ROADMAP FOR THE SOUND MANAGEMENT OF INDUSTRIAL CHEMICALS

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

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

April, 2021

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

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

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CONTENT

1. EXECUTIVE SUMMARY

The sound management of chemicals (SMC) should be considered as a key factor for the economic and sustainable growth of a country. For this purpose, countries should implement and ensure compliance with adequate regulatory frameworks, based on guiding principles such as the use of scientific evidence, that address chemicals and mixtures management throughout their life cycle.

Established in the principles of prevention, comprehensiveness, progressiveness, cooperation, articulation, efficiency, effectiveness and transparency, this document is the result of the **Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America (VWG-SMC-LA)** work. This group consists of regional governments, industrial associations and industries in the region and is coordinated by the International Council of Chemical Associations (ICCA). The roadmap has been prepared to promote a greater understanding of the **sound management of industrial chemicals**, and thus promote cooperation and convergence in the region for the development and implementation of effective regulations, aligned with global management initiatives. This document is intended for regulators, chemical company representatives and other stakeholders seeking to ensure SMC worldwide. In particular, it presents an overview of:

- What SMC means, with special focus on industrial chemicals.
- General description of methodologies, steps and best practices for the implementation of the SMC.
- Opportunities for Regulatory Cooperation.

SMC can be considered as the adoption of all possible measures to guarantee that chemicals are handled in such a way that the environment and human health are protected against the harmful effects that may result from them, throughout their life cycle and value chain (production, trade, use, releases, and disposal). Some benefits associated with the SMC are: improvement in the protection of workers, general population's health and the environment; reduced "costs of inaction"; governmental and industrial reputation enhancement; increase in international productivity and competitiveness; progress on the availability of high-quality information and data at the regional level; industry gains in efficiency, resource savings and reduced compliance costs.

Chemicals and waste are part of global development, and their sound management has been supported for decades in numerous international frameworks. These act as guiding principles for best practices and regulatory policies and promote platforms for the generation and exchange of information. Among the **main global agreements and actions**, we can mention the Organisation for Economic Co-operation and Development (OECD); the 2030 Agenda for Sustainable Development and its 17 Sustainable Development Goals (SDGs); the Inter-organization Programme for the Sound Management of Chemicals (IOMC); the International Conference on Chemicals Management (ICCM) and the Strategic Approach to International Chemicals Management (SAICM), along with other multilateral environmental agreements (MEAs) and international instruments.

This document provides an overview of the main **SMC elements** -building blocks-, based on the compilation of existing information from internationally recognized sources (including the **IOMC Toolbox[1] and OECD requirements**). The analysis is based on the **life cycle approach** and is limited to brief descriptions of each SMC basic component. Waste management is not within the scope of this document. Aspects related to

[1] Access: https://iomctoolbox.org/

technical and implementation issues will be developed in future specific guidance documents.

The diagram in Figure 1 aims to present all the SMC elements from a life cycle perspective.

MAIN ELEMENTS OF THE SMC

1. **National Plan.** The roadmap proposes to begin with the development of a SMC National Plan and the establishment of dialogue mechanisms with stakeholders. It also highlights the importance of conducting cost-benefit and regulatory impact analysis and ensuring that regulatory policies are implemented gradually and can be well managed by authorities and industry.
2. **Hazard Classification and Identification.** The first key phase for the SMC is the implementation of the Globally Harmonized System of classification and labelling of chemicals (GHS), a system to identify and communicate essential information to workers and users, making processes and products improvements and preventing accidents.
3. **Chemicals information (inventories/ registers).** The purpose of the inventories and registers is to know the identity of the chemicals present in the country and the essential baseline information to proceed with the identification and management of associated risks. Most existing systems require basic data such as: identification of the substance, volume/quantity imported and/or produced, recommended, or identified uses, and hazards according to GHS. The various terminologies and approaches of these requirements are addressed in the relevant section. This information is essential for the decision-making process and facilitates the implementation of international conventions, such as the Rotterdam Convention. The document also addresses other important issues, such as the treatment of confidential information and acceptance of external data.

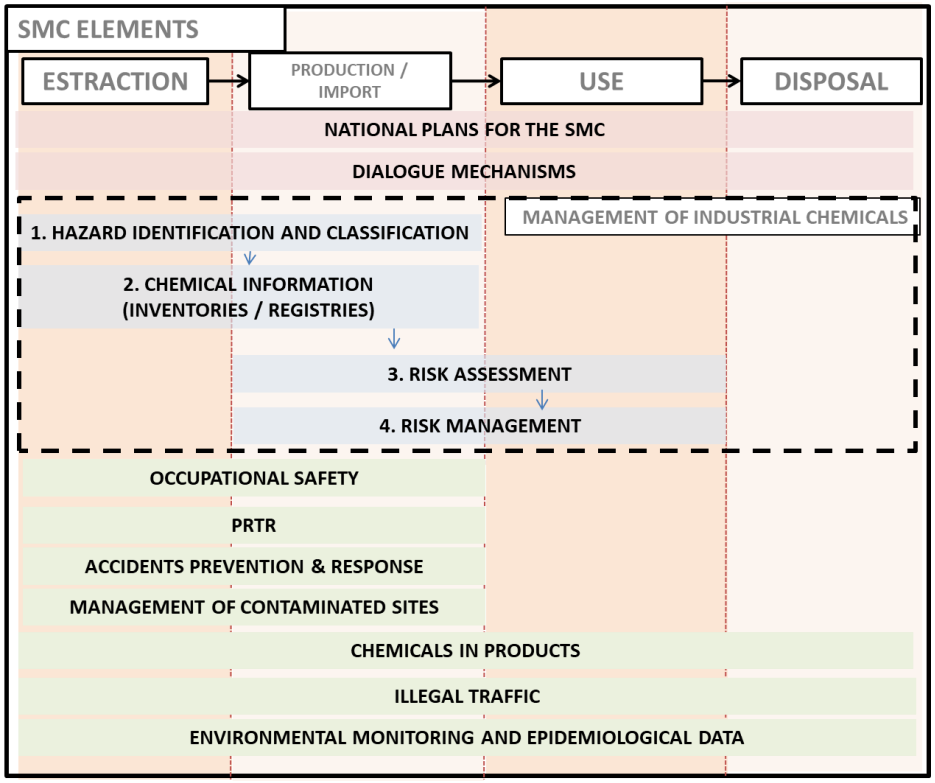

Figure 1: SMC Elements. Source: VWG-SMC-LA.

This figure is intended to briefly represent both the general chemicals management framework (full chart), and the specific elements closely related the industrial chemicals management (dotted line block). For each element, a direct relationship with the life cycle stages of chemical substances and mixtures -in its reduced version- has been established to facilitate understanding. All elements are explained throughout the document. NOTE: it should be noted that in the case of "production / import" several scenarios may occur import as a prior step to production; only import, or production without intermediate stages.

4. **Prioritization, risk analysis, assessment and management.** Inventoried/registered substances are prioritized according to their potential risk, based on the analysis of their intrinsic properties, recommended or identified uses and exposure scenarios. The prioritized substances are studied through a detailed scientific evaluation, where potential risks to human health and the environment are identified,

based on their hazard and exposure derived from their manufacture, fractionation, handling, distribution, storage, use, transport and disposal. Following the OECD recommendations, it is suggested to use risk assessments made by other countries or international organizations and to maintain agreements with the relevant government areas, involving all relevant actors, in order to speed up the actions, reduce costs and generate harmonized requirements. Risk management is a subsequent process, where decisions are based on the results of the risk assessment, in order to develop, analyse and compare regulatory and non-regulatory measures for risk mitigation and control, to be implemented by the different actors, with the aim of reducing the impacts on health and the environment identified.

