RISK APPROACH IN THE INDUSTRIAL CHEMICALS MANAGEMENT SCHEME

PRIORIZATION

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

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

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

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

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1. INTRODUCTION

Founded on the principles of prevention, comprehensiveness, progressivity, cooperation, articulation, efficiency, efficacy and transparency, this document is part of a series of reports from **the Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America (VWG-SMC-LA),** conformed by government representatives, industry associations, industries and intergovernmental organizations, coordinated by the Latin American Regulatory Cooperation Forum (LARCF), and supported by the International Council of Chemical Associations (ICCA).

The first piece of the series was published in 2021. The **"Roadmap for the Sound Management of Industrial Chemicals"**[1] is a guide with general descriptions on the methodologies, steps and best practices for the implementation of the **Sound Management of Industrial Chemicals (SMC)**. In 2022, the document **"Risk approach in the industrial chemicals management schemes: inventories"**[2] was launched, aimed at capturing the key elements for the implementation of inventories of industrial chemicals.

In line with the steps recommended in both documents (Figure 1), this third report aims to describe a prioritization methodology developed by the VWG-SMC-LA. Likewise, it identifies possible criteria to be used and other aspects for developing regulation and its implementation. In absence of examples of prioritization schemes in Latin America and the Caribbean, this document is based on **international best practices**. For this purpose, models from Australia, Southeast Asia, Canada, China, the United States, and the European Union have been studied (see Annex 1, Case studies). Likewise, the existing bibliography has been consulted, among others, the document of the Organization for Economic Cooperation and Development, **OECD ENV/JM/MONO(2019)34**[3], which provides an analysis of the approaches used in countries with experience in risk management of industrial and consumer chemicals[4], and suggests guiding principles and best practices to be considered in the development of these schemes.

VWG-SMC-LA guidance documents seek to promote debate among representatives of Latin American governments and industries on the set of principles and technical concepts related to the development and implementation of regulations and should not be interpreted as mandatory regulatory requirements. Likewise, it is recalled that this resource seeks to provide a simple roadmap on the fundamental elements to understand prioritization methodologies. To explore more exhaustive technical analysis, it is suggested to consult the sources referenced in footnotes and in the Bibliography section.

The document begins with a brief introduction to the concept of prioritization, highlighting key principles that serve to contextualize the technical content that is presented below. The phased methodology proposed by the VWG-SCM-LA is described below, where essential elements of the process are detailed, such as prioritization criteria, data processing and cross-sectorial interaction. Finally, case studies that were part of the analysis for the development of the methodology are presented.

[1]Access: https://icca-chem.org/wp-content/uploads/2021/06/210419-Roadmap-para-el-SMC-ES_final.pdf
[2]Access: https://icca-chem.org/wp-content/uploads/2022/04/VWG-SMC-LA_Inventarios.pdf
[3]ENV/JM/MONO(2019)34: "International Best Practices for Identification of Priorities within Chemicals Management Systems"
[4]The information was collected through a survey of OECD working groups. Were received twenty-five responses of nine countries/regions . **Germany :** Manual Screening for Regulatory Action , Prioritization for different REACH processes, assessments and regulatory measures, Human medicinal products (HMP), Veterinary medicinal products (VMP), POPs-related prioritization projects , Consumer exposure considerations for screening activities in different REACH processes. **Australia:** Inventory Multi-tiered Assessment and Prioritization (IMAP) . **Canada:** Priority Substances List Organization, Categorization of the Canadian Domestic Substances List , Ecological Risk Classification Approach for Organic Substances , Ecological Risk Classification of Inorganic Substances , Approach for the Identification of Risk Assessment Priorities , Scoping and Prioritization for the Indoor Air Contaminants Assessment Section, Prioritization of the Revised in Commerce List, Organization , Prioritization of Nanoscale Forms of Substances , Proposed Regulatory Amendments for Environmental Risk Assessment of Medicinal Ingredients in Drugs, Drinking Water Chemicals Prioritization Process. **United States:** TSCA Chemical Prioritization Process . **Finland:** Matrix for risk-based prioritization. **Japan:** Priority Assessment Chemical Substances. The Netherlands: Prioritization tool for chemical substances in consumer products . **New Zealand :** Flexible Reassessment Categorization Screening Tool" (FRCaST) . **European Union :** Trade Union Priority List for REACH , Screening as part of the integrated regulatory strategy , NORMAN Prioritization framework .

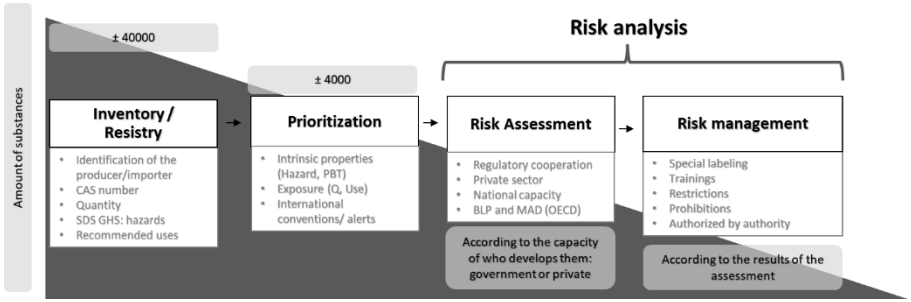


FIGURE 1. SUGGESTED STAGES FOR THE SOUND MANAGEMENT OF INDUSTRIAL CHEMICALS. SOURCE: VWG-SMC-LA

Most existing prioritization schemes are based on available data, so it is rare to generate data on hazards and exposure properties to solely inform the prioritization process[5]. Since prioritization is part of the SMC, the general approach focuses on using the information provided in the **inventories** as the primary source of local data.

