2] The boundaries, names and designations appearing in the maps of this report do not imply official endorsement or acceptance by the United Nations.

As shown in Figure 2RE, the risk management of industrial chemicals is not fully regulated to date within the region, and, therefore, not implemented. In countries where specific regulatory frameworks for these types of substances certainly do exist (Chile, Colombia y Costa Rica),[3] these are high-level standards that outline the main aspects of the systems to be implemented and describe the status of the creation of inventories and registries. In all these cases, the standards show the need for secondary regulations (for instance, technical regulations) about the subsequent stages, i.e., prioritization, risk assessment and risk management. Delegates of the aforementioned nations have reported that drafts of the proposed regulations are not yet available, but are currently under development. In summary, no countries in the region have been recognized as possessing regulated frameworks or methodologies for the prioritization or performance of risk assessments.

In this report, the regional scenario is presented and contrasted with the institutional strengthening experiences of Canada, the United States of America, the European Union (EU) and the countries suggested by the OECD in order to analyze the regional institutional strengthening requirements.

In accordance with the findings, the following gaps in capacity and need for strengthening of LAC countries in the prioritization and risk assessment of industrial chemicals have been identified:

1. **The limited general understanding of the management of industrial chemicals makes its regulation difficult.** Only five countries of LAC are identified to have regulations that include the risks management of industrial chemicals.[4] However, those who have accomplished this have only set forth general frameworks that need secondary regulations in order to become totally operative.

    - **Training opportunity:** It would be appropriate to provide training on general concepts for the management of industrial chemicals and its regulation, not only seeking a common bedrock of knowledge, but also encouraging the exchange of experiences with those countries of the region that have moved forward in their regulatory frameworks.

2. **The technical complexity that implies the development of detailed or secondary regulations significantly delays the times of implementation.** Given that all the secondary regulations of the region are in progress, there is a need for developing capacities when designing the instruments of technical character about the stages of prioritization and risk assessment. There is also a need for analyzing the impacts that the said legal requisite could entail in the public and private sectors.

    - **Training opportunity:** It seems appropriate to provide training on basic concepts of environmental chemistry, toxicology and eco-toxicology, alternatives for prioritization schemes and methodologies for risk assessments, as well as their advantages and disadvantages and application cases in other regions. For those countries that have still not defined their regulatory frameworks, it would be essential for them to understand the resource burden that implies both the performance and the review of risk assessments in order to measure their needs and, therefore, choose the most appropriate regulatory strategy.

[3] It should be highlighted that presently, only the Program of Industrial Chemical Products Management is known for Costa Rica. According to the survey, the legislation is under legal review for each of the institutions. **MORE INFORMATION.**

[4] These are: Chile, Colombia, Costa Rica, Cuba and the Dominican Republic. Only the first two have drawn up regulations that include all the stages of the management of industrial chemicals suggested in the Figure 1RE.

3. **Lack of knowledge of the tools available to gather and create data on chemical substances, safety reports or risk assessments.** Most of the interviewees admitted that the tools available, either developed by organizations such as the OECD, or by governments such as the United States of America and the European Union (EU), are not well-known within the region. Similarly, it is unclear to governments how information is used in their respective countries, what happens with the intellectual property, and what alternatives of international cooperation exist to enable information exchange. Thirdly, it has been determined that there is a lack of information regarding the regional sources of data pertaining to local conditions when it comes to the usage of industrial chemicals.

    - **Training capacity:** It is recommended that countries are informed about the use of data and computing tools available that would facilitate their procedures and prevent them from additional investments in personnel and financial resources. Moreover, the use of current knowledge and the deployment of new data generation processes cut costs and animal testing.

4. **Limited knowledge of the main difficulties when gathering and managing data and the quality principles.** In the prioritization and risk assessment processes, there is frequently insufficient data or data from disparate sources that have not been harmonized. Countries that are currently in the stage of developing secondary regulations admit that choosing the adequate strategy to handle these types of situations implies an extremely technical complexity.

    - **Training opportunity:** It is essential to train countries about the information and data requisites needed in the different stages of the industrial chemicals management process, and how complex the information collection becomes. Additionally, as the information collection may generate discrepancies, there is a need for instruction on various approaches to discuss these situations and the fundamentals of data reviewing (i.e. the burden of evidence).

5. **The need for identifying the profiles and skills needed to educate the public sector personnel who are dedicated to the management of industrial chemicals as well as the opportunities arising from the inter-sectoral alliances.** Some of those interviewed expressed that it would be valuable for authorities in the region to learn what a risk assessment report looks like, understand how the information is submitted and what expertise and education technicians must possess in order to examine the reports in case the government assumes that responsibility.

    - **Training opportunities:** As the conditions of the countries do not permit the creation of large institutional structures, such as an agency specializing in the analysis of chemical substances, governments could benefit from understanding which skills and specific knowledge should be acquired by the professionals to whom the implementation of the industrial chemicals management will be delegated. Likewise, there are opportunities to explore, such as the formation of inter-sectoral consulting groups and connections with the private and academic sector, among others.

6. **Need for engaging and training non-specialist public sector personnel in the management of industrial chemicals.** In developing a new standard, numerous government officials are involved in addition to individuals from technical fields who submitted the regulation. Despite their lack of specialized knowledge, the legal fields should participate in the establishment of standards for the management of industrial chemicals at both the executive and legislative levels.

    - **Training oppotunity:** Some of those interviewed emphasized that it would be beneficial to provide training that explains the objetives of regulating the management of industrial chemicals in a simple manner, as well as the main concepts and processes, using case studies and international frameworks as references.

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1. INTRODUCTION

1.1 REPORT OBJECTIVES

The United Nations Environment Program (UNEP) is implementing the initiative **"Strengthening capacities and Regulatory Framework for the Sound Management of Chemicals and Waste in Latin American and Caribbean countries (LAC)"** with the support of the Swedish Chemicals Agency (KEMI) and the Basel Convention Coordinating Centre - Stockholm Convention Regional Centre for Latin America and the Caribbean (BCCC-SCRC), headquartered in Uruguay. The aforementioned initiative, in accordance with the priorities set forth in the **Work Programme 2021-2022** of the Intergovernmental Network of Chemicals and Waste for Latin America and the Caribbean (hereinafter referred to as "the Network"), seeks to create and share knowledge to support the decision-making on the regional management of chemicals and waste, among other goals.

One of the main scopes of institutional strengthening defined by the Network is related to the **risk assessment of chemicals**. In this context, this report has the following objectives:

- Reviewing the regulatory frameworks, the institutional approaches and the practices related to the prioritization and risk assessment of industrial chemicals[5] in the countries of the LAC region, including the identification of stakeholders and key actors;
- Identifying the needs for the creation and strengthening of capacities based on global experiences, starting with the analysis of common elements;
- Designing the implementation of a regional training, taking into account capacities and ongoing initiatives in terms of prioritization and risk assessment.

In this context, this document attempts to answer, among others questions, the following:

1. What are the different instances of regulations that exist globally for the management of industrial chemicals?
2. What is the outlook for the LAC region?
3. What are the resources involved?
4. Are there any distinctions between the treatment of new and pre-existing substances?
5. Who are the responsible parties in each circumstance?
6. What information is used? What are the sources? How is it handled and communicated?
7. Which methods exist for creating and analyzing information?
8. What are the identified challenges, the expected improvements and the most recent developments?

[5] This report focuses on industrial chemicals which are deemed herein as all those chemicals produced and/or traded in relevant quantities (greater than 100 kg per year) that are not regulated by specific standards (e.g., acitve ingredients in pesticides and pharmaceutical products, waste and natural chemical substances, among other substances regulated by specific standards). Source: UNEP, 2021 (adapted by the OECD).

1.2 METHODOLOGY

In May 2022, a survey was carried out to the governmental focal points of the Network for the development of this report. This survey aimed to identify the stakeholders and key actors at both national and regional levels, regulatory advances, institutional arrangements and current practices related to the **industrial chemicals prioritization and risks assessment (for health and the environment)**. The following legal standards were considered: regulations amended by official bodies (executives or members of parliament), regulatory projects/standards formally introduced to the Congress/issuer body; projects that went througn private/public consultation, technical standards and/or voluntary agreements. Likewise, the surveys were addressed to other governmental actors potentially involved with the risk assessment, and a special session was held with the Caribbean sub-region with the support of the Basel Convention Regional Centre for Training and Technology Transfer for the Caribbean (BCRC-Caribbean). In total, responses from nine LAC[6] countries were obtained.

Based on preliminary information gathered from the surveys and the findings of the Technical Report No. 1 of the Network (UNEP, 2021),[7] some witness countries were identified (i.e. countries of the region considered representatives of regulatory matters on risks management of chemicals, especially, Argentina, Brazil, Chile, Colombia, Costa Rica and the Dominican Republic). Efforts were made to hold an in-depth interview with each of them,[8] and the information was completed with official documents and accessible literature. **Annex 1** shows the list of participants in the surveys and interviews conducted to prepare this report.

Moreover, the regional scenario was contrasted with methodologies, regulatory approaches, arrangements and institutional capacity for the risk assessments of industrial chemicals (for health and the environment) in baseline countries and organizations of other regions. Canada, the United States of America, the European Union (EU) and the Organization for Economic Co-operation and Development (OECD) were included in the analysis because they are crucial to comprehending best practices and lessons learned. Then, capacity gaps, common elements and criteria lists to select priority substances in LAC countries were found. For this purpose, relevant documents and guidelines were utilized, including the documents for Guidance on Chemicals Control, developed by UNEP with the support of KEMI.[9] These and other documents of interest are listed in the **Bibliography and Additional Resources.**

1.3 SCOPE

As presented in the Technical Report No. 1 of the Network (UNEP, 2021), the prioritization and risk assessment of industrial chemicals are usually included as the main elements of an **overall regulatory framework** that involves other stages, such as the preparation of inventories and registries and risk management (Figure 1). International experiences have shown that each government can apply different strategies for each stage involved in the processes of substances investigations and their effects.

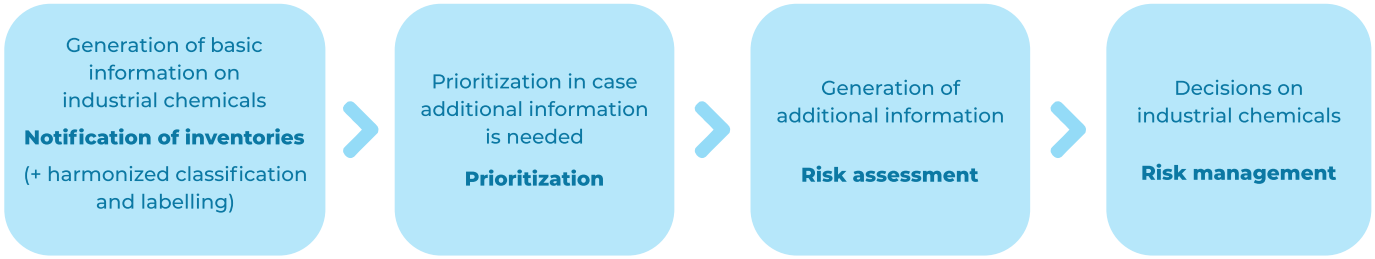
[6] Barbados, Chile, Costa Rica, Honduras, Nicaragua, Peru, the Dominican Republic, Suriname and Trinidad and Tobago.