5. **Occupational safety[2].** The implementation of a safety system for workers and establishments is the first step to help prevent or reduce the risks of occupational diseases, injuries and accidents during the manufacture, fractionation, handling, distribution, storage and transport of chemicals and prevent adverse effects on the environment. Elements of the security practices of the establishment and worker include: personnel training, process safety, facility design, occupational health and safety, pollution prevention, waste management and transportation safety. These approaches must be risk-based and flexible enough to enable the industry to grow and deliver good long-term performance.
6. **Pollutant release and transfer registry (PRTR).** Its aim is to strengthen countries' capacities to track the release and transfer of certain chemicals by industrial facilities and diffuse sources, which could pose a threat to human health and the environment. The document highlights the importance of promoting greater harmonization of PRTRs to achieve a global analysis of pollutants emissions and facilitate cross-country comparisons and highlights the role of the Escazú Agreement in promoting registries in Latin America and the Caribbean.
7. **Accident prevention, preparedness and response.** Regarding this element, the document indicates that information and training are critical components for the successful implementation of any accident program with chemicals in the workplace and, therefore, efforts should be made to guarantee that it is always available, accessible, and up to date. It also indicates that countries can design and implement their plans based on the information generated under the GHS and/or risk analysis, centrally in the country or region. The involvement of all stakeholders is essential at each stage related to accident preparedness and response, including the preparation and training of civil organizations and the population in evacuation and isolation from events that exceed the manufacturing area, when necessary.
8. **Remediation of contaminated sites.** The document is based on the "Polluter Pays Principle", adopted by the OECD Council in 1989. Furthermore, it indicates that based on the enormous variety of site characteristics and nature of chemicals, risks for human health and the environment also vary. In that respect, some countries and industries are implementing a risk-based corrective action (RBCA) approach, as a consistent decision-making process for the assessment and response to chemical contamination.
9. **Chemicals in products/articles.** Some chemicals classified as hazardous under the GHS are found in consumer products throughout the world. This results not only in the potential exposure of workers during manufacturing, but also of the general population during use, of the informal sectors involved in recycling and disposal and of the environment, through waste releases. It is emphasized that the exchange of information through the value chain is key to identify and address the

[2] In some countries, facility and occupational safety matters are treated by specific norms not related to the SMC. In some others, they are included under the element "Accident prevention, preparedness and response".

safe handling of hazardous chemicals according to the GHS in consumer products/goods.

10. **Illegal Trade.** This document highlights the importance of instruments such as SAICM, which establishes specific goals regarding illegal trade, including the strengthening of mechanisms for the implementation of existing multilateral agreements and the promotion of information exchange among countries, such as the Rotterdam and Basel Conventions.
11. **Environmental and epidemiological data monitoring.** Monitoring data is valuable as confirmatory information for exposure assessment, effectiveness of management measures, determination of compliance with regulatory standards, identification of future problems, research and technological development.

Finally, this document explains **Regulatory Cooperation**, its implications and benefits, as a measure that governments can use to make efficient use of resources. When establishing a new chemical regulation or updating existing regulations, countries can use and take notice of lessons learned from existing regulations in other countries and adapt them according to their local needs and circumstances. Although it is a highly beneficial approach, international Regulatory Cooperation remains largely undervalued by governments.

In Latin America, an approach to these initiatives has been observed in recent years, as some economies work to comply with international commitments, are part of trade blocs where common regulations exist or are being worked on, or seek to join economic organizations (e.g., OECD). This context represents a great opportunity to develop a regulatory framework jointly, on the basis of mutual recognition of approvals, databases and digitization.

2. KEY TERMS

Chemical product / chemical [3] **:** substance and/or mixture of substances with certain percentages or percentage ranges of the chemical. *Note: The term product is sometimes used to refer to chemicals, mixtures and articles.*

Hazard[4]**:** Inherent property of a substance or mixture to cause adverse effects when an organism, system or (sub)population is exposed to that chemical.

Industrial chemicals[5]**:** defined by default as any chemicals that are NOT managed through legislations dedicated to specific uses, such as pharmaceuticals, pesticides, biocides, etc.

Mixture[6]**:** Mixture or a solution composed of two or more chemicals /substances in which they do not react. The term preparation is synonymous to mixture.

Sound management of chemicals[7] **(SMC):** Adoption of all possible measures to ensure that chemicals are handled in such a way that the environment and human health are protected against the harmful effects that may result from them throughout their life cycle.

Substance [8]**:** Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

[3] Source: IOMC Toolbox
[4] Source: adapted from OECD
[5] Source: OECD
[6] Source: IOMC Toolbox
[7] Source: adapted from Basel Convention. Note: Other possible terms for "sound" are "integrated" or "safe".

3. INTRODUCTION

Chemicals are fundamental components of the world we live in. They are essential for products manufactured every day. Intrinsic hazards and exposure derived from their different uses can generate risks that, if not properly managed, can negatively impact human health and the environment.

SMC allows economies to reap the benefits that their use can offer. It can be considered as the adoption of all possible measures to ensure that chemicals are handled in such a way that the environment and human health are protected against the harmful effects that may result from their use, throughout their life cycle and value chain (production, trade, use, releases, and disposal)[9].

Chemicals and wastes are part of global development, and their sound management has been supported for decades in various international frameworks. These act as guiding principles for best practices and regulatory policies and are platforms for the generation and exchange of information. The main global agreements and actions include:

- **The Organisation for Economic Co-operation and Development (OECD):** Founded in 1960, it assists countries in the implementation of policies and instruments for the establishment of robust and efficient chemicals management systems, to protect human health and the environment. With a considerable number of legal instruments, OECD has a remarkable role as a promoter of SMC in the region, since there are numerous cases of countries that, based on their interest in joining as members, begin very serious processes

[8] Source: GHS – Substance definition
[9] More information available in: APEC Committee on Trade and Investment (CTI) *Chemical Dialogue (2020). Survey for Review of Chemical Management Regulatory Systems Worldwide*. Available at: https://www.apec.org/Publications/2020/04/Survey-for-Review-of-Chemical-Management-Regulatory-Systems-Worldwide

of institutional strengthening in this matter with the consequent adoption of the OECD Council Acts Related to Chemicals and Environmental Policies.

- **The 2030 Agenda for Sustainable Development and its 17 Sustainable Development Goals (SDG),** adopted by the United Nations General Assembly in 2015 (sound management of chemicals and wastes is directly related to SDGs 3, 6, 7, 11, 12 and 14).
- **Inter-institutional Programme for the Sound Management of Chemicals (IOMC),** which has brought together nine intergovernmental organizations since 1995, intending to strengthen international cooperation and increase the effectiveness of international programs.
- **The International Conference on Chemicals Management (ICCM) and the Strategic Approach to International Chemicals Management (SAICM),** a policy framework for promoting chemical safety worldwide, organized by the United Nations Environment Program, which was born in support of the fulfilment of the 2020 goal agreed at the World Summit on Sustainable Development in Johannesburg in 2002.
- **Other multilateral environmental agreements (MEAs) and international instruments** [10].

In 2006, ministers, heads of delegation and representatives of civil society and the private sector, met at the International Conference on Chemicals Management (ICCM) and declared in the Dubai Declaration on International Chemicals Management:

"The sound management of chemicals is essential if we are to achieve sustainable development, including the eradication of poverty and disease, the improvement of human health and the environment and the elevation and maintenance of the standard of living in countries at all levels of development."

Other benefits of sound management of chemicals include:

- **Improving the protection** of the health of workers, general population and the environment.
- **Reducing costs of inaction.** By taking preventive measures to minimize the adverse effects of chemicals on human health and the environment (and thus reduce, for example, the number of work-related accidents or unintentional poisonings), governments reduce costs related to healthcare and accident response.
- **Improving of governments and industry reputation when management is effective and predictable.** The general public is increasingly concerned about the safe use of chemicals and, at the same time, acknowledges and expects action by governments in this regard. As governments and industries demonstrate that they are protecting public health and the environment by promoting SMC, the confidence of the general public increases.
- **Increasing productivity and competitiveness.** Information improves workers' safety and therefore reduces the number of accidents and the occurrence of occupational diseases. As a result, a healthier population is more productive and generates wealth.

[10] Among others: The International Convention for the Prevention of Pollution from Ships (MARPOL); ILO Chemicals Convention No.170 which provides the basis for the sound management of all types of chemicals at the workplace; and Mo.174 on the prevention of major industrial accidents; the Vienna Convention for the Protection of the Ozone Layer and the Montreal Protocol on Substances that Deplete the Ozone Layer; Basel Convention on the Control of Transboundary movements of Hazardous Wastes and their Disposal; Paris Agreement -The Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction-; Globally Harmonized System of Classification and Labelling of Chemicals (GHS); Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; Stockholm Convention on Persistent Organic Pollutants; Minamata Convention on mercury.