2. FUNDAMENTALS OF PRIORITIZATION

The prioritization of inventoried or registered substances is intended to identify those that preliminarily represent a higher level of risk (for health and/or the environment), on which further detailed information will be obtained at a later stage to enable an exhaustive risk assessment and determine its safe conditions of use. This selection is generally based on hazard and exposure data on which comparisons are made and relative weights are assigned based on their relevance.

Considering that there are between **40,000 and 60,000 industrial substances in use in the global market**[6], the implementation of a prioritization process becomes necessary due to the limited financial, technological, and personnel resources of the countries, required to perform or evaluate risk assessments. To date, Latin American countries are still in very early stages of the process since many are working on the development of broad encompassing regulations. Based on these observations and the analysed bibliography, a series of principles recommended by the VWG-SCM-LA are listed below in order to guide the design of prioritization schemes and regulations in the region:

1. **Environmental and health risk basis:** The scheme should be based on the concept of **risk**, which involves consideration of both environmental and health hazards, and real or estimated exposure. All industrial chemicals should be subject to a review process, and, if appropriate, prioritized for further evaluation.

> This principle is supported by the working group that developed OECD document ENV/JM/MONO(2019)34. It recommends that prioritization be based primarily on risk (sometimes referred to as "potential"* in this document), assigning higher priority to substances for which there is information suggesting a potential concern, due to both exposure and hazard.
>
> *Explanation: In this instance of the process, the risk of the substance is still unknown. "Risk approach" refers to an assessment to obtain a probable risk profile of the substance from the hazard and exposure data available at this instance. As a result, it will be possible to determine the priority with which the substance should be subsequently evaluated in order to know its risk.

2. **Objectivity and support in science:** The scheme should be based on criteria chosen from a scientifically based analysis. To ensure practicality, the criteria must be possible to meet, taking into account current technical conditions.

[5]According to OECD document ENV/JM/MONO(2019)34, only a minority of schemes (6/25) reported generating some required data. For example, in Canada, toxicity studies are requested in order to generate de Novo specific information essential for the process.

[6] Estimated total considering only chemical substances for industrial use. Source: UNEP & ICCA. (2020). Knowledge Management and Information Sharing for the Sound Management of Industrial Chemicals Access: https://icca-chem.org/wp-content/uploads/2020/05/Knowledge_Information_Sharing_Study_UNEP_ICCA.pdf

3. **Possibility of change:** Given the frequent changes in the production and use of chemicals, the availability and level of understanding of relevant data, such as hazard characteristics and other properties, and the continuous development of technology (e.g., monitoring), the methodologies and results of the prioritization of chemicals may need to be frequently adjusted. Therefore, the process should consider technological and scientific advances, so that criteria can be incorporated or modified to improve the accuracy of the identification of priority substances.

4. **Transparency and clarity:** Adopting a national policy that clearly indicates the criteria and types of substances to be prioritized for risk assessment and management contributes to transparency, clarity, and certainty vis-à-vis the regulated entities and helps to anticipate measures that may have a significant socioeconomic impact.

5. **The lack or variability of information should not be sufficient reason for not prioritizing a substance.** In these cases, principles such as weight of evidence could be applied[7] or more conservative approaches could be used, such as applying worst exposure and hazard scenarios[8].

3. DESCRIPTION OF THE PRIORITIZATION PROCESS

3.1 Phased approach

Although a mechanism could be thought where the information from the inventories is taken and weighed directly -without a prior instance of review-, the prioritization is normally a gradual procedure, occurring in more than one stage. Figure 2 simply illustrates the general steps recommended by the VWG-SCM-LA and Annex 2 provides a more detailed flowchart.

Initially, the aim is to select a small number of inventoried/registered substances from the available information, using clearly defined selection rules. The global prioritization process is based on the potential risk of the substances and the way in which the selection criteria are applied varies according to the stage of the process, taking into account the progressive refinement of data. That is, it begins with hazard and exposure criteria in a disaggregated manner, which in the last stage are combined and weighted to obtain a final potential risk score.

In the first instance, the aim is to **reduce** the number of substances according to their hazards and/or associated exposure, while in the final instance, the scheme seeks to **sort** the substances according to the combination of these data. An intermediate instance aims **to review the information,** allowing evaluators the possibility to fill gaps and ensure the quality of the data during the process.