[7] UNEP, 2021. Legal and institutional framework report for the integrated management of chemical products in Latin America and the Caribbean. Intergovernmental Network of Chemicals and Wastes for Latin America and the Caribbean. MORE INFORMATION.

[8] Interviews were held with Argentina, Chile, Colombia and the Dominican Republic

[9] Among them: UNEP (2019). UNEP GUIDANCE DOCUMENT. Tools to reduce risks to control chemical products. MORE INFORMATION.

As aforementioned, this report focuses on the stages of **prioritization and risk assessments of the industrial chemicals**, to be addressed thoroughly in the following sections:



1.4 INTRODUCTION TO INDUSTRIAL CHEMICALS MANAGEMENT IN LATIN AMERICA AND THE CARIBBEAN

Industrial Chemicals Regulatory Frameworks

In an attempt to avoid and minimize the potential adverse impacts to human health and the environment, the global community acknowledges that each country must assess and manage chemical risk. For substances placed on the market, the creation of mechanisms that promote systematic investigation is recommended, while for new substances, an assessment before they are placed on the market is recommneded.[10]

While in other regions of the world, the regulation of industrial chemicals risk under the described framework dates back several decades, LAC is still in its early stages of development. In accordance with the information obtained during the preparation of this report, among the countries of the region, different levels of advancement can be identified (see Figures 2a and 2b). These have been classified as: non-advancement informed or identified (namely, no advances are found as per cited works), planning in progress (the country has a general legal framework that foresees the creation of specific instruments for industrial chemicals), under development (current efforts are found such as drafts and/or agreed projects of legal standards, work plans of the intergovernmental committees, cross-sectors meetings, etc.) and partial regulation (the country approved a regulation instrument for industrial chemicals, but its full regulation is pending). The greatest advances are identified in those countries that are members of the Organization for Economic Co-operation and Development (OECD), acknowledging the management of chemicals as the bedrock of their decisions and recommendations, or in those countries that have shown interest in becoming members.

[10] For this matter, there are two crucial OECD instruments: one of the reference institutions for this issue: (i) OECD, Decision-Recommendation of the Council on the On-going Investigation of Existing Chemicals, OECD/LEGAL/0232 OECD, Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals, OECD/LEGAL/0199, and (ii) OECD, Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment, OECD/LEGAL/0154

Regulatory progress for industrial chemicals in LAC

Figure 2a. Scenario map of regulatory frameworks on industrial chemicals in LAC. Source: Own compilation based on the surveys and interviews with focal points of the Network carried out within the context of this work.

Regulatory progress for industrial chemicals in LAC

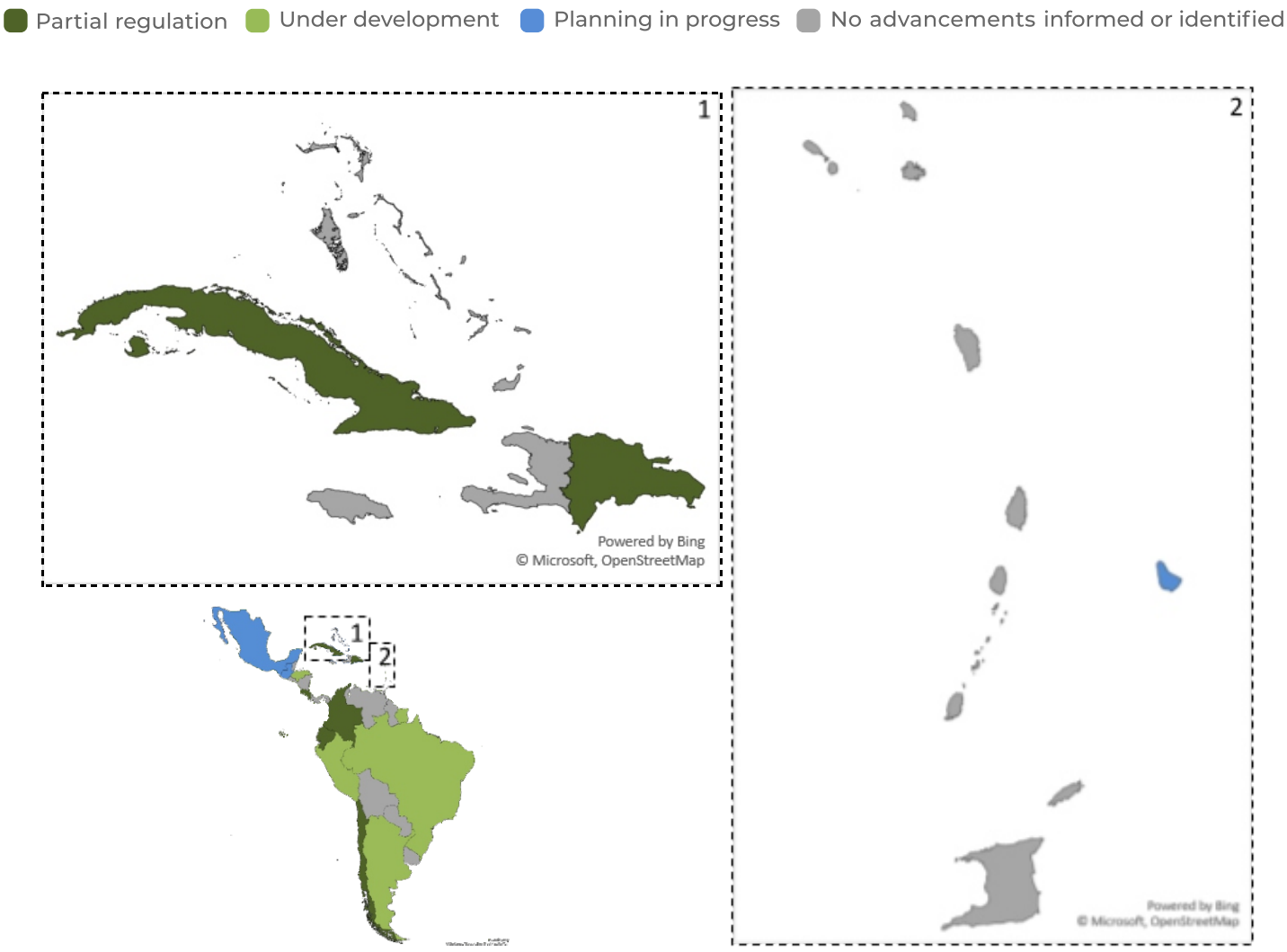


Figure 2b. Scenario map of regulatory frameworks on industrial chemicals in LAC. Source: Own compilation based on surveys and interviews with focal points of the Network carried out within the context of this work.

As it can be observed, there are no cases in the region where the risk management of industrial chemicals is fully regulated to date and, therefore, fully implemented. In the countries where progress has been made on this issue (Chile, Colombia and Costa Rica),[11] the established standards are of high-level and outline the main aspects of the systems to be implemented, focusing primarily on the stage of inventories and registries creation. In all these cases, the standards demonstrate the need for **secondary regulations** (such as technical regulations) for the subsequent phases, i.e., prioritization, risk assessment and risk management. Delegates of the aforementioned nations have reported that drafts of the proposed regulations are not yet available but are currently under development.

Nevertheless, relevant information obtained from the interviews and current initiatives at a regional level will be introduced in the following sections in order to be contrasted with the experiences of other regions and identify the capability shortages.

[11] It should be highlighted that presently, only the Program for the Management of Industrial Chemical Products is known for Costa Rica and according to the survey, the legislation is under legal review for each of the institutions. MORE INFORMATION.

Challenges and Opportunities in LAC

Few countries of LAC have moved forward in terms of general regulations on the risk assessment of industrial chemicals, and none of them have completed the creation of a comprehensive regulation. Since the secondary regulations are emerging, an opportunity is given to strengthen capacities to support the design of technical instruments

In **Annex 2**, the regulatory scenario within the LAC region for the chemicals management framework with an emphasis on industrial chemicals[12] is presented. In general, there is a common effort to develop **comprehensive instruments** with several control mechanisms. For instance, Chile has recently regulated within a unique instrument, Decree 57/2021,[13] the implementation of the Globally Harmonized System (GHS) for the classification and labelling of chemicals, as well as the mechanism of notification and risk assessment. Likewise, the bill that is under development in Argentina also includes the classification and registration of chemicals as well as the assessment and risk management of hazardous substances.[14]

Governmental bodies involved in the management of industrial chemicals

The agencies responsible for environmental management - and to a lesser extent, health agencies - usually lead the activities involved in developing regulations, and in many studied cases, **inter-sectoral working groups or roundtables** have also been created. Participating in these roundtables are organizations responsible for production, commerce or industry and labor.

The regulations studied usually appoint the environmental bodies as the **competent authority** responsible for managing the inventories and registries. This may be associated with their responsibility under international treaties, their representation within organizations such as OECD and the delegation of faculties through national standards that aim to protect human health and the environment.

Decree 1630/21 of Colombia[15] assigns the inventory control to the environmental authority, as well as granting responsibilities to the Ministry of Commerce, Industry and Tourism, as well as to the Ministry of Health and Social Protection, but it does not define a competent authority.

In the regulatory proposal from Peru, currently under development, the governance of the National Registry would be in charge of the Ministry of Environment.[16]

[12] This table is non-exhaustive and it was filled in as per the information received through surveys that had been sent to the Network focal points and other governmental actors identified by the regional centers.

[13] Decree 57/2021 Ordinance of classification, labelling and notification of Chemical Substances and dangerous mixtures. MORE INFORMATION.

[14] Based on an interview held with a representative of the country.

[15] Decree 1630/21 on comprehensive management of industrial chemicals included its risk assessment and other determinations. MORE INFORMATION.

[16] As per the survey response, the instrument approval is pending. Some details have been informed in the Technical Report No. 1 by UNEP (UNEP, 2021)

In per Costa Rica, the authority that regulates the registration of hazardous chemicals is the Ministry of Health according to the Decree 40.705-S.[17] In Chile, the action is conducted jointly between the Ministry of Environment and the Ministry of Health.

Moreover, the regulations set out the creation of inter-governmental committees whose purpose is to promote cooperation in the dissemination of information and the systematic review of pre-existing substances, as well as to articulate the decision-making process regarding risk management, among other things.