- **Increasing regional availability** of high-quality data and information on chemicals and how to use them safely.
- **Increasing industry profits in terms of efficiency, resource savings, and reduced compliance costs.** SMC enables the industry to: identify improvements in process safety; reduce insurance and maintenance costs; and prevent business risks related to liability claims.

4. DOCUMENT OBJECTIVES

This document is the result of the **Virtual Working Group on the Sound Management of Chemicals in Latin America (VWG-SMC-LA)** work. It consists of representatives from regional governments, industrial associations and industries and is coordinated by the International Council of Chemical Associations (ICCA).

The roadmap aims to provide an overview of the main SMC elements, based on the collection of existing information from relevant and internationally recognized sources. Each chapter is limited to brief and general descriptions, while aspects related to technical and implementation issues will be developed in future specific guidance documents.

The principles that guided the preparation of this document are the following:

- **Prevention:** Identify and implement measures based on science and a risk-based approach to avoid, and -when it is not possible- to minimize, the negative effects that industrial chemicals and substances could cause on health or the environment.
- **Comprehensiveness:** Management of industrial chemicals occurs in all life cycle stages.
- **Progressivity:** The objectives should be gradually design, with milestones and final goals, establishing periodic reviews based on experience to improve the system.
- **Cooperation:** Collaborate with others to promote the development and dissemination of best practices and innovations in regulatory policy and governance.
- **Articulation:** Promote the development of regulations in coordination among the different government sectors, with the active participation of the private sector, academia and civil society organizations.
- **Efficiency:** Regulatory Cooperation as a mechanism to save resources, based on existing regulations of other countries and customizing them according to local needs and circumstances.
- **Efficacy:** Provide a regulatory framework that promotes an impact analysis on health, environment and socio-economic matters, to ensure the safe and sustainable use of chemicals and provide a business operating environment that stimulates investment, growth, innovation and trade without unjustified load.
- **Transparency:** Open procedures and ensure participation in the decision-making process.

5. ROADMAP FOR THE SMC

In order to have a complete understanding of the SMC, it is relevant to understand the regulations, tools and methodologies that comprise it. To this end, based on the approach proposed by the **IOMC Toolbox[11] and OECD requirements** for chemicals management, among other documents, a breakdown of the SMC elements throughout in the life cycle is presented below.

The **life cycle approach** covers the entire supply chain, from resource extraction, synthesis and processing of a chemical substance or mixture, to waste management. It also includes the manufacture, use and handling of the product at the end of its useful life (e.g. recycling).[12] To limit the scope of this document, it should be specified that aspects related to waste management have not been included in this instance and will be developed in future specific guidance documents.

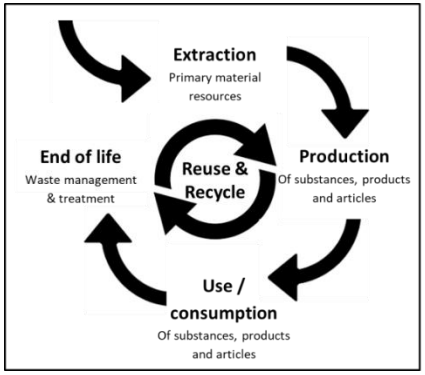

Figure 1: Chemicals life cycle stages. Source: Environmental European Agency (2014)[13], adapted by the VWG-SMC-LA

The scope of the following sections is limited to brief descriptions of each basic component of the SMC. Technical aspects and implementation approaches will be developed in specific guidance documents.

The diagram in Figure 1 aims to show all **the SMC elements** from a life cycle perspective.

National plan for the SMC and stakeholder dialogue mechanisms

The first challenge for countries is to assess their current situation, identify priorities according to national needs and circumstances and implement actions in a coordinated and integrated manner with the participation of all stakeholders.[14]

Any regulatory policy should be designed with a gradual approach, increasing complexity over time, to develop capacity and knowledge in the regulated sector and regulators, and to ensure that regulations can be well managed. The development of a national plan should ensure a cost-benefit analysis process associated with the implementation of any regulation, allowing governments to explore options for regulatory approaches and promoting alignment and consistency among the systems already installed in the country. In recent years, conducting **Regulatory Impact Assessment** (also known as RIA) has become an essential element within good regulatory practices. The OECD places particular emphasis on this resource, including it in its Recommendations on Regulatory Policies and Governance (2012).[15]

The highest priority when designing a plan for the sound management of chemicals is to clearly define roles and responsibilities of stakeholders, both from industry and government, especially with regard to generation,

[11]Access: https://iomctoolbox.org/
[12] MZ Hauschild, Assessing environmental impacts in a life-cycle perspective, Environ. Sci. Technol., 2005, 39, 81A –88A
[13] Available in: https://www.eea.europa.eu/soer/2010/synthesis/synthesis/chapter4.xhtml

[14] The OECD Environmental Performance Reviews for countries that aim to join the organization are also helpful during this process.
[15] OECD (2020). Regulatory Impact Assessment, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris. Available at: https://www.oecd-ilibrary.org/governance/regulatory-impact-assessment_663f08d9-en

dissemination and management of information. The government is responsible for developing laws and regulations and enforcing legal requirements. Manufacturers and importers must comply with regulations on chemicals prohibited, restricted or subject to authorization. Among others, they must classify and label all hazardous chemicals; maintain and share information (through notification in an inventory or registry) with the government as needed; and generate **Safety Data Sheets (SDS)** to distribute them later, as manufacturers and importers have the best knowledge of the products they produce or import. They also need to organize their data and provide safety instructions for employees, among other functions. Downstream users and retailers should follow regulations on prohibited and restricted chemicals; verify labelling; handle chemicals properly; properly package and store chemicals; and maintain and share records with the government as needed[16].

It is recommended that any framework for the management of industrial chemicals be subject to an open and transparent process of discussion with all stakeholders (government, industry, non-governmental organizations, academia and civil society organizations). Each stakeholder should contribute their specific expertise and interest in developing the plan.

Hazard classification and identification

The first key phase for the sound management of chemicals is to **identify and communicate essential information** about the products to workers and users (e.g. identification, physicochemical properties and hazards).

In order to harmonize existing hazard classification systems and converge into a single global one, experts from different countries, international organizations and stakeholders created the **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** with the publication of the "Purple Book " in 2003.

HAZARD

Hazard is the inherent property of a substance having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that substance.[17]

This work, which took more than 10 years to complete, is based on extensive scientific knowledge and experience ranging from toxicology to fire protection fields and is subject to a continuous updating process, conducted by the **United Nations Sub-committee of Experts on GHS (UN-SCEGHS)** every 2 years. It was developed based on harmonization principles (see GHS 8th Rev., page 4). The GHS provides:

- Harmonized criteria for classifying chemicals according to physical hazards, health hazards and environmental hazards; and
- Harmonized hazard communication elements, including labelling and SDS requirements.

The 8th version of the GHS adopted in 2019 is available on the website of the United Nations Economic Commission for Europe (UNECE).

Scope of the GHS

The UN-SCEGHS carefully agreed on three critical parameters to apply the GHS in a country or region:

1. While the system covers all hazardous chemicals, how the hazard communication elements of the GHS are applied may vary depending on the product category or life cycle stage. The system's target

[16]More information available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/28403/ChemContAut.pdf?sequence=1&isAllowed=y y https://wedocs.unep.org/bitstream/handle/20.500.11822/28402/ChemContLeg.pdf?sequence=1&isAllowed=y

[17] Source: OCDE

audiences include: consumers, workers, transportation workers and emergency personnel;

2. The establishment of uniform test methods or the promotion of additional tests is not mandatory under the GHS;
3. Human experience, epidemiological data and clinical tests also provide important information to be taken into account in the application of the GHS.

It should be noted that the wide availability of existing -and validated- information on chemicals significantly facilitates the implementation of these systems in the countries, especially for governments and companies with limited resources. Among other available resources, the OECD has promoted the **e-Chem Portal**[18], which is continuously updated and refined, taking information from databases, inventories and registers, from countries with long experience in chemicals regulation.

The GHS covers four key sectors, namely: workplace, agriculture, transportation, and consumer products. Countries may decide to prioritize GHS implementation in some sectors, depending on their needs.