[7]Weight of evidence" (WoE) method is the process of weighing different sources of evidence based on the combination of their impact and relevance. This is a common practice that evaluators use to analyze all the data collectively and make a decision using best professional judgment. More information in the OECD guide: "Guiding Principles and Key Elements for Establishing a Weight of Evidence for Chemical Assessment Series on Testing and Assessment No. 311". Available at: https://www.oecd.org/chemicalsafety/risk-assessment/guiding-principles-and-key-elements-for-establishing-a-weight-of-evidence-for-chemical-assessment.pdf

[8]To advance preliminary assessments, these schemes are applied in the cases of Canada and the European Union.

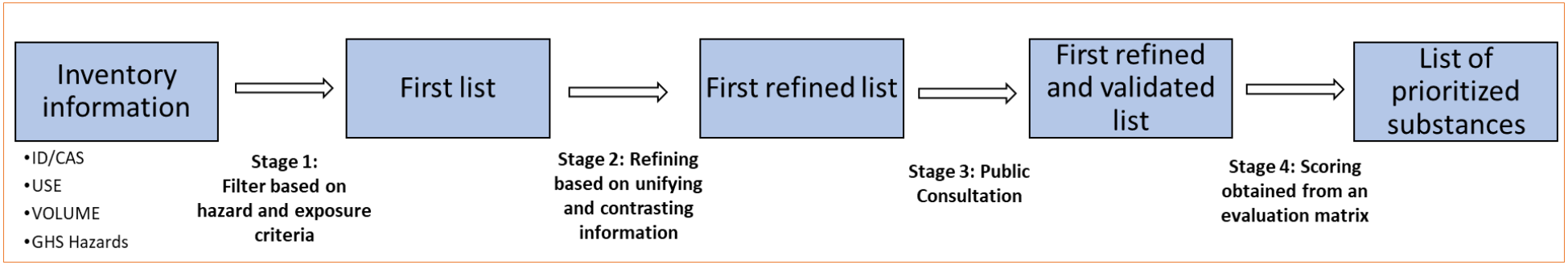


FIGURE 2. GENERAL STAGES OF THE PRIORITIZATION OF SUBSTANCES

It is worth noting that the approach presented is not the only one possible, since, for example, there are other ways of assessing dangerousness, as exemplified in the Case Study section. Likewise, the list of criteria and the weighting methods that are illustrated in the document should not be considered as an explicit recommendation of the VWG-SCM-LA, but as a knowledge guide so that each country can make its own decisions.

3.2 Prioritization criteria

Choosing the criteria to apply to decide which substance is most relevant is not a simple task, since there are a large number of characteristics and properties of substances in relation to their mobility, behaviour and effects on health and the environment. Many schemes consider properties such as persistence, bioaccumulation, specific hazards (generally classified under the **Globally Harmonized System of Classification and Labelling of Chemicals, GHS**) and data representing exposure scenarios. In addition to these data, other existing approaches have complementary prioritization criteria, such as third-party risk assessments (national or international)[9], emerging concerns from other jurisdictions and agencies[10], and particular listings by authorities[11].

Although there is the case of China, where the government offers a public consultation period to identify substances to be prioritized for environmental risk assessment, or Germany, where third parties are requested annually to nominate substances, according to the OECD report it is not a common practice for the public or other interested parties to propose substances to be prioritized. In countries where this possibility exists, nominations are made through public consultation and scrutinized by several government organizations[12]. In addition, this step usually requires the submission of certain information to start the process.

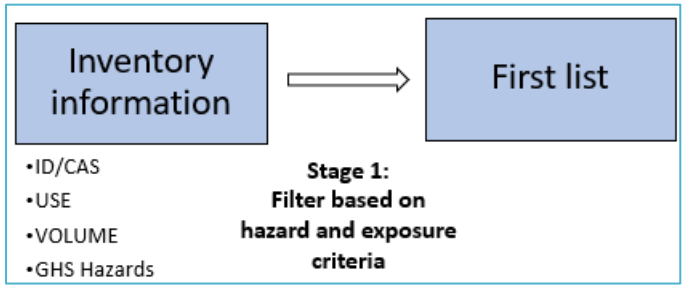
[9]For example, the New Zealand Environmental Protection Agency reviews actions taken internationally to test for prioritized chemicals in the country. Likewise, Canada's IRAP (Identification of Risk Assessment Priorities) scheme takes into account the classification decisions and risk assessments of other countries. Source: OECD ENV/JM/MONO(2019)34

[10] For example, Canada's prioritization process for chemicals in drinking water. Source: OECD ENV/JM/MONO(2019)34

[11]For example, in the United States, Congress has the power to amend the Toxic Substances Control Act (TSCA) to include or exclude certain chemical substances. Source: OECD ENV/JM/MONO(2019)34

[12]In Canada public nominations are not formally requested, but are allowed under CEPA. On the other hand, the US allows manufacturers to request that the EPA conduct a risk assessment. The New Zealand EPA allows external parties to request a review of approvals for a particular substance. Source: OECD ENV/JM/MONO(2019)34

Stage 1: Selection filter based on hazard and exposure criteria



In the first place, it is desirable that the substances can be prioritized based on the information provided in inventories.[13] Considering the use, volume and the GHS hazard classification commonly requested in inventories, this stage consists of choosing selection criteria to reduce considerably the number of substances to advance to the next stage of the process: risk assessment. This is the instance that deals with the largest number of substances and, as far as possible, it is essential that it is done in such a way that the need for human resources and manual tasks is minimized. For example, one option is to opt for IT tools with algorithms that allow the selection of substances that comply or not with a condition. Below are examples of some options for selection criteria to be used at this stage of the process.