In Colombia, for example, Decree 1630/21 establishes an Inter-sectoral Follow-up Technical Roundtable on Industrial Chemicals Management to guide and coordinate the implementation of instruments for the management of industrial chemicals. The Ministry of Health and Social Protection, the Ministry of Labour and Social Security, the Ministry of Commerce, Industry and Tourism, as well as the Ministry of Environment and Sustainable Development are all responsible for its integration. In Argentina, an Inter-ministerial Chemicals Roundtable was created by Decree 504/19, and its members include agencies of environment, customs, production, agroindustry, health and labour, among others.[18] This intergovernmental working group's primary responsibility is to clarify the objectives and negotiate mutual work commitments. During 2018-2022, the Roundtable contributed to the drafting of legislation pertaining to the risk management of chemicals.

In **Annex 2**, the leading bodies and other parties involved in the establishment of regulatory frameworks for the management of industrial chemicals are mentioned.

Non-governmental Actors Involved in the Management of Industrial Chemicals

In the studied countries, non-governmental actors have been permitted participation in the development of regulations through **public consultation** or **formal dialogue processes**. Particularly noteworthy is the case of Brazil, which in 2013 established the Working Group "CONASQ" (Brazilian acronym for National Commission of Chemical Safety), with participation from a wide range of sectors, including the government, the private sector, trade unions and Non-Governmental Organizations (NGOs). This group is tasked with drafting a bill that sets the regulatory framework for the safe management of chemicals in accordance with the OECD recommendations and the Brazilian context. In 2018, CONASQ approved the final version of the bill as a result of their intense consensus-building efforts and following a public consultation with extensive public participation.

In this context, it is paramount to mention that non-governmental regional actors with relevant experience in this issue have been identified within the region, from whom governments could seek advice not only during the development of legislation, but also during its implementation. Among these is the Latin America Regulatory Co-operation Forum (LARCF), an initiative of chemical associations in Latin America that aims to strengthen the region's capacity for the sound management of industrial chemicals and promote the dialogue between the government, private sector and industrial associations.

[17] Technical Regulation RTCR 478:2015 Chemical Products. Hazardous Chemical Products. Registry, Import and Control. MORE INFORMATION.

[18] MORE INFORMATION.

Among the activities carried out by the said Forum is the creation of a Virtual Working Group for the Sound Management of Chemicals in Latin America (VWG-SMC-LA),[19] comprised of government representatives of the region and the industrial sector, as well as representatives of relevant organizations such as UNEP. VWG-SMC-LA attempts to explore the key ideas associated with the proper management of chemicals and works on the preparation of related guidance documents.[20]

It is also important to mention the Society of Environmental Toxicology and Chemistry (SETAC), a global non-profit organization with approximately 5,000 members and institutions in over 90 countries. It focuses on studying, analyzing and resolving environmental issues, managing and regulating natural resources, and researching, developing and providing environmental education. SETAC Latin America was founded in 1999 and, among other pertinent activities, hosted a symposium in Brazil in 2017 on Chemical Risks Assessment and Management in Latin America.

The Toxicology Network of Latin America and the Caribbean (RETOXLAC, in Spanish) was founded in 1999 with the purpose of integrating toxicology professionals of the region with the Centres of Information, Consultation and Toxicology Assistance, Laboratories of Clinical Toxicology Analysis, Toxicology Societies and Associations, Toxicology Networks and University Toxicology Chairs.[21]

During the preparation of this report, the identification of civil society organizations interested in technical aspects of the industrial chemicals regulations was not accomplished. Salud Sin Daño (Health Care Without Harm), RAPAM-IPEN Hub of Latin America and the Caribbean or the Caribbean Poison Information Network (CARPIN), among others, may be interested in this topic.

1.5 INTRODUCTION TO INTERNATIONAL FRAMEWORKS

In order to analyze the capacities of LAC, the chemical management schemes set out in Canada, United States of America, the European Union and the OECD are evaluated below. In this document, they are introduced briefly, with the expectation that they will be discussed in greater depth during the relevant training events.

The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) instrument in the European Union includes both the prioritization of substances for dossier revision and the risk assessment process for substances whose information should be complemented. Although each stage has its own specialists doing restricted tasks, the European Chemicals Agency (ECHA) is the regulatory authority responsible for the legislation.[22] In addition, each EU member state is responsible for REACH enforcement. Notably, the REACH instrument has existed for more than 15 years, and ECHA has more than 600 experts devoted to reviewing and generating information.[23]

[19] Coordinated by the International Council of Chemical Associations (ICCA), and Latin America Regulatory Co-operation Forum (LARCF)

[20] MORE INFORMATION

[21] MORE INFORMATION

[22] J. Pon, Guevara Y. (2017) Regulation of Chemical Substances. Approaches available for the Regulation of industrial chemicals, trends and case studies in Latin America and the Caribbean.

[23] MORE INFORMATION

Canada's system is another framework with significant experience. Since nearly three decades, the Canadian Environmental Protection Act (CEPA, 1999)[24] has been used to regulate the dangers of chemical compounds. Through the Management Committee, this instrument is managed jointly by the Ministry of Environment and Climate Change and the Ministry of Health (1990). Among other things, the aforementioned Committee performs prioritization and risk assessments, approves regulatory control measures and suggests amendments. Similarly, Canada has sub-committees that are responsible for new chemicals and substances considered toxic by law. Additionally, there are groups like the National Consultant Committee, which is comprised of representatives of federal states and national ministries, that aim to promote national actions and prevent the duplication of regulatory activities.

The Toxic Substances Control Act (TSCA) governs chemical substances in the **United States of America**.[25] This 1976 law stipulates that the Environment Protection Agency (EPA) is responsible for implementation through its Toxic and Contamination Prevention Bureau, with nearly 300 employees in 2020.[26]

The OECD has approved the following instruments that define and/or recommend essential aspects related to the management of industrial chemicals:[27]

- Recommendation OECD/LEGAL/0154 (1977), *establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment and Decision* OECD/LEGAL/0199 (1982), *concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals*. These instruments recommend procedures to predict the effects of chemicals and a minimum set of data to assess their risks for health and the environment. Prior to the introduction of a new product to the market, it is required that member nations have access to adequate information regarding the product's properties.

- Decision-Recommendation OECD/LEGAL/0232 (1987): Systematic Investigation of Existing Chemicals. This instrument mandates that members set out or bolster national programs to systematically analyze existing chemicals in order to identify those that require management.

- Decision-Recommendation OECD/LEGAL/0441 (2018): *Co-operative Investigation and Risk Reduction of Chemicals*. It dictates that the members should cooperatively develop harmonized prioritization methodologies, hazard and exposure assessment of chemicals in order to align the approaches and identify chemicals that may pose a danger to the environment and human health. It also promotes the creation and circulation of hazards, exposure and risk assessments, agreed upon chemicals of mutual interest, and, where applicable, categorization and labelling of these chemicals. Finally, it mandates the implementation of GHS to promote the communication of hazards within the supply chain.

[24] MORE INFORMATION.
[25] MORE INFORMATION.
[26] Own estimations based on the document available at: MORE INFORMATION.
[27] Note: The first instruments (OECD/LEGAL/0154, OECD/LEGAL/0199) were mainly focused in new chemical substances , the subsequent covered the pre-existent substances (OECD/LEGAL/0232), and the latest are not distinguished between those categories (OECD/LEGAL/0441).

Regarding the **LAC region**, the competent authorities, often the Ministries of Environment and Health, have only a single section with limited number of officers to assist with the management of industrial chemicals and other challenges. Therefore, when comparing regional schemes, it is vital to take into account, among other factors, differences in available resources, organizational structures and standards. Chile is one of the LAC countries that has advanced in these systems, relying on computing resources that make the most of existing information to drastically minimize the quantity of staff required.[28]

Challenges and Opportunities in LAC

There is a perception that the countries in the region generally tend to make the most of existent resources globally, including the data generated and the lessons learned from those countries with decades of experience. Likewise, there is also a general consciousness of the limited resources, mostly human, that encourage the authorities to rethink strategies that require the least number of hours from manual work. *The computing tools, the use of shared data and the cooperation between different agencies and sectors* are supporting points that should be the bedrock of the regional discussions, preferably in practical approaches and clear methodologies.

2. PRIORITIZATION OF INDUSTRIAL CHEMICALS

2.1 INTRODUCTION

When conducting (or revising) risk assessments, an intense and specialized job is involved. Thus, taking into account the large number of chemicals available in the market, governments usually harness all their efforts and resources available only in those substances that prove to be of highest priority according to its **hazard profile, exposure and relevant information** available.

As previously stated, the region lacks regulations describing the methodologies, institutional arrangements and actors involved in the prioritization process for industrial chemicals. Consequently, the purpose of this section is to contrast the applied approaches in the international frameworks with the submitted regulatory frameworks[29] in effect or under development in LAC. The objective is to identify the primary challenges facing the region and to suggest the design of the training in response to the identified gaps and strategies stemming from the interviews.

[28] Information obtained by interviews.

[29] Supporting documents to create this section: OECD (2019). International Best Practices for Identification of Priorities within Chemicals Management Systems. ENV/JM/MONO(2019)34. OECD Series on Testing and Assessment, No.314, Environment, Health and Safety, Environment Directorate, OECD; Adam D.K. Abelkop and John D. Graham (2015). Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union, 32 Pace Envtl. L. Rev. 108. Available at: MORE INFORMATION.

2.2 PRIORITIZATION STRATEGIES

Prioritization schemes within the analyzed international frameworks have undergone changes and improvements throughout time, indicating that the search for better practices in this field continues. Nonetheless, two major strategies for prioritization (Figure 3) are described in the following paragraphs.

On the one hand, some regulatory frameworks oversee individual prioritization procedures for certain groups of substances that are classified in special lists or are chosen from a set of substances that are then subject to weighting. This stage is referred to as **pre-prioritization**. However, it should be noted that, although working with private entities, these countries do not exclude substances considered low priority and, in fact, include them in the new roundtables for amendment.

Throughout the years, Canada has relied upon, among other things, specific programs for substances of the petroleum industry and organic/inorganic substances. Prioritization in the United States is made based on a group of substances previously prioritized in their Work Plans since 2012. Meanwhile, REACH includes a prioritization stage that focuses on the list of Substances of Very High Concern (SVHC), for which a particular methodology exists.[30] Furthermore, ECHA has been consolidating its functioning mechanisms using a set of structurally comparable chemicals as opposed to individual substances.[31] The grouping is undertaken through computing algorithms, and the groups of substances are mainly created based on: i) similar structure using the substance information identity in the registration dossiers and the CLP notifications (the system of classification and communication of hazards in the UE) and ii) extrapolation and categories using the information received from the industry's registration dossiers and external sources.