Substances, their solutions and mixtures are part of the scope of GHS. "Articles" are beyond the scope of the system.[19]

GHS does not cover the harmonization of risk assessment or risk management procedures. These are more complex processes than hazard classification.

Building blocks approach

Hazards are classified into three types: physical hazards, health hazards, and environmental hazards. The GHS has developed clear and harmonized criteria for each class, which constitutes a system comprised of elements from which a normative approach can be formed, and can be seen as blocks. Under the GHS, governments are free to determine the blocks to apply, as long as they maintain the consistency of the system. Hazard classes can be considered blocks, as well as a category within a hazard class. For the latter, certain restrictions have been established to ensure system coherence (see GHS Rev. 8, page 8).

Since the building-block approach allows governments to customize GHS regulations to better suit each country, this can lead to significant discrepancies among countries and thus trade barriers. It is suggested that governments carefully consider how they implement this system through their national regulatory processes. The best approach would be an alignment with the systems of main trading partners, which would increase trade opportunities while protecting human health and the environment.

Currently, many Latin American countries are implementing or considering the implementation of GHS. Although the system is restrictive in the definitions of the hazard classes, it is noted that modified local systems may lead to inconsistencies in the classifications of chemicals[20]. As international trade continues to increase, it becomes essential to minimize technical barriers. An aligned GHS approach across the region (building blocks adopted, scope of implementation) would not only ensure that workers and

[18]Access: https://www.echemportal.org/ y https://www.icca-chem.org/chemical-industry-calls-for-global-data-sharing-on-chemicals-to-improve-chemical-safety-worldwide/

[19]Under the standard 1910.1200 of the United States Occupational Safety and Health Standards (OSHA), "Article" means *a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.*

[20] It is worth to mention that even if they could be minimized, it is not possible to eliminate differences because the sources of data are not harmonized.

citizens are protected and informed by regulations that have proven to be effective but would also facilitate the trade of chemicals.[21]

Chemicals information (inventories / registers)

Driven by safety concerns, governments and other stakeholders endeavour to safely evaluate and manage chemicals in their life cycle. To achieve this goal, many countries have established their own regulatory frameworks for chemicals which, despite differences in purpose and scope, all establish an initial inventory or register[22] of chemical substances manufactured, imported and/or used in the respective jurisdictions. The main objective of these instruments is to screen the substances present in the country and gather the necessary information to proceed with their risk identification and management.

The diagram in Figure 3 summarizes the steps that are commonly taken during the development of inventory/register, risk analysis, assessment and management regulations, aspects that will be developed in greater detail in subsequent sections.

Most countries request notification from producers or importers when their annual average import or production amount exceeds a certain value[23]. The notification includes: chemicals identification –for which the CAS number (Chemical Abstracts Service) is usually used-, volume/quantity imported and/or produced -which can be notified in ranges or averages-, recommended or identified uses[24] and hazards identified according to GHS. It should be clearly defined if additional information is required -this generally applies only to larger volumes or quantities and in relation to the risk profile of the substance-[25].

As inventory or registry information is completed, governments must verify that it corresponds to what was requested. Such a scheme should ensure that all submissions are safe and secure, not just those containing confidential information.

Confidential business information should be available only to authorized persons. Government officials must have the legal authority to collect data and protect confidential business information. Government departments must have access to all stored information that is necessary for their work. All information should be collected in a centralized, electronic system for data and reports presentation. The stored information should be made available to interested parties so that they can fully participate in subsequent risk management steps. The public should have access to non-confidential information relevant to health and environmental safety.

[21] An example to illustrate inconsistencies in the implementation of GHS is the Project ECONORMAS MERCOSUR (2009-2015), from which an exhaustive legal analysis led to the identification of differences among members' legislation and GHS requirement.
[22] In this document, for the sake of simplicity, the terms "inventories" and "registers" are treated as equivalent. However, it is highlighted that they can be treated differently in some jurisdictions and documents, such as in the "UNEP Guide on the development of legal and institutional infrastructures and measures to recover the costs of the national Administration in the rational management of chemicals" Sections 4.4.1, 4.4.4 and 4.4.1. Available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/12224/LIRA_Guidance%20Report_Spanish.pdf?sequence=3&isAllowed=y
[23] Some examples: 100kg (Australia, Canada -new substances-, South Korea and Sweden, among others), 1000kg (Canada –pre-existing substances-, Japan, and the European Union through REACH, among others).
[24] The VWG-SMC-LA recognizes the existence of multiples options to refer to this requirement (among others: "intended uses", "destined uses"). Under GHS, it is considered any use for which the chemical is intended or recommended.
[25] IOMC Toolbox provides some examples of additional information: notifier/registrant, production/import, foreseen uses, estimated and measured exposures for the stages of the life cycle, hazard information, risk assessments for the foreseen uses, risk management through labelling, and safety data sheets.

Developing new individual inventories may not always be the most appropriate scheme, particularly if major trading partners have already established inventories that contain a similar list of substances. As an alternative, countries can implement a "Mutual Acceptance" scheme[26], by accepting the information provided in another country's inventory, or a combination of these two approaches. On the other hand, the OECD's Mutual Data Acceptance System is a multilateral agreement that aims to avoid duplication of studies in a country through the validation of data already generated by external parties. OECD requires that tests be performed under protocols, ensuring quality and integrity.[27] This type of scheme is essential in economies with limited resources, and for that reason, the region is urged to consider its implementation when designing national policies.

It should be noted that inventories by themselves do not provide a mechanism to identify chemicals that may represent an unreasonable risk to citizens and the environment, but they are the first necessary step to implement a risk management scheme. Likewise, inventory information is essential for the implementation of the prior informed consent procedure of the Rotterdam Convention, which requires governments to be aware of the chemicals used in their country.

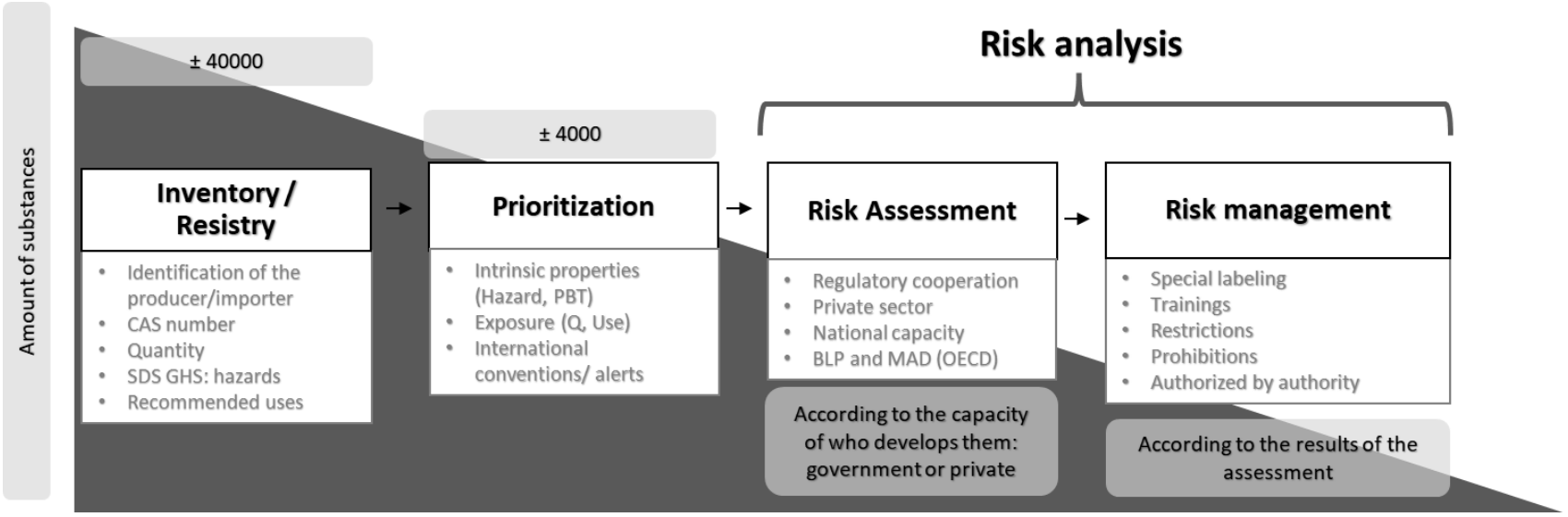

Figure 3: Common steps for the development of inventories/registers, prioritization, risk analysis, assessment and management regulations. Source: VWG-SMC-LA

[26] For example, Mutual Acceptance of Data of new substances between Australia and Canada. More information in: https://www.ec.gc.ca/subsnouvelles-newsubs/default.asp?lang=En&n=7BB979DD-1

[27] All OECD member countries, as well as non-member provisional and full adherents, participate in MAD but to different degrees. The determining factor is whether a government's national GLP compliance monitoring programme has undergone a successful OECD evaluation. More information in: https://www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm

Special Considerations: New Substances, Articles and Mixtures

When applying a phased approach, at least during the initial stages of the implementation, it is not recommended to include the notification or evaluation of mixtures, but rather to focus on individual substances and those present in mixtures. The large existing number of mixtures and articles makes their inclusion extremely complex and requires numerous resources from government and industry.