Selection by hazard (based on the GHS)

An option to implement in the first instance is to select all those substances that present certain priority hazard classification/s.[14] Considering that the GHS currently includes a total of 29 classes of hazards, some are considered more relevant than others, since they imply severe and irreversible effects and its safe handling cannot be assumed by all users to ensure personal and third parties protection.[15] As it can be seen in the Case Studies, these is a criteria commonly used by other models.

The following are examples of GHS hazard classes that are typically used as selection criteria at this stage:

- **Carcinogenicity (C)**
- **Mutagenicity (M)**
- **Reproductive toxicity (R)**
- **Specific Target Organ Toxicity (STOT) single or repeated Exposure**
- **Toxicity to the aquatic environment (T) – chronic or acute**

Persistent, bioaccumulative and Toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances are also the focus of analysis in prioritization processes since, no matter how small their emissions are, being resistant to degradation, their concentrations in the biota may increase over time and also their long-term effects are rarely predictable.[16] However, only toxicity to the aquatic environment (T) is reported as a hazard class under the GHS[17], and therefore if P&B is not reported in inventories, its inclusion as a selection criteria would make the prioritization process more complex. Alternatively, countries may opt for indicative criteria, such as **chronic toxicity to the aquatic environment,** which, as indicated by the GHS (GHS 9th revision, p. 254), is related to the degradability of the substance or its persistence in the environment and its bioaccumulation potential. For organic substances, the octanol-water partition coefficient (Kow) can also be an indicator of bioaccumulation potential, always considering the factors that can affect this relationship (ibid., p. 503-504). On the other hand, chronic toxicity is generally also associated with organic substances that do not present easy biodegradation, since they have a

[13]For more details on the design and implementation of inventories, consult the document "Risk approach in the management of industrial chemicals: inventories". Access: https://icca-chem.org/wp-content/uploads/2022/04/VWG-SMC-LA_Inventarios.pdf
[14]In principle, the proposal aims for this selection to be made regardless of the category.
[15] Swedish Chemicals Agency (KEMI). (2018). Guidance on national chemicals control. Risk reduction of chemicals. Article number: 511 293.

[16]More information on the official ECHA site: https://echa.europa.eu/pbt-expert-group
[17]Although persistence, degradability and potential bioaccumulation are part of the criteria for classifying substances as hazardous to the aquatic environment under GHS, these properties are not considered hazard classifications per se and for that reason in some jurisdictions they are often included in the list of minimum requirements, because they are usually a prioritization criterion in later steps. These data must be provided in the Safety Data Sheet (point 12: ecotoxicological information).

prolonged exposure potential (ibid., p.508). In conclusion, countries could conduct their prioritization process based on the toxicity for the aquatic environment and, in future stages, request the missing data for this specific group of substances. Similarly, hazards such as reproductive toxicity could be indicators of **endocrine disrupting potential**. However, this effect is in the very early stages of identification[18].

Frequently prioritized substances

OECD (2019) identified that most of the schemes prioritize substances considered "carcinogenic, sensitizing, endocrine disrupting, persistent, bioaccumulative and toxic (PBT), and neurotoxic" (p. 14).

NOTE: Also supported by UNITAR (2020) in its report "Chemicals of Global Concern. A strategy and criteria for their identification".Access here

Some data may be difficult to obtain in practice. However, anticipating future technological and scientific advances, regulations could be designed to allow for the possibility of modifying the selection criteria when the data becomes available. [19] In any case, it should be clarified that, for a substance not to be prioritized, its use and volume still remains to be evaluated. Each Country must ensure that the decision of the hazard classes to use as selection criteria responds to national interests, the availability of data and existing resources.

Selection by exposure data: use

In a risk-based prioritization scheme, not only are hazard classes considered as a selection criterion, but also **exposure** to substances is indicative of their relevance. Among the local data that can be utilized, use and volume are common basic indicators of the magnitude and nature of the exposure.

Depending on the level of detail with which the uses are described in the inventories, substances with a higher or lower level of rigor may be selected. Each use is associated with different exposure scenarios. Considering the diversity of uses that can be associated with substances on the market, it is recommended that governments carry out a grouping and categorization of uses for the purposes of the prioritization process. It is for this reason that the definition of **categories of uses** in the instance of inventory development is essential for the prioritization process.

An example of simple categories of uses is shown below.

- **"Consumer use":** use of a substance, as such or in a mixture, by consumers/general public.

- **"Commercial/professional use":** use of a substance, as such or in a mixture, in a commercial context for the delivery or generation of goods and/or services.

- **"Industrial use":** use of the substance, as such or in a mixture, in industrial facilities (small or large), for, among others, the manufacture of other substances, the formulation of preparations or aiding the process.