The other possible methodology is the prioritization of all the listed substances based on a **weighting method**, with no pre-prioritization or distribution into specific lists. According to the information gathered during the interview conducted as part of this work, Chile's initial proposal for this process would be as follows:

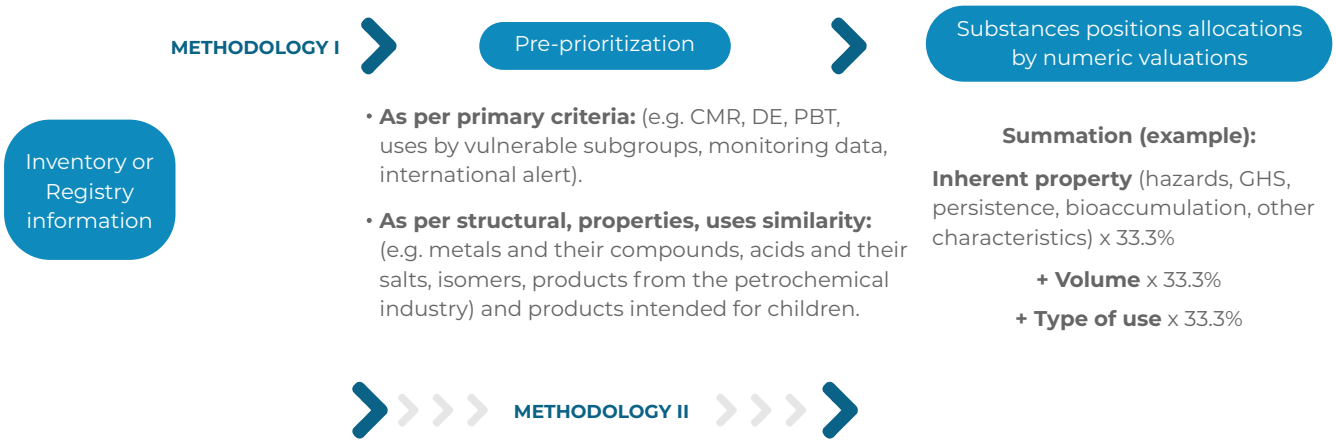


Figure 3. Simplified Scheme of two prioritization methodologies. CMR: Carcinogenic, Mutagenic, Toxic for Reproduction DE: Endocrines Disruptors, PBT: Persistent, Bio-accumulative and Toxic.

[30] It is crucial to explain that in the case of the European Union, the prioritization is based on substances that the private sector has already provided sufficient information to be analyzed by the authorities. In other words, what is prioritized is the need for reviewing the assessments of chemical safety dossiers, and not the need for conducting the assessment.

[31] MORE INFORMATION

Challenges and Opportunities in LAC

As the countries that have moved forward with the regulations on chemical substances management issues are still at an early stage of developing specific standards related to the prioritization stage, it seems appropriate to provide training *on schemes options and prioritization methodologies, their advantages and disadvantages and application cases in other regions and countries.*

In other cases, it is crucial to **define the criteria** that combine the data of hazards and exposure, or the altered use of them, in a specific instance of the process. Thus, the majority of prioritization schemes are risk-based (hazard and exposure). Regarding the hazard, the intrinsic properties of substances, as well as their hazard classification or other properties such as persistence, bio-accumulation potential and toxicity (PBT), are usually used as the prioritization criteria, whereas volume and type of use (industrial, professional, consumption) are typically preferred with regard to exposure.

Even though Chile, Colombia and Costa Rica are the sole countries in the region that have published standards for specific industrial chemicals schemes, they have not yet made their prioritization methodologies public. As for the interviews conducted as part of this work, however, their representatives stated that the criteria to be applied will include both hazard and exposure data. In the case of Chile, chemicals will be prioritized numerically taking into account all the hazards, excluding physical ones, as well as the volume and types of use. In the case of Colombia, it is unclear which criteria would be prioritized, although the country's approach will take into account both environmental and health dangers. On the other hand, in the Brazilian bill (approval pending in the Legislative Power),[32] the proposed criteria are: persistence, bio-accumulation, toxicity for the environment, carcinogenicity, mutagenicity, reprotoxicity, capacity of endocrine disruption, potential exposure level, amount of production and export, overall usage deviations that have as a result a damage to health and the environment, exposed vulnerable communities, or that the substance is linked with some treaty, agreement or international convention that Brazil has joined, or under international alert and the chemicals for which the Brazilian authorities have not undertaken a risk assessment process. The emerging project in Peru sets out that importers and manufacturers of chemicals classified as carcinogenic, mutagenic, reprotoxic or hazardous for the environment must include in their Environment Management Strategies specific measures for the reduction and management of health and/or the environment risks.

[32] **MORE INFORMATION** (last consulted on July 18, 2022)

Challenges and Opportunities in LAC

It is recommended that governments assess their priority criteria before creating inventories or registries, since the process often begins with the information provided by producers or importers. Therefore, countries are interested in determining which criteria are more suitable based on *available resources, data and local concerns*. This includes knowing how to access data that would be retrieved from external databases (such as properties not included by the GHS as hazards, such as endocrine disruption, persistence, bio-accumulation) and which standards should be established for defining the data (for instance, how to define an adequate value in order to describe a substance as persistent). Similarly, it is crucial to train countries on the *different prioritization stages according to the increasing levels of information requisites*. In other words, releasing the increasing complexity of data to be collected and the moment at which the most refined data is required.

In some circumstances, prioritization schemes studied by the OECD apply a **scoring system** to assign priorities.[33] This mechanism facilitates the decision-making and helps to improve the transparency and the reproducibility of outcomes. The process consists of assigning a score to some relevant properties of the substance (for instance, the properties aforementioned in the previous section about criteria), and a score related to exposure. These are then combined, generally through summation, and the final outcome is used to determine the substance priority and the measures to be followed after the prioritization (Figure 4).

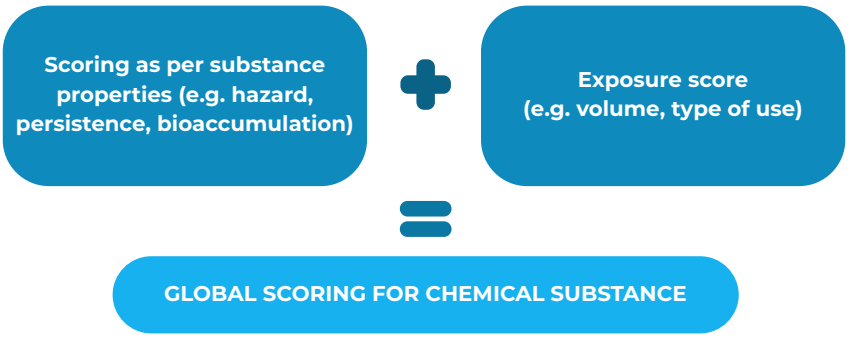


Figure 4. Prioritization Equation. Note: The relative weights were not included for simplicity

[33] Document OCDE ENV/JM/MONO(2019)34. MORE INFORMATION.

The preceding information reflects some of the main points of uncertainty and topics of study that countries face when developing their prioritization systems. Based on the surveys, Chile brought forward that the scoring system would include three criteria: hazardousness (defined according to the Chilean harmonized system), volume of the substance production/import and type of use (defined according to the computing system associated to the national inventory). Likewise, the country would not assign differentiated scores to the hazards of the substances. In other words, the final result would display higher values for substances with a greater number of hazards, and the hazards would not be differentiated based on their nature.

Colombia is an exception, since the definition of the scoring criteria is still being debated; Within a set of criteria and cross-criteria comparison, the weightings are still being assessed. Although there have been no advancements in Argentinean prioritization since its interview, national efforts have been documented to choose priority substances to be monitored in several environmental matrices. While these efforts are dissimilar from the approach of chemicals management proposed in this document, they may serve as useful background information when discussing the region's lessons learned, challenges and opportunities.

Challenges and Opportunities in LAC

Countries are interested in understanding the scoring assignation process and the development of the final equation to rank the substances. Given that this activity is difficult to comprehend in its abstract form, it would be interesting to address the possibility of conducting hands-on exercises to identify how each variable of the selected schemes can alter the order of the prioritized substances.

2.3 DATA QUALITY ASSESSMENT

These schemes involve the establishment of mechanisms to assess the quality of data provided by the companies in the national inventories or registries. For instance, processes of the US Environmental Protection Agency (EPA) are based on the best scientific evidence available and the burden of proof, both requirements set out in its regulatory instrument. Canada and the EU also rely on the application of principles such as the importance of the evidence and the precautionary principle by applying the worst exposure scenarios and conservative estimations of hazardous properties.[34] An information review can be conducted in different ways, depending on the assessment instance. For example, ECHA is entitled to examine any registration dossier at any time to verify that all the information submitted by the registrants complies with the legal provisions.[35]

[34] Adam D.K. Abelkop and John D. Graham, Regulation of Chemical Risks: Lessons for Reform of the Toxic Substances Control Act from Canada and the European Union, 32 Pace Envtl. L. Rev. 108 (2015) MORE INFORMATION.

[35] MORE INFORMATION.

It is particularly challenging for both the experienced countries and countries in the region to implement a strategy to address the **lack of harmonized classifications**, with regard to the hazard classification of substances. Despite the existence of an international system (GHS) and national efforts to achieve harmonized classifications,[36] no harmonization has been reached globally. As a result of this difficulty, some countries in the region have started to examine alternative prioritization strategies that incorporate some form of evaluation based on external data, while specific disputes are left to expert review, as in the case in Chile. As a means of expediting prioritization, the VWG-SCM-LA has assessed different scenarios, such as using the most conservative reported classification at national and international levels.

Challenges and Opportunities in LAC

Among the most pressing concerns of LAC countries, those that stand out are:

1) Understanding which data require the highest level of control;

2) Determining at which stage the data provided should be reviewed and which mechanisms (computerized or manual) governments should employ;

3) Identifying which external and internal databases can be consulted in order to compare their data with the national inventories;

4) Knowing the basic principles underlying data analysis (such as the weight of evidence);

5) Analyzing the different strategies for addressing discrepancies, such as non-harmonized hazard classifications or the scope of recommended usage.

2.4 ACTORS

Governments with experience in prioritization schemes rely on specialized areas within their environment, health or chemicals agencies responsible for defining and improving the processes. For instance, the ECHA Prioritization Unit, under the management of the Prioritization and Integration director,[37] is responsible for developing and applying the prioritization approaches, coordinating the identification and prioritization of substances and groups of substances that require further regulatory actions, supporting the launching of applicable regulatory measures and managing the prioritization of substances of the Community Rolling Action Plan of the European Union (CoRAP) and of the Authorization List (Annex XIV). In Canada, the Division of Existent Substances is responsible for identifying, prioritizing and analysing the risks of existing substances.[38]

[37] Procedure example under the responsibility of ECHA Prioritization Unit: MORE INFORMATION.

[38] MORE INFORMATION.