It is important to distinguish between products and articles. Certain chemicals can be added to articles, others can be used to formulate products and others are used for both. For the purposes of exposure assessment, products and articles are treated differently. The formulations, conditions of use and available approaches to estimate exposure are different.

With regard to the notification requirements for new substances, countries must differentiate between pre-existing substances, those that have been on the market before implementing the chemical inventory or registers, and new substances. For example, while the submission of a risk assessment may be a requirement for trade of new substances, for pre-existing ones it is not. The latter should be subject to a systematic review, and the submission of risk assessments must be based on a prioritization mechanism, as will be seen below.[28]

Prioritization, analysis, assessment and risk management

Prioritization[29]

To implement the SMC, a country may use criteria to identify those chemicals subject to priority risk management action. Priority setting should be based on the potential risk to human health and the environment, and the opportunity to reduce it, focusing on the inherent properties of the substance, recommended or identified uses and associated exposure scenarios[30].

Government and industry resources should focus on prioritized chemicals and allow certain exclusions for risk management of non-prioritized, being able to establish two categories: low priority and high priority. Low-priority chemicals would require no further action or review, while high-priority chemicals would be subject to risk assessment.

Priorities should be based on aspects such as health and environmental hazards, volume of the chemical in trade; recommended or identified uses (with special attention to certain circumstances, for example, products for children); detection in biomonitoring programs; persistent or bioaccumulative properties, among others. Criteria for the selection of chemicals to be prioritized for the development of risk assessments may include, among others:

1. Persistence and toxicity to the environment.
2. Bioaccumulation and toxicity for the environment.
3. Persistence, bioaccumulation and toxicity for the environment.
4. Carcinogenicity, mutagenicity or toxicity for reproduction.
5. Characteristics of endocrine disruptors, based on scientific evidence.
6. Relevant potential or evidence of human or environmental exposure.
7. Be under international alert, or in any international agreement or convention of which the country is a signatory.

[28] ICCA Toolbox
[29] ICCA Toolbox
[30] Additional information is available in the American Chemistry Council (ACC) document "ACC Prioritization Screening Approach": https://www.americanchemistry.com/Prioritization-Document/#:~:text=An%20initial%20screening%20approach%20for,elements%20that%20define%20risk%20potential.&text=For%20initial%20screening%20purposes%2C%20the,used%20to%20rank%20all%20substances

The definition of low concern substances could be based on considerations such as: low hazard, low volume, use in research and development (R&D), or particular cases such as polymers of low concern[31].

Since the same substance can involve different exposure scenarios with differentiated risks depending on its use, some approaches propose that prioritization also be carried out based on the **high priority uses** of a substance.

The way in which different countries approached prioritization has been studied and compared over the years, serving as a source of consultation for those that have not yet established these mechanisms. To explore possible options, it is suggested to consult the recent OECD document "*Best International Practices for Identifying Priorities in Chemical Substances Management Systems*" [32], which describes the prioritization schemes of Germany, Australia, Canada, the United States, Finland, Holland, Japan, New Zealand, and the European Union.

Risk analysis and assessment

Once the highest priority chemicals are identified, they must undergo a risk assessment. Since there is often confusion regarding the terms risk analysis and risk assessment, this document follows the recommendation of the WHO guide[33] which considers that "risk analysis" is a process that incorporates three elements: risk assessment, risk management and risk communication. Regarding the risk assessment of an industrial chemical substance, the following definition is taken:

A risk assessment consists of scientific analyses, the results of which are quantitative or qualitative expressions of the likelihood of harm associated with exposure to a chemical substance – Source: WHO, 2021[34]

These assessments are intended to identify and evaluate potential risks to health and the environment derived from the manufacture, fractionation, handling, distribution, storage, use, transport, and disposal of the chemical. Evaluations must use quality data and information -e.g., validated internationally-, with objective and accepted protocols, and in a transparent manner (peer-reviewed). Business partners can join efforts and collaborate in the development of risk assessments.

Risk characterization can be performed at an initial level with base information and deepened by going through a more detailed and/or complete level. Since the greater the progress at the level of risk characterization, the greater the resources required (more sophisticated data and evidence), such assessments are often considered for high priority chemicals.

Given that resources are limited, the proposed implementation steps for this sub-element are:

1. Make use of risk assessments done by other countries or international organizations;
2. Agree on the risk assessment with the relevant government areas and with stakeholders' involvement. This should include the consideration of whether the use conditions of the substance in the country are comparable to those that are being used as a reference.

[31] The OECD Working Group on Polymers (2009) established that *"polymers of low concern are those deemed to have insignificant environmental and human health impacts. Therefore, these polymers should have reduced regulatory requirements."* However, no specific criteria were defined by OECD. More information available in: https://ec.europa.eu/environment/chemicals/reach/pdf/FINAL%20REPORT%20POLYMER%20SI671025.pdf

[32] OECD (2019) International Best Practices for Identification of Priorities within Chemicals Management Systems. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2019)34&doclanguage=en

[33] World Health Organization (WHO). (2021). WHO human health risk assessment toolkit: chemical hazards, second edition. Geneva. IPCS harmonization project document, no. 8. Licence: CC BY-NC-SA 3.0 IGO. https://apps.who.int/iris/bitstream/handle/10665/350206/9789240035720-eng.pdf?sequence=1&isAllowed=y

[34] Ut supra

RISK CHARACTERIZATION

Risk characterization is a process aimed at calculating or estimating the risk to a given target organism, system or (sub) population, after exposure to a chemical and/or mixture, considering its inherent characteristics, as well as the characteristics of the specific target organism, system or population. The determination should be qualitative and, wherever possible, quantitative and include the likelihood of known and potential adverse effects of the chemical and/or mixture occurring under defined exposure conditions, and uncertainties.

Risk characterization is part of the final stage in a risk assessment and is performed using the results of both the hazard assessment and the exposure assessment.

Risk assessment and socio-economic analysis involve the establishment of a qualitative or quantitative relationship between the risks of exposure and the socio-economic benefits of the chemical. It implies a complex process of determining the impact of identified hazards, exposure scenarios and estimated risks for the system under evaluation, as well as the weight of the benefits associated with trade and use of the chemical and its mixtures.

Risk management

Risk management is a decision-making process to develop, analyse and compare regulatory and non-regulatory control and mitigation options to be developed by different actors, and select and implement those that allow reducing the defined impact on health and the environment. It involves the consideration of relevant information, obtained from the risk assessment, related to the hazards and exposure to a chemical, and the socioeconomic aspects (political, social, economic and technical factors), which could include the benefits associated with the measures.

Chemicals that present an unacceptable risk to human health or the environment in certain uses or applications must be subject to risk management. The set of measures to prevent or manage risks can include: adopting safe handling practices; codes of conduct, training and education; special labelling requirements; restrictions on use, of manufacture or of quantity released into the environment; or, when there is an unreasonable risk that is not otherwise manageable, bans and phase-outs.

Risk assessments are based on progressive analyses where the level of risk reduction or elimination is studied by taking a certain management measure. For that reason, prohibitions or restrictions should only be used as a last resource, when other means of risk control run out.

Other options -voluntary or mandatory- to anticipate and prevent risks include, for example: additional tests to determine the hazard; monitoring (human health or environment); pollution prevention; reduction of hazardous waste and emissions; environmentally sound recovery and waste recycling; application of green chemistry principles for safer alternatives; informed substitution and cleaner production; *Chemical Leasing*[35]; job safety programs and public awareness campaigns.