Categories of uses are ordered in descending order in terms of the degree of exposure (and, therefore, also of risk) since, on the one hand, it is considered that in industrial facilities the conditions of use are more controlled, whereas it is not possible to ensure the same regarding the conditions of use by consumers. Likewise, in general, consumer use involves exposure of a greater number of people and areas. In any case, it is reminded that the most common exposure scenarios focus on both the environment and the human population in general.

[18]For more information, see: https://echa.europa.eu/es/hot-topics/endocrine-disruptors , https://www.efsa.europa.eu/es/topics/topic/endocrine-active- substances , and https://www.unep.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/endocrine-disrupting-chemicals

[19]If it is of interest to a country to learn more about the treatment of PBT characteristics, there are currently 11 different global criteria identified that can be consulted: UNECE, POP Protocol, UN POP Convention, Ospar, REACH, TSCA, California Green Chemistry , Canada, K-Reach, China-Reach, Japan and Australia. More information at: Matthies M. et al. (2016). The origin and evolution of assessment criteria for persistent, bioaccumulative and toxic (PBT) chemicals and persistent organic pollutants (POPs). Environ. Sci .: Processes Impacts, 2016, 18, 1114.

Countries can decide whether to proceed with a subcategorization of uses for prioritization, always remembering that this could imply greater complexity in the process. For example, there are schemes that have chosen to select substances with use directly related to vulnerable groups (for example, boys and girls[20]) -see *Case Studies*-.

Selection by exposure data: volume

Just as the categories of uses are indicative of possible exposure scenarios, so is the volume of production/import of the substance. Broadly speaking, a higher volume in the market is associated with a greater magnitude of exposure and, consequently, with a higher risk. However, it should be remembered that a substance, even in small volumes, due to its toxicity or behaviour in the environment (bioaccumulation, biomagnification) may represent a high risk. This is not a minor aspect that countries should consider if they decide to include volume as a prioritization criterion. The volume could be used in the final stage as a "weighting" criterion.

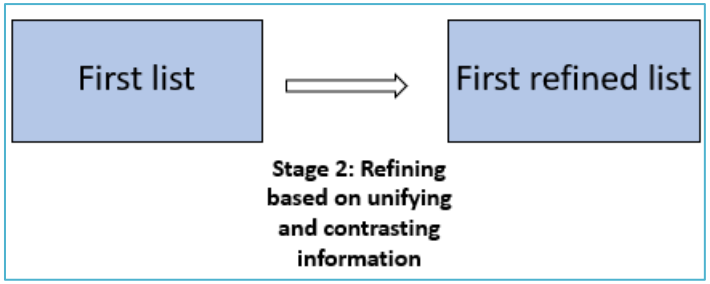
On the other hand, the choice of a **volume threshold** as a criterion for the prioritization process -as a volume threshold is used for the purposes of notification in inventories- should be based on the local context. In order to define a threshold, the value must be representative in terms of exposure (considering the distribution of the substance in the environment, and its potential to reach people) and also consistent with the prioritization process (a threshold too low would not have much influence on the filter process). The inventory is a source of relevant information that would make it possible to make an evaluation at the national level and define a threshold that is representative. In the absence of national data, examples can be found in the *Case Studies* [21].

It is also important that the legislation is flexible enough to allow the update of the volume thresholds used to assess exposure. If more refined data exists, it should be added or used.

Selection by monitoring results

Available widespread and/or known exposure data from, for example, monitoring studies or epidemiological surveillance programs that give rise to a cause for concern, could be evaluated at this stage of prioritization to justify the selection of a substance. So far, the criteria described apply both to substances on the market before the creation of the national inventory (pre-existing) and to substances to be marketed after the creation of the inventory (new), while the monitoring data can only be indicative of the behaviour and the effects of pre-existing substances. To decide on the inclusion of this criterion, it is recommended that the countries review whether the existing databases are reliable and if their information can be exploited and systematized.

Stage 2: Refinement based on unifying and contrasting information



At some point in the prioritization process, since the information comes from the inventories, it will be necessary to evaluate the data with which the selection/weighting is made to ensure its reliability and validity.

[20]According to OECD ENV/JM/MONO(2019)34, more specific subpopulations are considered less frequently. The category of "vulnerable subpopulation" has different definitions by country and even by organizations within the same country. In general, babies, children, pregnant women and the elderly are considered within this subgroup, and may also include, for example, people with genetic polymorphisms, people with pre-existing diseases, those who are very close to a source or activity, workers and passers-by.

[21]For example, in the European Union system (REACH) detailed chemical safety information (risk analysis) is requested for substances that exceed a threshold of 10 tons.

For example, the notification of hazard classes by several companies can lead to inconsistencies, although to advance in the prioritization process it is necessary that a substance has a single classification, otherwise, the same substance could be counted more than once. In addition, - as described in the second technical report of the VWG-SMC-LA-[22] there are technical challenges related to the use of numerical identifiers for substances, such as the CAS number. On occasions, there may be substances without an assigned CAS number or there may be the same CAS assigned for a group of different substances.