In most LAC countries, the prioritization process is in its earliest stage of development; It is unclear which actors will be responsible for its regulation as well as for its implementation. Generally, the leading agencies of the integrated industrial chemicals instruments are those that address the prioritization issue. The interviewed representative of Chile explained that the system would be solely electronic and would only be delegated to technical personnel from the Ministry of Environment and the Ministry of Health should some conflict cases may arise (lack of information or misinformation), which might require further revision. In addition to those two agencies, in Colombia, the Ministry of Labor is also included in these discussions. Other proposals, such as the case in Argentina, are based on the creation of inter-disciplinary technical committees incorporated with other agencies apart from those of environment and health (labor and industry). Initiatives that encourage participation or an active role of scientific institutions dedicated to environmental chemistry, toxicology and ecotoxicology are unknown. These said initiatives may be useful within the context where the national ministries' resources are limited.

Challenges and Opportunities in LAC

Given the countries' conditions, there is little likelihood of creating large institutional structures such as an agency specialized in chemicals analysis. Thus, governments may benefit from their understanding of which *capacities and specific knowledge* the professionals of the areas, to whom the definition of the prioritization process and its subsequent implementation will be delegated, should acquire. There are several opportunities, therefore, such as the creation of consulting inter-sectoral groups and relationships with the private and academic sectors, among others.

2.5 INFORMATION SOURCES AND COMPUTING RESOURCES

It is uncommon for governments to generate data on hazards and exposure to inform the prioritization process on a global scale. According to the OECD document ENV/JM/MONO(2019)34, the majority of the international schemes are based on the **data available**, since only six out of twenty-five schemes studied by the OECD are confirmed to have generated data.[39] The data used for prioritization is obtained from a range of publicly-accessible sources, such as peer-reviewed scientific literature, grey literature and national and international databases, including inventories and registries.

Although there is plenty of information in the literature about the description of databases on industrial chemicals,[40] it is unclear to some countries in the region how their systems could be integrated to obtain and utilize these databases for both the prioritization and the risk assessment processes. The most common questions are: How can we systematize the search for information on online platforms? Which resources should be invested in? Which international agreements should be carried out to ensure that information is used? Are there any barriers with regard to the protection of rights over the data available on free platforms such as eChem Portal[41] or IUCLID?[42]

[39] In Canada, toxicity studies are requested for the purpose of creating specific and new information which is crucial for the process.

[40] The UN Environment Programme (UNEP) and the International Council of Chemical Associations (ICCA) document. (2020). Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals compiles information on 100 databases of industrial chemical substances in 50 countries of 4 continents.

[41] OECD portal with free access to information on physicochemical properties, transport and environmental behavior, eco-toxicity, toxicity, GHS classification.

[42] IUCLID is the International Database of information on Chemical Substances, screenshot software, storage, maintenance and data transfer about intrinsic chemical properties. Developed by the European Union.

Colombia's inclusion of explicit restrictions regarding the use of information by third parties[43] and measures to ensure data reliability in Decree 1630/21 may serve as an example of how local authorities could lay the foundations for implementing these type of strategies.

Challenges and Opportunities in LAC

The need to generate new data for prioritization processes is not desirable, according to regional authorities. Nevertheless, they share a common interest in knowing which *computing tools* they have access to - and at what cost - to automatize information revision and decision-making, especially for highly-technical issues, such as the grouping of substances according to their structural similarities.

3. RISK ASSESSMENT[45]

3.1 INTRODUCTION

Risk analysis is a process consisting of three elements: risk assessment, risk management and risk communication.[46] This document concentrates primarily on the first (risk assessment), which entails scientific analyses whose outputs are quantitative and qualitative expressions of the possibility that a given chemical substance exposure may cause harm.

In a simplified manner, this process requires the identification, compilation and integration of information about the hazards of one or more substances, human and environmental exposure and the relationships between exposure, doses and adverse effects. Nevertheless, there is a wide diversity of approaches and instances ranging from the type, amount and the level of detail of the information to be included.

[43] Decree 1630 (2021) ARTICLE 2.2.7B.1.6.3. Information Use. The information used by third parties should be included in the compliance framework of the management instruments set out in Article 2.2.7B.1.2.1 of this decree, data exchange and other aspects related to the access, delivery and disclosure of the information referred to in this Chapter, should be in compliance with the laws and applicable legislation.

[44] Decree 1630 (2021) ARTICLE 2.2.7B.1.6.1. From the existent reliable data. For the purposes of all the provisions of this chapter, the data that is used in the management instruments defined in Article 2.2.7B.1.2.1 should come from reliable information sources that comply with some of the requisites set out in the numerals 2 and 3 of Article 5 Decree 1496 ,2018, or be recommended by the Ministries of Health and Social Protection, Labor and Environment and Sustainable Development.

[45] Section prepared based on the following documents: Guidance on national control of chemical products.Hazards and risk assessment of chemical substances – an introduction (KEMI, 2022); "Who: Human Health Risk Assessment Toolkit: Chemical hazards. Second Edition" (2021) World Health Organization and (WHO) and the International Program on Chemical Safety (IPCS).

[46] In addition to the risk assessment, effective risk management also includes aspects such as risk perception and socioeconomic issues, elements that should be reflected during the risk communications process.

Furthermore, the methodologies for the risk assessment of chemicals continue to evolve over time as more knowledge, experiences and technologies are developed. Currently, there are some initiatives of international collaboration, such as the Chemical Risk Assessment Network of the WHO, created in 2014,[47] that substantially contribute to the development of harmonized approaches and with a future vision for risk assessment.

As described in the previous section, only three regulatory frameworks that include provisions regarding the industrial chemicals have been approved within the region: Chile, Colombia and Costa Rica. However, the **secondary regulations** that would turn them fully operational and would regulate, among others, the mechanisms of risk assessment have not yet been issued. Representatives of Chile and Colombia pointed out that, years ago, they worked on technical guidance about risk assessments that would serve as the foundation of their instruments, but these technical guidelines have yet to be approved.[48] The reason for the delay is likely because the implementation of inventories, registries and prioritization processes must be determined before the regulation of risk assessment can be implemented. Therefore, this section compares the international framework approaches with the information collected from interviews in order to provide the region with useful information for decision-making once the development of specific regulations starts.

Challenges and Opportunities in LAC

Some of those interviewed expressed that it would be valuable for the authorities in the region to understand what a report of chemical safety or risk assessment looks like, *how the information is submitted* and what *expertise and education* technicians must possess in order to examine the reports, in the case that the government assumes that responsibility.

[47] MORE INFORMATION

[48] Colombian representatives noted that the regulations of risk assessment shall be linked with the work outcomes of 2018 (available online) through which the reference terms were defined in order to conduct those assessments. For its development, they have relied on the Chemical Committee of the OECD, the requirements of the United States of America and the European Union. Those interviewed by the government of Chile stated that in 2018 the Ministries of Environment and Health created two procedures: one of prioritization and the other of risk assessment. Although they are ready, the COVID-19 pandemic postponed their enactment for public consultation. Chile relied on the benchmark used by Canada and Sweden.

3.2 INDUSTRIAL CHEMICALS RISK ASSESSMENT OBJECTIVE

It is important to point out that the objective of these assessments within the management of the industrial chemicals framework is not to define actions in response to accidents, but rather to determine whether a substance (or group of substances) poses an **irrational risk** to health and the environment under certain conditions of use.[49] This is a common misconception when studying legislation regarding the management of chemicals. Based on the interviews conducted and the survey responses received, a large number of initiatives and regional efforts to manage chemicals have been identified, including the control of the international trade, registries of emissions and transfer of contaminants and the management of accidents. Nevertheless, many instruments fall outside the scope of this document if the proposed approach for the management of industrial chemicals is considered: **1)** inventory creation, **2)** prioritization, **3)** risk assessment and **4)** risk management. Simply put, the analysis focuses on the entire life cycle of a chemical substance.[50] This does not imply that the information collected in parallel systems should be overlooked, but rather that countries should take measures to prevent data duplication by increasing interactions between systems.[51]

Differences between an Assessment on the Environment and on Human Health

Due to the fact that a substance may have varying levels of concern and requirements for ecological and human health risk assessments, it is common practice to employ a separate approach for each. Similarly, although the concepts for the processes outlined below are identical, the required data, and hence the actors and disciplines, vary.

Challenges and Opportunities in LAC

Due to the early stage of the regulations, this is the best moment for the governments of different countries to consolidate their fundamental understandings associated with the risk assessment of industrial chemicals, emphasizing primarily their differences from other assessments and processes, and their specific objectives. For instance, there is a clear need to differentiate the risk assessment of industrial chemicals within a *context of integrated management or of risk assessments outlined in other contexts or life cycle stages, such as those linked to accident management.*

[49] Adapted from EPA **LINK 1** and **LINK 2**

[50] For further details see the Technical Report No. 1 of the Network (legal frameworks) (UNEP, 2021).

[51] For instance, to include exposure data and feed its prioritization process, the United States referred to the TRI data (its national registry of emissions transfer and releases). Source: US Environmental Protection Agency. (2012). TSCA Work Plan Chemicals: Methods Document. Office of Pollution Prevention and Toxics.

3.3 RESPONSIBILITY ASSIGNMENT: DIFFERENT POSSIBLE SCHEMES

As the development of risk assessment requires specialized work with a heavy information and analysis burden, debates usually take place over which sector holds the responsibility of completion. The requisites on substance information to predict the negative effects on human health and the environment are referred to in the OECD-LEGAL-0154 document, whereby the OECD establishes that the responsibility for creating and assessing the necessary data to determine the potential effects and safe use of chemicals in relation to human health and the environment should lie with and be incorporated into **industry functions**.[52] Producers and importers are those who have most of the information and resources available when introducing a substance into the territory for the first time.

In general, the pivate sector is considered responsible for conducting risk assessments on substances that are considered new for a country (i.e. they are not present in the territory prior to a certain date set out by regulation); This is the case in the United States and the European Union. As for existing substances that are present in the territory prior to a certain date set by regulation, assessments are carried out by authorities or the private sector, as is observed in the cases of Canada and the United States. In the latter, the risk assessments are carried out by the Environment Protection Agency on the basis of the prioritization outcome or as per the manufacturers' requests. As far as the EU is concerned, for both new substances and existing substances that exceed 10 tons annually, the private sector is responsible for providing information on chemical safety, otherwise known as a risk assessment. In any case, whether it is conducted by the public or private sector, both the development of a risk assessment of chemicals and its review entail a heavy burden of work and resources.

Regarding the region, both in Chile (as per Decree 57/21) and Colombia (as per Decree 1630/21), the responsibility for submitting assessments of prioritized substances falls on the manufacturers and importers. Under certain circumstances, the authorities could be responsible for reviewing those submissions. In Chile, for instance, the submission is given by a committee composed of representatives of diverse sectors according to what was informed in the interview. In Brazil, the submission of risk assessments and analyses based on recommended uses is mandated. Therefore, a committee of chemicals assessments is established with the responsibility of assessing risks and recommending management actions. However, it is unclear whether the committee will be public or mixed (public-private).