Regulatory Cooperation can also promote alignment among business partners on risk management measures, although regulatory decisions must remain sovereign for each state[36].

The resources required for risk management will depend on the number of chemicals included in the work plan and the elements of risk assessment required.

[35] More information available at: https://www.unido.org/sites/default/files/2013-08/Chemical_Leasing_Spanish_0.pdf

[36] ICCA Toolbox (modified)

Work safety

The implementation of a safety system for workers and the workplace is the first step to help prevent or reduce the risks of occupational diseases, injuries and accidents during the fractionation, handling, distribution, storage and transport of chemicals, and prevent adverse effects in the environment. Safety practices include: personnel training; process safety; facility design; occupational health and safety; pollution prevention; loss analysis; waste management and transport safety. These approaches must be risk-based and flexible enough to allow the industry to grow and deliver good long-term returns.[37]

RISK-BASED

Risk-based means "based on the integration and evaluation of data and information on hazards and exposure to one or more substances, mixtures or chemical products, including the circumstances in which they are used."[38]

As indicated by the OECD[39], there is a need to establish high standards of corporate governance and essentially ensure commitment from the industry to implement those standards.

Effective control of chemical hazards in the workplace requires an efficient flow of information from manufacturers or importers to users on existing hazards and on safety precautions to be taken. This flow of information must be followed by daily actions taken by employers to ensure that the necessary measures are established to protect workers and, consequently, the public and the environment.[40]

Occupational and facility safety systems should aim to:

- Ensure that all chemicals are evaluated for their hazards;
- Provide employers with a mechanism to obtain information from suppliers on chemicals used in the workplace so that they can implement effective programs to protect workers from chemical hazards;
- Provide workers with information on chemicals in their workplace and facilitate them training on appropriate preventive measures to enable them to participate in protection programs;
- Establish principles for such programs to ensure chemicals are used safely.

Key elements[41]

- **Identification of chemicals, classification system, labelling, and generation of SDS:** Suppliers must ensure that updated SDS of hazardous chemicals are prepared and provided to employers. Workers and their representatives should have the right to access to them and to receive information in languages and formats that they can easily understand.
- **Information and training:** Employers must train workers on continuous basis on the practices and procedures to be followed for the safe use of chemicals at work including the hazards associated with exposure, how to obtain and use the information provided on labels and SDS, how to use the SDS of a chemical together with workplace-specific information.
- **Storage and transport:** The establishment of specific rules and conditions for safe storage and transport reduces the risks of

[37] ICCA Toolbox (modified)
[38] ICCA Toolbox
[39] OECD (2012). *Corporate Governance for Process Safety. Guidance for Senior Leaders in High Hazardous Industries.* Available at: http://www.oecd.org/chemicalsafety/chemical-accidents/corporate%20governance%20for%20process%20safety-colour%20cover.pdf
[40] International Labour Organization (ILO). *Safety in the use of chemicals at work.* Available at: https://www.ilo.org/wcmsp5/groups/public/---ed_protect/---protrav/---safework/documents/normativeinstrument/wcms_107823.pdf
[41] IOMC Toolbox, https://iomctoolbox.org/node/50035/steps

accidents and adverse events. Hazardous chemicals must be stored under conditions specific to their inherent properties to ensure safety and in accordance with established criteria.

- **Disposal:** Hazardous chemicals that are no longer needed and containers that have been emptied, but may contain residues of hazardous chemicals, should be handled or disposed of in a manner that eliminates or minimizes the risk to health and the environment, in accordance with national standards and best practices.
- **Exposure:** Reduce exposure to hazardous chemicals as much as possible, ensuring that workers are not exposed to an extent that exceeds exposure limits or other exposure criteria.
- **Operational controls:** Employers must conduct workplace hazard assessments in order to take control measures that reduce or eliminate worker exposure to hazardous chemicals.
- **Biomonitoring and environmental monitoring:** Periodic control of the parameters of interest in workers and the work environment to evaluate the effectiveness of prevention and control measures.

Pollutant Release and Transfer Register (PRTR)

A Pollutant Release and Transfer Register (PRTR) is a publicly accessible catalogue or database of releases and transfers of potentially harmful chemical substances that includes information on the nature and quantity of such releases and transfers. Data for PRTRs can be collected from point sources of pollution, such as factories, as well as non-point sources, such as means of transportation. A PRTR generally covers emissions to air, water and soil, as well as wastes transported to treatment and disposal sites.[42]

Its objective is to strengthen the capacity of countries to track the amount of certain chemical substances released that may represent a threat to human health and the environment. The collection of this data helps to support decision-making processes and constitutes a means of information, linking industry, government, non-governmental organizations and the general public.[43]

PRTR SYSTEMS PRINCIPLES

When designing a PRTR, a country should consider the principles related to the establishment of PRTR systems outlined in the OECD Council Recommendation on the Implementation of Registers of Pollutants Releases and Transfers for the implementation of PRTRs.[44]

Goals and specific objectives

A PRTR shall be used to:

- Provide data to support identification and assessment of potential risks to human health and/or the environment by identifying sources and quantities of pollutant releases and transfers to all environmental matrices;
- Promote the prevention of contamination at the source, for example, by installing cleaner technologies or closed processes;
- Evaluate the progress of environmental policies and assess the extent to which environmental objectives are or may be achieved;

[42] OECD, Implementing a National PRTR Design Project: A Guidance Document. Available in: http://cwm.unitar.org/cwmplatformscms/site/assets/files/1219/unitar-_1997_implementing_a_natl_prtr_design_project.pdf

[43] IOMC toolbox

[44] OECD (2018). Recommendation of the Council on Establishing and Implementing Pollutant Release and Transfer Registers (PRTRs). Available at: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0440

- Promote corporate responsibility and compliance with environmental obligations; and
- Strengthen public access and participation in decision-making processes.

Many of the currently existing PRTR systems were originally designed for a single country or region. As such, the data collected by each system has been shaped by specific factors related to them and is often not comparable with the data collected by other PRTR[45]. In its recommendations, the OECD proposes that national systems allow, as far as possible, comparison and cooperation with other global PRTR systems and possible harmonization with similar international databases.

Further harmonization of PRTR data would provide greater opportunities for a global analysis of pollutant emissions and facilitate cross-country comparisons. This is particularly important for pollutants of global concern, such as greenhouse gases, persistent organic pollutants (POPs), and metals such as mercury, which are known for their long-distance transport through the environment to regions where they are not have been used or released.

In line with the above, it should be noted that the Regional Agreement on Access to Information, Public Participation and Access to Justice in Environmental Matters (Escazú Agreement) in Latin America and the Caribbean contains specific provisions on PRTR. It establishes in its Article 6.4 that *"Each Party shall take steps to establish a release and transfer register covering air, water, soil and subsoil pollutants, as well as materials and waste in its jurisdiction. This register will be established progressively and regularly updated"*.

Chemical scope

The OECD PRTR Implementation Council recommends that countries consider that "*PRTR systems should include coverage of an appropriate number of substances that are released or transferred and can be potentially harmful to humans and/or the environment*". To improve the consistency of chemical coverage across registers, the OECD compared five systems and the Kiev Protocol (OECD, 2012). As a , the Organization developed two lists of chemical substances:

1. The *"Long List of Chemicals"* with 1,184 chemicals covered by the PRTRs studied;
2. The "*Short List of Chemicals*". It includes 126 chemical substances covered by MEAs such as the Stockholm Convention, the Kyoto Protocol and the Kiev Protocol, as well as others identified in 4 or more of the PRTRs under study.

To ensure that the chemical coverage of a PRTR is comparable, a country could include in its system at least all chemicals from the OECD "Short List".

Accident prevention, preparedness and response

Safe handling of chemicals and sustainable business success cannot be separated. Failures when controlling major hazards and poor process safety management lead to extremely costly consequences and deficient long-term

[45] OECD (2014). Guidance on Elements of a PRTR: Part I) Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono%282014%2933&doclanguage=en
OECD (2015): Guidance on Elements of a PRTR: Part II. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2015)45&doclanguage=en

OECD (2014): Global pollutant release and transfer register, proposal for a harmonised list of pollutants. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)32&doclanguage=en

performance for industries. Serious accidents may not only affect their profitability but could even wipe it out completely.[46]

Emergency response systems address chemical accidents, especially those that occur in facilities and during transportation. To be effective, these systems require planning and careful preparation, rapid access to information, and cooperation among emergency response personnel and governmental and private sectors[47].