The prioritization must be done by substance and not by notifier. Therefore, this stage involves a process of evaluation of the quality of the information, and of validation and unification, where it is verified that the hazards and the characteristics of the substances that have been notified are coherent with the available information. It is recommended that countries address these cases early in the process. Here are some suggested strategies to address these difficulties:

- **Same substance, multiple notifications with different hazards or uses:** the most severe hazard class or the category of use with the greatest dispersion can be opted (more conservative approach). It is suggested that this process be carried out through IT systems, in order to reduce manual tasks. As an alternative source of information for choosing a single hazard classification, a comparison with international listings could also be made.
- **Substance not included due to subclassification:** To avoid subclassification resulting in not considering a substance in the following prioritization stages, one option is to review the lists of internationally prioritized substances (see Annex 3) and compare them with the first draft list of prioritized substances at the national level. In this way, countries can ensure that substances of global concern follow the prioritization process in their countries.
- **Substances without CAS, or groups of substances with a single CAS:** The treatment of these situations is complex, and in general is carried out on a case-by-case basis, making it difficult to automate the work. One option is to assign national identifiers to these substances and make the choice of properties based on that identifier, instead of the CAS. Another option, in the case of multiple substances grouped with a single CAS, is to assign the most stringent hazard classification and, in a subsequent public consultation process, to access more detailed information that determines which substance(s) would apply such dangerousness, before finalizing the prioritization process.

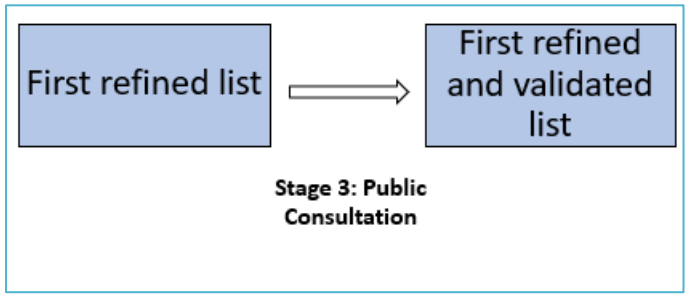
At this stage, substances that are already strictly regulated in current regulations can also be discarded. The rationale is that if a substance has its conditions of use strictly controlled, considering its risk to the environment and health, then no additional steps would be required. At most, it could be assessed whether the risk management measures adopted are adequate.[23] In cases where the current regulations control a single risk aspect (for example, the risk to health -without considering the risk to the environment-), it is recommended to evaluate the substances within the framework of the prioritization process, considering the unregulated aspects.

It is suggested that this stage be designed in such a way as to make the most of computing resources. In this sense, it is essential that the verification and unification mechanisms are foreseen from the beginning, in order to be able to make the respective adaptations to the computer system, avoiding the need to make future modifications that may imply a greater workload.

Stage 3: Public Consultation

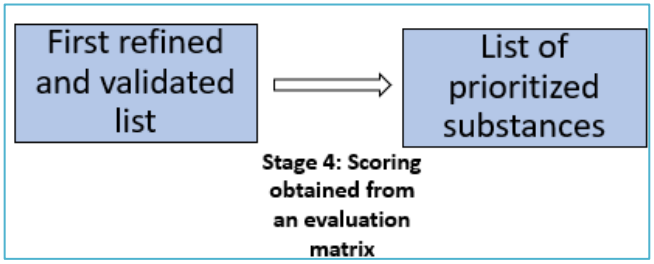
[22] "Risk approach in the management of industrial chemicals: inventories". Access: https://icca-chem.org/wp-content/uploads/2022/04/VWG-SMC-LA_Inventarios.pdf

[23] Framework regulations that set industrial chemicals management schemes -including the prioritization process- already define exclusions, which implies a preliminary filter. A few schemes do not explicitly exclude substances and instead choose to assign them very low priority. Further information on this latter point can be found in the document OECD ENV/JM/MONO(2019)34.



After the refinement stage, it is suggested that the first refined list be placed under **public consultation**, allowing sufficient time to receive comments on the chemical identities, hazard classes, and use categories that have been assigned by the authorities (some examples of deadlines can be found in the Case Studies section). Foreseeing instances of consultation with producers, importers and subjects responsible for notification during the prioritization stage is a good strategy to make the process more efficient. Additional information on the identity of the substances and their composition (in the case of multi-constituent substances) may be obtained which may explain why different manufacturers have different classifications for the same reported CAS number. Consultations can also be made to databases and relevant stakeholders -including notifying parties- in the event of a lack of consensus or the need for more information (see section 2 of the principle "the lack or variability of information should not be a sufficient reason not to prioritizing a substance"). Based on the comments obtained from the public consultation, and once the classifications and properties/exposure criteria of the substances have been reviewed, the authorities will be in a position to publish a first list of refined and validated prioritized substances.

Stage 4: Scoring obtained from an evaluation matrix



Almost half of the prioritization schemes reported to the OECD that they use a quantitative **scoring system** to identify substances to prioritize, i.e., one score is assigned for the properties of the substance and another for its exposure scenarios, which are then combined, in general, through a summation (Figure 3a). The final score is obtained by combining these values using an evaluation matrix to determine the priority of the substance (Figure 3b). This stage is based on the fact that chemical substances with high danger and high exposure potential must be evaluated first. This mechanism not only facilitates decision making, but also helps to improve the transparency and reproducibility of the results.