Challenges and Opportunities in LAC

For those countries that have not yet defined their schemes, it is crucial to understand the *resource burden* that implies both the preparation of schemes and the revision of assessments, so that they can measure their *emerging needs* and choose the most appropriate regulatory strategy. Furthermore, there is a need for measuring the *impacts* that the said legal requisite could entail for the public and private sectors.

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

3.4 RISK ASSESSMENT STAGES

It should be noted that the risk assessment models are generic and scientific. The basic steps for the risk assessment are **hazard assessment, exposure assessment and risk characterization** (see Figure 5).

Figure 5. Risk assessment essential steps. Source: own compilation

Defining the Risk Characterization in the Region

In accordance with the Working Group VWG-SMC-LA, *"risk characterization is a process aiming to calculate or estimate the hazard for an organism, (sub)system or a given population target after being exposed to a chemical substance and/or mixture, taking into account the inherent characteristics of the substance in question, as well as the organisms' characteristics, system or specific target. The resolution should be qualitative, and, whenever possible, it should be quantitative and include the likelihood of the occurrence of known or potential adverse effects of the chemical substance and/or its mixture under defined exposure conditions. The risk characterization is the final stage of a risk assessment and is conducted using the outcomes from both the hazard assessment and the exposure assessment."*[53]

Hazard assessment (or characterization)

The purpose of hazard **characterization** is to identify a numeric value that can be used as a benchmark when considering the exposure in the risk characterization. The first evaluations are of the hazards for human health and for the environment. Furthermore, it is usually valued on its own if the substance is PBT (persistent, bio-accumulative, and toxic) or vPvB (very persistent and very bio-accumulative).

- **Human health hazards assessment:** Its aim is to identify an exposure level that is below the level where no adverse effects are found, which is in turn referred to as the point or benchmark dose. In the context of REACH, this exposure level is known as the Derived No-Effect Level (DNEL). This value is obtained from the indicators (descriptors), such as the No- Observed Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), or the Benchmark Dose (BMD) and the use of safety factors (assessment factors, AF).[54]
- **Environmental hazards assessment:** The objective is to determine one dose below where no adverse effects are expected to occur on the environment at the environmental compartments. In the European Union framework, the Predicted No-Effect Concentration (PNEC) is used; It is obtained by applying the AF to the benchmark concentration such as the Lethal Concentration (LC) or the Adverse Effect Concentration (NOAEC or LOAEC).

[53] Source: Adapted from the VWG-SMC-LA Roadmap for the Sound Management of Chemicals (page 16)

[54] Source: LINK

- **PBT/vPvB:** The objective of the PBT/vPvB properties assessment consists of determining if a given substance meets the criteria to prove that it is persistent in the environment during long periods of time, and if it has a high potential to be concentrated in the biota. The criteria are based on the half-life time in water and sediment, the bio-concentration factor (BCF) and the toxicity.

Challenges and Opportunities in LAC

It is important to take into account that the safety factors definition largely requires a *political definition*, and, generally, the existence of international benchmark values (for instance, WHO values) arise from *assumptions* that are not necessarily applicable to every context. Therefore, the countries of the region should have a basic knowledge of the mechanisms used to obtain the *benchmark values* so that they can make decisions on whether to incorporate them locally, and, if necessary, create their own benchmark values.

Exposure Assessment

The objective of the exposure assessment is to calculate quantitatively or qualitatively the substance dose or concentration to which humans and the environment may be exposed under the conditions of use specified within a certain scenario. The assessment should include all the substance life cycle phases, stemming from the manufacturing and identified uses. The process includes two phases: 1) the creation of exposure scenarios and 2) exposure estimation.

It should be noted that although the intrinsic substance properties are the same regardless of their use, that is not the case with exposure. Thus, when it is known that the substance pattern of use or volume in a country differs in comparison with others, it is necessary to conduct a local risk assessment.[55] Even though this process may be complex, the lack of detailed data about exposure should not hinder the authorities to conduct a risk estimation for the environment or human health. Initially, as indicated by KEMI (2021), it may be sufficient to rely on **available information**, such as the volumes of a substance that is imported, manufactured or placed on the market, declared uses and monitoring data. Conversely, the substance's properties, including its vapor pressure, water solubility, molecular weight, octanol water partition coefficient (K_{ow}) and biodegradability must be considered.

Some available resources may help in the process. For instance, the OECD has prepared emission scenarios documents (ESD) that describe the sources, production processes, pathways and patterns of use of (groups of) chemicals. Their objective is to quantify in the specific life cycle stages and the chemicals emissions into water, air, soil and/or solid wastes as per the information available or model outcomes.[56]

[55] Conversely, it is possible that a country can make use of the assessments stemming from other territories.

[56] For the ESD development 54 categories of use and 16 industrial processes have been applied. More information: Organization for Economic Co-operation and Development (2018b). OECD guidelines for the testing of chemicals, section 1: physical-chemical properties. LINK

The resources also give the alternative of estimating the exposure through default values, unless more specific data is available.[57] On the other hand, computer-based modelling may help to inform the assessment of human and environmental exposure.[58] The models are used in risk assessment and management to describe the relationship between emissions and concentrations, and to predict the outcome of the management measures. The advantage of using them is that they enable the assessment of outcomes of many processes that occur simultaneously, which would otherwise be extremely difficult (Meent & Bruijn, 2007). A broader use of models could be promoted to replace the expensive monitoring programs as appropriate, especially in countries with limited resources.

Challenges and Opportunities in LAC

Knowing that the exposure assessment entails the mapping of substance use, a generation of exposure scenarios, an emissions estimation, transport routes and behavior in the environment, it is of utmost importance that the countries of LAC can *predict the technical challenges* that each stage could involve. As an opportunity, lessons learned at the national level can be considered with regard to *other groups of substances*, e.g. plant protection products or pesticides with long-standing regulations in the region.

Risk Characterization

Risk characterization is the last stage of a chemical risk assessment in which it is specified whether the risks derived from manufacturing/import and uses of the substance are under control. It also involves the quantitative or qualitative estimation/description of the related uncertainties. The benchmark dose should be compared with the calculated exposure concentrations for human health and the environment. If the value is exceeded, risk management measures will be necessary. Otherwise, repeat the assessment with more detailed data.

$$\frac{\textit{Exposure}}{\textit{Baseline reference}} \begin{cases} \geq 1 \longrightarrow \textit{UNACCEPTABLE RISK} \\ < 1 \longrightarrow \textit{ACCEPTABLE RISK} \end{cases}$$

It should be noted that for non-threshold effects, the slope factor is used to determine the exposure level of low concern.

When the DNEL or PNEC of an identified toxicological or eco-toxicological hazard is unknown, a qualitative and semi-qualitative risk characterization should be conducted.

[57] There are guidelines available about the generic use of exposure scenarios to quantify the exposure appropriately. **LINK**

[58] The OCDE has made a general description of 21 categories with 56 specific models used in the assessment of human and environmental exposure available (OECD 2012).

Challenges and Opportunities in LAC

It should be noted that the information related to *local guidance levels and exposure scenarios* are crucial elements for risk assessment. Although international information sources are referred to in this report, there is a need for creating and consulting the local data within Latin America and the Caribbean. For instance, valuable insight can be obtained from national and local public institutions, (poison control and healthcare centers), the academic and scientific sectors, industries and social organizations.

3.5 REQUIRED INFORMATION AND DATA MANAGEMENT

Required information

One of the main aspects to be defined in the regulation is to indicate what information should be mandatory for conducting and reviewing a risk assessment. As per the EU case, a registration dossier should be prepared and sent online to ECHA through the REACH-IT portal. The dossier format should be taken from IUCLID, which has been prepared in cooperation with the OECD and has been approved by many national and international regulators. This registration dossier should include:

- Manufacturer/importer identity;
- Substance identity;
- Manufacturing and substance use information;
- Substance classification and labelling;
- Guidance on safe use of the substance;
- Comprehensive summaries of the studies on the intrinsic properties, where relevant;
- An indication of whether the manufacturing, use of information, classification, labelling, the summaries of studies or, where relevant, the chemical safety report have been reviewed by an assessor;
- Additional testing proposals, where relevant;
- With respect to substances registered in amounts of 1 to 10 tons, information on their exposure;
- An application whereby it is indicated which information should be considered confidential together with its adequate justification.

When a substance is manufactured or imported in quantities equal to or higher than 10 tons per annum, the following information should be added to the above-mentioned:

- Declaration of the applied risk management measures;
- Declaration of the communicated risk management measures;
- Final destination in the environment;

- Chemical safety assessment: Hazard assessment for human health; Hazard assessment for human health derived from the physicochemical properties; Hazard assessment for the environment; PBT and vPvB;
- Exposure assessment;
- Risk characterization.

A **lack of comprehensive information** becomes a hindrance in the risk assessment processes. In order to face this challenge without a high burden of resources, estimations are carried out based on the scientific understanding of a given chemical's, exposure, dose and toxicity, which usually overestimate the real risk, aiming to ensure the protection of the environment and the population. Accordingly, the risk assessment outcomes have associated **uncertainties** that should be communicated and fully explained. Among other reasons, this is why risk assessment schemes cannot rely solely on computing systems and, in turn, must rely on the work of experts from other fields. Nevertheless, uncertainty should not be used as an excuse for inaction when the evidence points to a risk.

4. NEEDS FOR THE STRENGTHENING OF CAPACITIES

In accordance with the situation analysis described above, the elements listed below pertain to the strengthening of capacities and transfer of knowledge in the region regarding the risk assessment of industrial chemicals.

1. **Limited overall understanding of the management of industrial chemicals the facilitation its regulation**. Few countries of LAC have implemented general regulations on the risk assessment of industrial chemicals, and those that have, have only established general frameworks that require secondary regulations in order to become fully operational. Training should be provide on the general concepts of the management of industrial chemicals and their regulation, not only to seek a common foundation of knowledge, but also to encourage the exchange of experiences between countries in the region that have advanced in the development of regulatory frameworks.

2. **The design of highly technical instruments and the understanding of industrial chemicals prioritization stages and risk assessments.** As secondary regulations are still emerging, there is an opportunity to develop capacities on the design of how to design instruments that have a rather technical nature, aiming to train professionals involved in the preparation of the related technical standards. It is appropriate to provide training on the alternative prioritization schemes and methodologies of risk assessment, their advantages and disadvantages and application cases in other regions and countries, as well as to reinforce environmental chemistry, toxicology and eco-toxicology concepts. For countries that have not yet defined their schemes, it is crucial to understand the resource burden associated with both the preparation and revision of the risk assessment, so that they may assess their emerging needs and choose the most appropriate regulatory strategy. In addition, it is necessary to measure the impacts this legal requisite could have on the public and private sectors.