The SDS contain very relevant information for emergency response plans. However, promoting risk assessment in the industrial environment and risk management can reduce the need for emergency response actions or improve their efficiency.

In the event of an emergency, as well as at each stage of preparedness, it is essential that all stakeholders involved, including chemical factories, transporters, storage facilities and emergency services, have access to reliable and updated information, thus ensuring the implementation of adequate measures. The mandatory provision of SDS to workers exposed to chemicals throughout the value chain should be part of such programs. Civil organizations and the general public must also be involved in the preparation and response in case evacuation or isolation is necessary due to events beyond the manufacturing area. The Responsible Care Program© of the chemical industry prepared the document "Community Awareness and Emergency Response Code" that develops this topic in greater depth.[48]

Information and training are critical components for the successful implementation of any chemical accident program and, therefore, efforts should be made to ensure that the information is available, accessible, and regularly updated.[49]

Most countries do not have enough personnel or other resources to do everything that is intended in a chemical accident program. Therefore, realistic goals should be set, and measures taken to ensure that sufficient resources are available for meaningful implementation. In this sense, the benefits associated with collaboration between different organisms, such as non-governmental organizations, other countries and international organizations, should be recognized.

The OECD has developed "Guiding Principles for Chemical Accident Prevention, Preparedness and Response" [50] that are designed to be comprehensive, aiming at:

- Prevent the occurrence of incidents (accidents and near-accidents) involving hazardous chemicals (for example, loss of containment of chemicals, explosions, fires, etc.).
- Prepare for accidents and mitigate their adverse effects through emergency planning, land use planning and communication with the public.
- Respond to accidents to minimize adverse consequences for health, the environment and private property.
- Track accidents, including initial clean-up activities, accident reporting and investigation.

[46] OECD (2012). Corporate Governance for Process Safety. Guidance for Senior Leaders in High Hazardous Industries. Available at: http://www.oecd.org/chemicalsafety/chemical-accidents/corporate%20governance%20for%20process%20safety-colour%20cover.pdf
[47] ICCA toolbox
[48] Available at: https://gpca.org.ae/wp-content/uploads/2018/05/1-Community-Awareness.pdf
[49] It includes, for example: a dictionary of local names for hazardous chemicals; information on the characteristics of hazardous chemicals; risk assessment methodologies; first aid measures; identification of dangerous facilities; accident reports. Much of the information is available from existing sources and therefore only needs to be collected and organized. Source: IOMC Toolbox
[50] OECD. (2003). Guiding Principles for Chemical Accident Prevention, Preparedness and Response. Available at: https://www.oecd-ilibrary.org/environment/oecd-guiding-principles-for-chemical-accident-prevention-preparedness-and-response_9789264101821-en

Management of contaminated sites[51]

"Remediation" is considered both the processes of providing a solution to an adverse impact, as well as the substantive actions that can "counter" or "repair" it. The type of remediation or combination of appropriate solutions will depend on the nature and extent of the adverse impact. The following may help determine the appropriate methods of remediation:

- **Existing standards:** In some cases, there are national and international standards or laws that determine what constitutes an appropriate method of remediation.
- **Precedent:** In the absence of national and international standards, it is suggested to study similar cases.
- **Stakeholder preferences:** The perspective of those affected by the impacts on health and the environment is important when analysing remediation options.

Activities that are causing or contributing to adverse impacts must be discontinued by the organization, which shall address those impacts by providing or cooperating in their remediation. When it is not feasible to address all of them at once, the organization should prioritize the order in which it takes action, based on the severity and likelihood of the adverse impact, for example, analysing when a late response would make the impact irremediable. Once the most significant impacts are identified and addressed, efforts should be focused on addressing the less significant impacts. While the prioritization process is ongoing, in some cases, new adverse impacts may emerge that should be prioritized before moving to less significant impacts.

POLLUTER PAYS PRINCIPLE - ACCIDENTAL POLLUTION[52]

The Recommendation on the application of the "Pollutes Pays Principle" (PPP), associated with accidental pollution, was adopted by the OECD Council in 1989. The Recommendation encourages the application of the principle in the case of accidental contamination in "dangerous facilities".

Risk-Based Corrective Action (RBCA)

Some countries and industries implement Risk-Based Corrective Action (RBCA) at contaminated sites, based on protecting human health and the environment. The RBCA is a consistent decision-making process for assessing and responding to chemical releases[53].

Chemicals in products/articles [54]

Some hazardous chemicals classified under the GHS are found in consumer products/articles, resulting in potential workers exposure during manufacturing, from informal sectors involved in recycling and disposal of the general population during use -with an emphasis on women and children- and the environment, through waste releases. Measures to reduce adverse effects associated with hazardous chemicals under GHS contained in products must consider the entire value chain. Only a few are currently regulated or prohibited by international agreements such as the Stockholm and Minamata Conventions.

[51] OECD. *Due Diligence Guidance for Responsible Business Conduct*. Available at: https://mneguidelines.oecd.org/OECD-Due-Diligence-Guidance-for-Responsible-Business-Conduct.pdf
[52] OECD. *Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution.* Available at: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0251
[53] More information: ASTM E2081 - 00 (2015) *Standard Guide for Risk-Based Corrective Action*. Available at: https://www.astm.org/Standards/E2081.htm
[54] Available at: https://chemicalswithoutconcern.org/program/chemicals-products

Information exchange in the value chain is key to identifying and addressing any chemicals of interest in products. Downstream users in the value chain (e.g. retailers) often lack essential knowledge about the properties and hazards of chemicals used to manufacture products, or those that are direct ingredients. Therefore, they are often unaware of the hazards of the products they sell.

Transparency of information on chemicals in global supply chains has been an emerging policy issue for SAICM since 2009, leading to programs such as the UNEP Chemicals in Products Program (CiP). This program specifically focuses on textiles, toys, electronics and construction materials. According to SAICM, if documentation of hazardous chemicals in products exists and is available, it must be available through supply chains and used to promote sound management.

Illegal traffic

International illegal traffic of hazardous chemicals is a pressing problem for many countries, especially developing countries and countries with economies in transition. Actions are needed at the national, regional and global levels to prevent and detect it, and to achieve a more effective implementation of the international agreements in the field of transboundary movements. In this regard, SAICM's objectives concerning international illegal trade are:

- Prevent illegal traffic of toxic, hazardous, prohibited and severely restricted chemicals, including products that incorporate these substances, mixtures, compounds and wastes;
- Strengthen national and regional implementation mechanisms of existing multilateral agreements that contain provisions related to the prevention of international illegal traffic;
- Promote the exchange of information and strengthen the capacity of developing countries and countries with economies in transition at the national and regional levels for the prevention and control of international illegal traffic.

The Rotterdam and Basel Conventions [55] play a key role in this matter. The first aims to promote shared responsibility and cooperative efforts on the international trade of certain hazardous chemicals in order to protect human health and the environment, and contribute to their environmentally sound use, facilitating the exchange of information on their characteristics, establishing a national decision-making process on their import and export, and disseminating these decisions to the Parties.

The Basel Convention, for its part, focuses its goals on reducing the generation of hazardous wastes and promoting their environmentally sound management, the restriction of transboundary movements of certain wastes and the implementation of regulatory systems for cases where international movement is allowed. This Convention tries to prevent any illegal traffic of hazardous wastes. For example, its Article 4.3 stipulates that *the Parties shall consider that illegal traffic in hazardous wastes or other wastes is criminal,* and 4.4. determines that *each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Convention*[56].

[55] Official Rotterdam Convention Website: http://www.pic.int/ and Basel Convention: http://www.basel.int/

[56] Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Convention, including measures to prevent and punish conduct in contravention of the Convention. More information available at the Illegal Traffic Manual (Spanish version): http://www.basel.int/Portals/4/Basel%20Convention/docs/legalmatters/illegtraffic/trman-s.pdf

Environmental and epidemiological data monitoring
57, 58

Monitoring data is valuable as confirmatory information for assessing exposure, evaluating the effectiveness of management measures, determining compliance with regulatory standards, identifying future problems and for investigation. When available, measured data is preferred over model estimations. Obtaining quality data that reflects actual concentrations can be very expensive, which means that the design of monitoring programs shall be effective and that existing national monitoring programs shall be evaluated to understand how to integrate current and future approaches.