As for stage 1, countries should define the assigned value for each criterion, which implies carrying out a thorough analysis of which hazard classifications, uses and volumes are most relevant, among themselves and within their own category, and, therefore, they should be assigned a higher score. There are several examples identified in the literature and in international schemes (see Case Studies). It is suggested that countries explore all options, keeping in mind that the system should be simple and require as little manual work as possible. As an example of how different properties can be valued, Annex 4 presents priority levels proposed by different prioritization schemes.

Among the technical difficulties related to this stage, there may be cases of substances with more than one use or hazard classification. Some models address this situation through the combination and subsequent normalization of the scores obtained (see Case Studies: United States and ASEAN), others choose to choose the highest score assigned to any of the uses of the substance, and others simply they perform a summation for each characteristic within the same group (see Case studies: European Union).

Scoring for properties of the substance (1-4 increases in relevance)	Exposure score (1-4 increases in relevance)			
	1	two	3	4
1	2	3	4	5
2	3	4	5	6
3	4	5	6	7
4	5	6	7	8

FIGURES 3A AND 3B. CONCEPTUAL EXAMPLES OF SUMMATION AND WEIGHTING MATRIX FOR THE SUBSTANCE PRIORITIZATION PROCESS.

Countries should note that, in addition to establishing numerical values for each prioritization criteria, they can establish their relative weights in a prioritization equation. They could, for example, assign a higher coefficient to the hazard class "germ cell mutagenicity/carcinogenicity" than for the hazard class "skin corrosion/irritation", or assign a higher coefficient to hazards compared to volume.

3.3 Other possible strategies: prioritization by groups

For certain groups of substances, there is also the possibility of designing an **individual scheme**. Some schemes provide for prioritization processes that separate substances into groups according to their hazard and/or similarity of structural characteristics in order to develop a risk prioritization mechanism within each group. For example, Canada has a specific process to analyse the ecological risk of inorganic substances, leaving all organic substances excluded from this approach. Other schemes also work by **groups**, but do not explicitly exclude substances, but classify them as lower priority or in categories that require specific actions.[24]

3.4 Prioritization as a continuous process

Although the frequency with which the prioritization process is carried out varies greatly between different countries, in most schemes, the process is carried out more than once. Possible approaches - with their advantages and disadvantages - are continuous prioritization, prioritization at a set interval, or on demand. On the one hand, continuous prioritization allows new information to be examined as it becomes available, and appropriate action to be taken in a timely manner. For its part, through the prioritization process with an established term (annual, biannual, every four years), new information can be incorporated in a formal and structured manner.

3.5 Work team and relevant actors

When designing and implementing the prioritization methodology, governments usually rely on a **specific group or committee of experts** dedicated to both the prioritization and risk assessment processes. For example, the European Union has a Prioritization Unit, responsible for, among other activities, coordinating the identification and prioritizing groups of substances subject to regulatory action[25]. In any case, it is advisable that the working group should be guided by **clear directives,** defined by regulation, and at the same time have the **knowledge and scientific rigor** necessary to resolve situations that have not been previously clarified.

Collaboration between regulatory agencies (national and international) can contribute to improve criteria, incorporate new methodologies, identify gaps and quickly recognize emerging problems.

It is also suggested that **industries and civil organizations** be involved in the processes, through meetings, work groups, and/or public consultations. For the development and implementation of the prioritization scheme, a good practice is to generate consultation instances between government agencies, and local scientific and academic

[24]For additional information consult the Case Study of the European Union (Annex 1), and the site https://echa.europa.eu/es/working-with-groups

[25]Description of ECHA units on its official website: https://echa.europa.eu/en/about-us/who-we-are/directorates-and-units/directorate-b

institutions (in particular, with experience in public health, environmental health, toxicology, epidemiology, ecotoxicology, ecology and environmental sciences, environmental chemistry). For example, Canada's prioritization process for chemicals in drinking-water gathers input from different local agencies. Germany's regulatory actions assessment scheme draws on occupational safety experts, toxicologists, exposure and legal experts. (OECD, 2019).

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ANNEX 1. CASE STUDIES[26]

1.1 OECD

Broadly speaking, the document OECD ENV/JM/MONO(2019)34 highlights the following findings:

- It is recommended that the prioritization criteria and the relevant mechanisms are public and regulated through legislation. It is also important that, in their legislation, countries provide mechanisms to systematically incorporate new scientific knowledge into their prioritization schemes. Most commonly initiate prioritization from substances listed in their inventories.
- Simplicity, efficiency, flexibility and transparency in prioritization schemes are recommended. Emphasis is placed on simplicity, since in general the deadlines for the process are limited and, likewise, the information must be easily transmitted to the interested parties.
- The most common problem during the prioritization process is the lack of availability and variability of exposure or hazard data. Existing schemes address data scarcity in a variety of ways: some apply worst-case assumptions, while others rely on best-case ones. Other schemes choose to suspend the prioritization process when there is a lack of sufficient quality exposure or hazard data. On this last point, the OECD suggests as a best practice that prioritization decisions be based on risk, and that lack of data should not be a sufficient reason not to prioritize a substance.
- There is a need to explore similarities and differences in national substance inventories, particularly for substances with inconsistent names (e.g., the same substance with different identifiers), as this impacts consistency of processes prioritization and subsequent risk management measures. This effort would also help facilitate the grouping of similar substances to help fill data gaps and increase the efficiency of the prioritization process.