3. **Lack of knowledge of the tools available to obtain and generate chemical data, safety reports or risk assessments.** The use of available information and computing tools would facilitate the processes and obviate the need for additional investments in personnel, financial and structural resources that are not available in all countries. However, most of the interviewed countries admitted that the existing tools developed by organizations such as the OECD or by governments such as the United States of America and the European Union (EU) are not widely known within the region. Likewise, it is unclear to governments how information might be used in their countries, how intellectual property can be managed and what alternatives of international cooperation exist to enable the information exchange.

4. **Poor analysis level of the main difficulties when gathering and managing data, and of the basic principles to ensure its quality.** It is essential to train countries about the information and data for different stages of the process of managing industrial chemicals, as well as the complexity of information collection. Similarly, as information collection may generate discrepancies, there is a need for education on different strategies to discuss these situations and the fundamentals of data reviewing (i.e. the weight of evidence).

5. **The need to identify the profiles and skills needed to educate the public sector personnel who are dedicated to the management of industrial chemicals, and an opportunity to encourage inter-sectoral alliances.** As the countries' conditions do not meet the requisites to create large institutional structures, such as an agency specialized in chemicals assessment, the governments could benefit from understanding which skills and specific knowledge the professionals entrusted with the responsibilities of the management of industrial chemicals should have. Likewise, there are opportunities to explore such as the creation of inter-sectoral consulting groups and connections with the private and academic sectors, among others.

6. **Requisite of education for the personnel in the public sector who are not specifically dedicated to the management of industrial chemicals.** In addition to individuals from technical areas who have submitted regulations, there are numerous government officials participating in the development of new regulations. Individuals of legal backgrounds should be involved at both the executive and legislative levels in the development of standards, notwithstanding their potential lack of expertise in the management of industrial chemicals. Some of the interviewees stressed that it would be useful to provide training that explains the objectives of regulating the management of industrial chemicals, as well as the main concepts and processes, using case studies and international frameworks as references.

ABBREVIATIONS AND ACRONYMS

AF	Assessment factors
LAC	Latin America and the Caribbean
BCCC-SCRC	Basel and Stockholm conventions Regional Centre located in Uruguay (BCCC-SCRC Uruguay)
BCRC-Caribe	The Basel Convention Regional Centre for Training and Technology Transfer for the Caribbean
BMD	Benchmark Dose
CARPIN	The Caribbean Poison Information Network
AEC	Adverse Effect Concentration
CEPA	Canada Environment Protection Act
CLP	EU Classification, Labelling and Packaging (CLP)
LC	Lethal Concentration
CMP	Canada Chemical Management Plan
CMR	Carcinogenic, mutagenic and reprotoxic
CONASQ	Brazil National Committee in Chemical Safety
CoRAP	The Community Rolling Action Plan of the European Union
DNEL	Derived No-Effect Level
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
ESD	Emissions Scenario Documents
ICCA	International Council of Chemical Associations
IUCLID	International Uniform Chemical Information Database
KEMI	Swedish Chemicals Agency
LARCF	Latin America Regulatory Cooperation Forum
LOAEL	Lowest observed adverse effect level
vPvB	Very persistent and very bio-accumulative
NOAEL	No observed adverse effect level
OECD	Organization for Economic Cooperation and Development
WHO	World Health Organization
NGO	Non-governmental Organization
PBT	Persistent, Bio-accumulative and Toxic

PNEC	Predicted no-effect Concentration
UNEP	United Nations Environment Programme
REACH	The Regulation on the registration, evaluation, authorization and restriction of chemicals
RETOXLAC	The Toxicology Network of Latin America and the Caribbean
GHS	Globally Harmonized System of Classification and Labeling of Chemical.
SETAC	Society of Environmental Toxicology and Chemistry
SVHC	Substances of very high concern
TSCA	Toxic Substance Control Act
VWG-SMC-LA	Virtual Working Group for the Sound Management of Chemicals in Latin America
EU	European Union

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ADDITIONAL RESOURCES

- **eChemPortal: Global Portal to Information on Chemical Substances**

  Free access information on physicochemical properties, transport and environmental behavior, eco-toxicity, toxicity, GHS classification. EChemPortal allows to search databases and provides details on the sources and its quality. **ENGLISH.**

- **International Programme on Chemical Safety (IPCS) INCHEM: Chemical Safety Information from Intergovernmental Organizations**

  Access to internationally-recognized information on the most-used substances worldwide. Consolidates information on governmental organizations to assist with the management of chemical substances. **ENGLISH.**

- **OECD (Q)SAR Toolbox**

  Free software that contains transparent and reproducible information about the analysis of chemicals hazards. It offers functions to access experimental data, simulations and substances properties. It can be used to find chemical categories structurally analogs and serve as a source for the analysis of tendencies and extrapolation where there is a lack of information. **ENGLISH.**

- **WHO/ILO: International chemical safety cards (ICSC)**

  They provide information on the essential safety and health data of chemicals in a precise and clear way. Its primary objective is to encourage the safe use of chemical substances at the workplace. They were jointly created by the International Labor Organization (ILO) and the World Health Organization (WHO) with the cooperation of the European Commission. **ENGLISH AND SPANISH.**

- **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** Official Page of SGA or GHS of United Nations. **ENGLISH.**

- **IUCLID Website** IUCLID (International Database of information about Chemical Substances) is a screenshot software, storage, maintenance and data transfer on intrinsic properties of chemical substances. **ENGLISH.**

- **OECD Series on Testing and Assessment** Guidance to conduct an exposure analysis for human health and the environment, based on data monitoring. It has information on environmental levels, distribution of pollutants, forms to collect data and experiences of member countries. **ENGLISH.**

- **OECD: Harmonized Templates** These contain standard formats for data reports on chemical substances in order to determine their properties and effects. They are intended for database developers. **ENGLISH.**

- **OECD: Manual for the Assessment of Chemicals:** The Manual for the Analysis of Chemical Substances of the OECD is part of the initiatives of the Cooperative Chemical Analysis Program (CoCAP), based on the Program of Chemical Substances of large volume production. The aim is to guide the efforts towards hazard analysis agreed upon between the countries of the OECD. **ENGLISH.**

- **OECD: Procedures for Notification of New Chemicals** Publications of the Working Group "Clearing House on New Chemicals" seek to promote information exchange and teamwork on the notification and assessments of chemical substances, as well as to facilitate mutual acknowledgment and acceptance of notifications. **ENGLISH.**

ANNEXES

Annex 1. List of participants of the surveys and interviews carried out with focal points of the Network for the report preparation.

COUNTRY	NAME AND SURNAME	ORGANISM
Argentina	Agustín Harte	Ministry of Environment and Sustainable Development. Directorate of Substances and Chemical Products.
Barbados	Anthony Headley	Ministry of Environment and National Beautification, Green and Blue Economy. Environmental Protection Department.
Chile	Cristian Brito Cecilia Aburto	Ministry of Environment. Ministry of Environment. Bureau for International Affairs.
Colombia	Diego Escobar Ocampo Juan Carlos Sanchez Rodolfo Alarcón Natalia Uscategui	Ministry of Environment and Sustainable Development. Directorate of Sectoral and Urban Environmental Affairs.
Costa Rica	María del Mar Solano Trejos	Ministry of Environment and Energy. Chemical Substances Management.
Dominican Republic	Eduardo Julia Alexander Moreta Wilson Tejeda	Ministry of Environment and Natural Resources. Environmental Management.
Honduras	Marcia Suazo Yaris Jamilette Zavala Rodríguez	Natural Resources and Environment Secretariat in Honduras (My Environment). Pollutants Control and Studies Centre (CESCCO for its acronym in Spanish).
Nicaragua	Yelba de los Ángeles López González Jackeline Berroterán Mejía	National Commission for Registration and Control of Toxic Substances, Executive Secretariat . Ministry of Health.
Peru	Sonia Kathleen Farro Rios	Ministry of Environment.
Surinam	Radjni Ramsukul	National Institute for Environment and Development (NIMOS)
Trinidad and Tobago	Trisha Beejai Keima Gardiner	Environmental Management Authority (EMA). Ministry Of Planning and Development.

Annex 2. Regulatory scenario in LAC region with respect to industrial chemicals management frameworks

Note: Only were included those countries that answered the survey, and those for which relevant information was found through searches in official websites, available by October 2022.