The following are some limitations and challenges of monitoring:

- The data is usually not relevant for new chemicals.
- Due to high costs, it is not possible to monitor a large number of existing chemicals.
- It may be necessary to perform a preliminary risk analysis using estimates before considering establishing a monitoring program.
- It is necessary to consider a continuous assessment strategy to guarantee temporal and spatial representativeness.

Monitoring programs generate a wealth of data on actual environmental concentrations of hazardous chemicals, which can be very useful in risk assessment procedures. Existing programs can be modified in such a way that the resulting data is more suitable for these purposes and, for example, can be used to calibrate and validate models. However, many of the efforts to optimize monitoring programs focus primarily on evaluating generic environmental policies and management at the national level, rather than describing the environmental fate of the chemicals of interest for the benefit of the risk assessment protocols.

6. REGULATORY COOPERATION

When governments establish new chemical regulations or update them, resources can be saved if they build from existing regulations in other countries, taking note of their lessons learned, and adapting them to local circumstances as necessary.

Laws and regulations are pervasive in all areas of business and citizen life and are an essential part of the formulation of policies at the national level. However, they are often national in scope, while many of today's most pressing political challenges transcend borders. This mismatch endangers the ability of governments to fully achieve their goals and ensure the well-being of their citizens. Greater harmonization and consistency in regulations can reduce regulatory requirement compliance time and costs. It is also likely to generate substantial benefits for regulators, who can pool knowledge and resources with other countries. However, International Regulatory Cooperation (IRC) remains largely dismissed by governments[59].

The OECD recommends that governments consider relevant international regulatory frameworks when formulating regulatory proposals to foster global coherence and cooperate with other countries to promote the

[57] OECD. (2013). Guidance document for exposure assessment based on environmental monitoring. Available at: http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)7&doclanguage=en

[58] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2000)2&doclanguage=es

[59] OECD, Regulatory Cooperation Division (2018) International Regulatory Co-operation, “Adapting rulemaking for an interconnected world”.

development and dissemination of good practices and innovations in regulatory policy and governance[60].

In Latin America, as some countries are working to achieve international commitments, join trade agreements or join economic organizations (for example, the OECD), they spearhead processes of specific regulation elaboration. For example, efforts related to compliance with the OECD council acts have led several countries in the region to initiate the development of standards for the management of industrial chemicals.[61]

Other countries and regions have demonstrated successful results from RC-related activities. A prominent example is the Regulatory Cooperation Project of the Association of Southeast Asian Nations (ASEAN) which establishes virtual working groups on specific technical issues related to the management of industrial chemicals between ASEAN government agencies and chemical industry associations. As a result of these activities, the following guidelines were developed, among other documents: "ASEAN Guidance Document on GHS Implementation Alignment" and "ASEAN Guidance Document on Developing an Inventory of Chemicals". Another initiative worth mentioning is the Chemical Dialogue of the Asia-Pacific Economic Cooperation Forum (APEC), which developed the "Principles for Best Practice Chemical Regulation"[62] and joined the OECD to develop the "APEC-OECD Integrated Checklist on Regulatory Reform"[63].

The following are the benefits that Regulatory Cooperation provides to each stakeholder[64]:

GOVERNMENT

- Resource efficiency and knowledge sharing, leading to cost savings.
- Transparency within and among regulatory systems.
- Greater certainty for investors, resulting in the creation of new jobs, a decrease in unemployment and, therefore, economic growth.
- Increased economic growth, which leads directly to an increase in tax revenues.
- Strengthening of chemicals management programs by leveraging information.

INDUSTRY

- Easier access to other markets, especially for small and medium-sized enterprises (SMEs).
- Cost savings, allowing resources to be redirected to other areas, such as Research and Development (R&D).
- Increases in economic growth, resulting in higher net returns.
- Innovation promotion and time to market improved.
- More effective compliance.
- Level the playing field for foreign and national companies.

SOCIETY

- Increased confidence in the regulatory system.
- Higher economic growth as a result of investments, job creation and better living standards.

[60] OECD. (2012), Recommendation of the council on regulatory policy and governance. Available at: https://www.oecd.org/governance/regulatory-policy/49990817.pdf
[61] Among others, Argentina, Brazil, Chile, Colombia, Costa Rica, México, Perú.
[62] APEC. (2014). Principles for Best Practice Chemical Regulation. Available at: http://mddb.apec.org/Documents/2014/CD/CD/14_cd_002.pdf
[63] APEC-OECD. (2005). Integrated checklist on regulatory reform. Available in: http://www.oecd.org/dataoecd/41/9/34989455.pdf
[64] ICCA Toolbox (2018). Available at: https://www.icca-chem.org/wp-content/uploads/2018/04/ICCA-Regulatory-Toolbox-Version-2-0-FINAL-03-27-2018.pdf

- Increased access to innovative products and power of choice.
- Increased competition and opportunities in the domestic market.

There is no single approach for chemicals legislation, specific needs and circumstances of each country need to be recognized. However, countries are encouraged not to reinvent the wheel, but to consider elements of the systems of major trading partners when defining their own framework.

The RC is part of the Good Regulatory Practices (GRP). These are useful bases for laying the foundation for regulatory coherence and harmonization. As regulators assess the impacts of their rules, including on competition and trade, and their consistency with international instruments, they can avoid unnecessary deviations and promote convergence, even without being part of an international agreement.

GRP also provides the confidence in the regulatory regime necessary for active cooperation with other jurisdictions. Some GRP presented by the OECD in its report "International Regulatory Cooperation" [65] for the development of national standards are:

- Systematically consider accumulated experience and evidence in other jurisdictions on similar issues when developing or updating laws and regulations to ensure that they are kept up-to-date, cost-justified, cost-effective and consistent, and meet intended policy objectives.
- Facilitate inclusive consultation with interested parties (including foreign ones), to gather information on the implications of domestic regulation, and ensure that findings are incorporated into the regulatory process. This includes providing opportunities (e.g., online) for the public to contribute to the regulatory proposal preparation process and the quality of the analysis.
- When analysing the results and impacts of a standard already implemented (ex-post evaluation), include the link with international standards and the regulatory frameworks of other jurisdictions in the country.
- Establish a government mechanism to coordinate Regulatory Cooperation actions, centralize relevant information on RC practices and activities, and build consensus and common language.
- Integrate Regulatory Impact Assessment (RIA) in the early stages when formulating regulatory proposals.
- Clearly identify policy objectives, assess whether regulation is needed, and how it can be more effective and efficient to achieve those objectives.
- Consider other strategies besides regulation and identify the benefits of different approaches analysed to identify the best one.[66]

[65] OECD, Regulatory Cooperation Division (2018), International Regulatory Co-operation, "Adapting rulemaking for an interconnected world".

[66] OECD. (2012), Recommendation of the council on regulatory policy and governance. Available at: https://www.oecd.org/governance/regulatory-policy/49990817.pdf

7. ACRONYMS

APEC	Asia-Pacific Economic Cooperation Forum
ASEAN	Association of Southeast Asian Nations
CAS	"Chemical Abstracts Service" of the American Chemical Society
CiP	Chemical in Products
GHS	Global Harmonized System
GRP	Good Regulatory Practices
ICCA	International Council of Chemical Associations
ICCM	International Conference on Chemicals Management
IOMC	Inter-Organization Programme for the Sound Management of Chemicals
MEAs	Multilateral Environmental Agreements
OECD	Organisation for Economic Co-operation and Development
POPs	Persistent Organic Pollutants
PPP	Polluter Pays Principle
RBCA	Risk-Based Corrective Action
PRTR	Pollutant and Release Transfer Register
R + D	Research and Development
RIA	Regulatory Impact Assessment
SAICM	Strategic Approach to International Chemicals Management
SDG	Sustainable Development Goals
SDS	Safety Data Sheet
SMC	Sound Management of Chemicals
SME	Small and Medium Enterprises
UN-SCEGHS	United Nations Subcommittee of Experts on GHS
VWG-SMC-LA	Virtual Working Group on the Sound Management of Chemicals in Latin America

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