Country	Information source (e.g. standard, document, reference) and access	Description	Scenario (year)*	Leader organization(s) and other(s) stakeholder(s)	Management stages included PLP: Long-term policy C&E: Classification and labelling I/R: Inventory/Registry P: Prioritization ER: Risk Assessment				
					PLP	C&E	I/R	P	ER
Argentina	1) GHS (workplace). **Access** 2) Law proposal under development by the executive power and two Bills in the Congress. 3) Interview.	1) Approves the GHS implementation for chemicals produced or imported. Further details shall be defined by Decree. 2) Sets out a national registry of hazardous substances (RENASG as for its acronym in Spanish) – includes all sorts of substances, not only industrial.	1) GHS: Regulated (2015). 2) Under development at Congress (2022)	1) Superintendence of Labor Risks (SRT for its acronym in Spanish) 2) Leader: Ministry of Environment and Sustainable Development. Committee: environment, health, labor, industry y agroindustry. Private sector: chambers as CIQyP, CAPQ, UIA, CIAFA, CAPA, ALPHA, CASAFE, CAEM, COPAL, AFCP, CAFEPA, CEADS. Inter-ministerial board (see website).	NO	YES	YES	YES	YES
Barbados	As of the survey: 1) Management of hazardous chemical substances policy. 2) National Strategy for GHS implementation in Barbados.	1) Policy document for the management of hazardous chemical substances (and hazardous wastes) that will be applied to the legislation. This document identifies goals, objectives and policies for the management of hazardous substances. Relevant in-depth activities: Survey and inventory of hazardous chemical products report (1995-1998), Project on "management of chemical products and industrial wastes in CARICOM states developed by the Health Institute of the Caribbean (CEH for its acronym in Spanish) and the University of Dalhousie (Canada). 2) Non-informed.	1) Approved (2006) 2) Non-informed.	1) Technical Taskforce for Chemical Substances 2) Leading by: Environmental Protection Agency Other participants: Private sector, Committee. Inter-ministerial for management of chemical products.	YES	YES	NO	NO	NO
Brasil	1) GHS: **Access 1** and **Access 2** 2) Management of industrial chemicals: Law proposal in Congress: **Access**	1) Implements the GHS at the workplace. The technical provisions for the implementation are found in the standards of the Brazilian Association of Technical Standards (ABNT). 2) Creates an inventory for chemical substances contained in imported or produced mixtures > 1 tonnage per annum. Three years for register constant substances (existent). After three years, the substances will be considered new and, as per the substance profile, importers and producers should submit additional information (to be regulated). Set out a Technical Committee for Chemical Substances Assessment and a Deliberate Committee of Chemical Substances responsible for conducting the prioritization and risk assessment and issue binding measures to mitigate risks (to be regulated).	1) GHS: Regulated. Standard 14725 is currently under revision to adapt it to the revised 7th edition of GHS. 2) Industrial Chemicals: In Congress.	2) Leader: Ministry of environment. Technical Committee: Ministry of Environment; Instituto Brasileiro do Meio Ambiente e dos Recursos Naturais Renováveis (Brazilian Institute of Environment and Natural Renewable Resources) – Ibama; Agência Nacional de Vigilância Sanitária -(National Agency of Sanitary Surveillance) Anvisa; Instituto Nacional de Metrologia, Qualidade e Tecnologia (National Institute of Meteorology, Quality and Technology) Inmetro. Deliberative Committee: Ministry of Environment; b) Ministry of Health; c) Ministry de Industry, International Trade and Services. Private Sector: ABIQUIM; others: **Access**	NO	YES	YES	YES	YES
Chile	1) Industrial chemicals management Programme (PQI): **Access** 2) Decree 57-2021 - **Access /** Resolution under development. 3) Survey and Interview	1) This PQI (as per its acronym in Spanish) considers the notification of chemical substances import and production, the classification and labelling according to the GHS, the preparation of inventories and statistics of the chemical substances imported and produced in the country (hazardous and non-hazardous), the systematic investigation of substances based on their volume and hazardous nature), conducting substances risk assessments and definition of risk control measures for the prioritized substances. 2) Implements the GHS and sets out inventory of chemical substances and hazardous chemical substances in mixtures imported and produced in > 1 ton per annum. Sets out risk prioritization and management to be regulated through resolution.	1) Approved (2017). 2) Decree approved in 2021. Survey response: Resolution under development.	1) Working roundtable with actors with capabilities in the field, which was integrated by the Ministry of Health, Ministry of Environment, Pontificia Universidad Católica - with a technical secretariat role – and the Chemical Industrial Trade Union Association from Chile (ASIQUIM as for its acronym in Spanish). 2) Survey response: Led by the Ministry of Environment, in coordination with the Ministry of Health. Main actors involved: National Consulting Committee. Composition of the National Consulting Committee of the Ministry of Environment: **Access**	YES	YES	YES	YES	YES
Colombia	1) CONPES 3868/16 2) Decree 1496/18 3) Decree 1630/21 4) Interview	1) Risk management policy related to the use of chemical substances. 2) Adopt GHS for: workplace, pesticides, transport, consumer goods. Res 2075/18 implements GHS for pesticides (Andina Community), Res 773/21 implements GHS at the workplace. 3) Designs a chemical inventory (INSQUI) for hazardous substances and in mixtures > 100 kg per annum. Design a registry of prioritized chemical substances to gather more information (to be regulated). The importers and producers should submit a risk management program. (to be regulated). Sets out an environmental and poisoning surveillance plan (to be regulated). Sets out the MISQUIN (the Colombian Inter-sectoral Technical Roundtable) responsible for prioritizing, assessing the gathered information, recommending measures for risk mitigation, and others.	Decrees approved, regulations under development.	Leaded by Ministry of Environment MISQUIN includes: - Ministry of Health and Social Protection. - Ministry of Labor. - Ministry de Commerce, Industry and Tourism. - Ministry of Environment and Sustainable Development Industrial sector: ANDI	YES	YES	YES	YES	YES
Costa Rica	Survey: 1) Regulation on chemical substances Long-term policy (N°40148 - S-MINAE-MAG-MTSS-RE-H): **Access** Program for the Management of Industrial Chemicals: **Access** 2) GHS: Technical regulation RTCR 478:2015: **Access** 3) Hazardous substances: Decree 40705-S: Hazardous chemical products. Registry, import and control: **Access**	1) States the National Chemical Safety Policy as the public interest. 2) Regulates GHS for industrial use; agrochemicals; some final consumer goods; v6. 3) Sets out the requisites and procedures for registration, import and control of hazardous chemical products aiming to protect public health and the environment.	1) Approved (2016) 2) GHS Approved (2018) 3) Regulation of hazardous substances: Approved (2015) Survey response: Legal revision of each institution under development.	Survey response: Ministry of Health, Agriculture, Chemical Committee for OECD National policy; Ministry of Environment, Energy leads and coordinates through the Coordination Technical Secretariat for Chemical Substances Management created through the Executive Decree Num. 33104-RE-MAG-MINAE-S. The Ministries of Environment and Energy, Agriculture and Livestock, Ministry of Economy, Foreign Affairs and Worship , Labor and Social Security should take the required administrative measures. GHS and Technical Regulation of hazardous: Ministry of Health	YES	YES	YES	NO	NO
Cuba	Resolution Num. 253/22: Regulation for the management of hazardous industrial chemicals of the population consumption, and of the hazardous wastes. **Access**	Controls the management actions of hazardous chemical products- it is understood all that are used in the country with the exemption of pesticides and fertilizers-, and the generated wastes. It is implemented the National Registry of hazardous chemical products and the Environmental Regime License for all the actions involved in all the management of hazardous wastes that might be performed.	1) Approved (2022)	Ministry of Science, Technology and Environment.	NO	NO	YES	NO	NO
Dominican Republic	Survey: 1) Technical Environmental Regulation for the Management of Hazardous Chemical Substances and Wastes of the Dominican Republic Regulation on Labelling and Risk and Safety Information of hazardous materials Law 147-02 Risks Management and its application Num. 932-03. **Access**	1) In order to manage hazardous substances, materials, goods or products including wastes it should be registered and obtain a license from the Ministry of Environment and Natural Resources.	Approved (2020)	Leads: Ministry of Environment and Natural Resources. Inter-institutional Committee for the management of chemical substances and wastes at a national level.	NO	YES	YES	NO	NO
Ecuador	1) National Program for the Management Environmentally appropriate: **Access** 2) GHS: **Access** 3) Registry of Hazardous Chemical Substances: **Access**	1) Ministry of Environment and Water of Ecuador (MAAE for is acronym in Spanish) with the support of the United Nations Development Program (UNDP) , executes the National Program for the Management Environmentally Appropriate of Chemical Substances in their Life Cycle (PNCQ, as per its acronym in Spanish)" 2) Version 1. TRANSPORT, STORAGE AND HAZARDOUS MATERIALS MANAGEMENT. 3) Creates the Registry of Hazardous Chemical Substances (those that the National Authority gradually incorporates to a subsequent registry to an analysis of the impacts caused by the use of the substances, those that will be taken from the national lists of hazardous chemical substances of high toxicity, chronic toxicity and restricted use, and the treaties and international agreements from which Ecuador is subscriber member or adherent.	1) Under development 2) Regulated (2018) 3) Regulated (2015)	1) Standardization of Ecuadorian Service 2) Non identified 3) Ministry of Environment	NO	YES	YES	NO	NO
Guatemala	1) Policy for the Environmentally Sound Management of Chemical Products and Hazards Wastes Policy Guatemala: **Access**	The National Policy for the Environmentally Sound Management of Chemical Products and Hazardous Wastes seeks to promote the management of chemicals products' life cycle ensuring the participation of the governmental organizations, civil society, and all those sectors involved in the implementation of sustainable development strategies; and thus, guarantee a firm foundation on the effective assignment of resources aimed to protection activities against chemical products in each sector.	Approved (2013)	Ministry of Environment and Natural Resources - Policy Actors: Ministry of Environment and Natural Resources (MARN as for its acronym in Spanish), Ministry of Agriculture, Livestock and Food (MAGA as for its acronym in Spanish) Ministry of Public Health and Social Welfare (MSPAS as for its acronym in Spanish) Ministry of Labor and Social Welfare (MINTRAB for its acronym in Spanish), Chamber of Industry in Guatemala (CIG for its acronym in Spanish), Shippers Trade Unions, Chemical Laboratories Network (RELABSA as for its acronym in Spanish), others: **Access**	YES	NO	NO	NO	NO
Honduras	Survey: 1) Decree N.° 29/13/PCM – Policy on the Environmentally Sound Management of Chemical Products in Honduras: **Access** The regulation for the SMC for industrial use is under development.	Introduce a "coordinated system" through a policy that embraces the environmentally sound management of all the chemicals products, whether they are agricultural or industrial which are produced or used in the country.	Regulated (2013)	National Committee for the SMC (CNG): Natural Resources and Environment Secretariat Governance and Justice Secretariat; Education Secretariat; Health Secretariat; Finance Secretariat; Commerce and Industry Secretariat; Labor and Social Welfare Secretariat; Agriculture and Livestock Secretariat Others: Studies Center and Pollutants Control (CESCCO as for its acronym in Spanish), SALTRA Honduras.	YES	NO	NO	NO	NO
México	1) Comprehensive National Policy on Chemical Substances Management: **Access** 2) GHS: **Access** 3) Inventory (catalogue): **Access**	1) Rely on a comprehensive and appropriate State policy which ensures rigorous protection of population health and the environment against the risks associated with exposure to chemical substances and products. 2) GHS: Workplace; v5 3) Inventory: promotes the identification of chemical substances through an accredited nomenclature which facilitates the assessment, management and communications of risks as well as the creation of Statistical and Geographic Information of National Interest.	1) Proposal agreed upon for an upcoming law (2019). 2) Regulated (2018). 3) Non-regulated (was voluntary)	3) National Institute of Ecology and Climate Change through the General Coordination of Environmental Health and Pollution.	YES	YES	NO	NO	NO
Nicaragua	Survey: 1) Law 941 Law Founder of the National Commission of Registry and Control of Poisoning Substances (CNRCST as for its acronym in Spanish) 2) Resolution 001-2018 on Requisites and Licenses (including industrial chemicals.	1) The Commission's objective is the standardization, regulation, implementation, provision, development, and coordination of policies, actions and activities related to import, export, production, marketing, distribution, use and consumption of all that is related to poisoning substances. 2) Sets out licenses for, among others, the export, import and production of industrial chemicals.	1) Approved (2016) 2) Approved (2018)	1) Ministry of Health; Ministry of Environment and Natural Resources; Institute of Farming Protection and Sanity. Ministry of Development, Industry and Commerce; Ministry of Labor; Ministry of Transport and Infrastructure ; Farming Technology Institute from Nicaragua.; General Directorate of Customs Services.	NO	NO	YES	NO	NO
Peru	Survey: 1) Comprehensive Management of Chemical Substances.	The published instrument is still unavailable.	Approval is pending (2022)	Ministry of Environment Others: Ministry of Health, Ministry of Agriculture and Irrigation, Ministry of Transport and Communications, Ministry of, International Trade and Tourism, Ministry of Production, Ministry of Energy and Mining, Ministry of Labor and Employment Access, National Superintendence of Customs and Fiscal Administration, decentralized governments.	NO	YES	YES	YES	YES
Suriname	Decree Hazardous Substances and its Technical Regulation on implementation.	The published instrument is still unavailable.	Under development and planning, respectively.	NIMOS, Ministry of Territory Planning, Ministry of Economic Affairs (import and export of chemical products), Customs, Suriname University Laboratories.	NA	NA	NA	NA	NA