In addition to the aforementioned report, through which multiple approaches used in its member countries are illustrated, the OECD legal instruments are useful tools to consult when defining how to design the schemes. For example, Figures A1a and A1b below list the health and environmental effects, and characteristics related to exposure that could be considered as possible prioritization criteria. They are found in Decision-Recommendation 0232 on Systematic Review of Pre-existing Substances.

Effects

Health effects:
- Mutagen effects;
- Carcinogenic effects;
- Embryotoxic and teratogenic effects;
- Effects on reproduction;
- General toxicity and effects on specific organs, including:
  (i) Effects on the immune system;
  (ii) neurotoxic effects;
  iii) Irritation of eyes, skin and mucous membranes.

Environmental Effects:
-
- Effects on aquatic ecosystems;
- Effects on terrestrial ecosystems;
- Effects on other systems, including:
  (i) Role of biological wastewater treatment systems;
  (ii) Atmospheric changes.

Exposition

Workplace exposure
- Production volume and import/volume of industrial use;
- Industrial use patterns;
- Physicochemical characteristics;
- Conditions and activities of operation in plant;
- Route of exposure;
- Degree of exposure;
- Characteristics of the exposed working population.
-

Exposure of the general population
- Production and import volume/volume in trade;
- Usage patterns;
- Release to the environment;
- Physico-chemical characteristics (including physical and matrix form);
- Environmental destination;
- Characteristics of the exposed population;
- Follow-up of information.

Environmental exposure
- Detection in the environment;
- Potential for release to the environment
  (i) Production and import volume/consumption volume;
  (ii) release into the environment during manufacture and processing;
  (iii) Patterns of use;
  (iv) How waste is disposed of.
- Environmental fate, including:
  i) Environmental distribution;
  (ii) Transformation/degradation;
  iii) Bioacumulación.

FIGURES A1A AND A1B. EFFECTS AND EXPOSURE DATA THAT CAN BE CONSIDERED AS PRIORITIZATION CRITERIA ACCORDING TO OECD RECOMMENDATION 0232

[26] This Annex has not yet gone through a formal translation process, so it could present errors and inconsistencies.

1.2 United States

In the United States, the prioritization of chemicals has been carried out in different instances and for different purposes. The most current processes (2012 onwards) are reflected in the scheme of Figure A2 and are described below. More detailed information is available in United States Environmental Protection Agency (US EPA or EPA) documents in the Bibliography section.

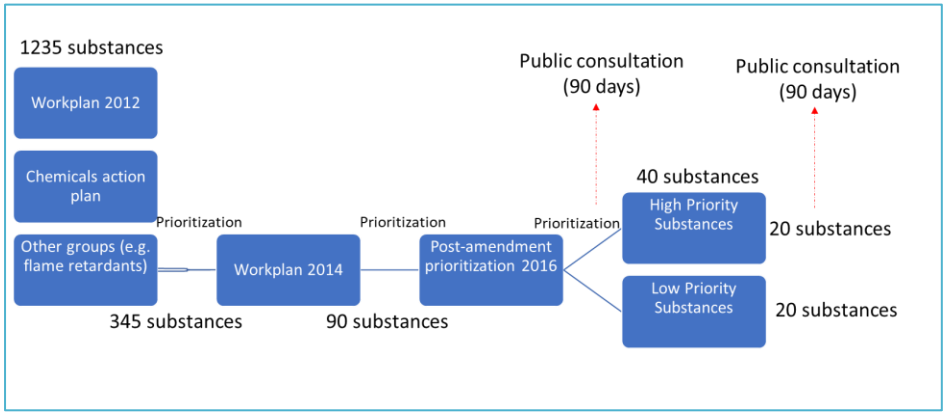


FIGURE A2. GENERAL PRIORITIZATION PROCESS CARRIED OUT BY THE EPA, UNITED STATES. SOURCE: SELF-MADE.

TSCA (Toxic Substances Control Act) Work Plan with information from the inventory (Chemical Data Reporting Rule or "CDR") and data reported in the Toxic Release Inventory (TRI). Substances that met any of the following selection criteria were selected:

- **Carcinogenicity:** Taking as sources the Integrated Risk Information System (IRIS): 1986 Class A, B1; 1996 Known or Probable; 1999 or 2005 Carcinogen, Carcinogens according to the International Agency for Research on Cancer (IARC) -Group 1, 2nd-, Known carcinogens from the National Institute for Occupational Safety and Hygiene (NIOSH) Technical Notes on Prevention (NTP) of the United States Joined;
- **Persistence, Bioaccumulation and Toxicity:** According to the Toxic Release Inventory (TRI), the Great Lakes Binational Agreement, the Abbreviated Long-Range Transboundary Air Pollution Convention (LRTAT), and the Stockholm Convention;
- **Child's Health:** According to IRIS, the National Toxicology Program (NTP), Centre for the Evaluation of Risks to Human Reproduction (NTP CERHR): Infants Any Effect or Pregnant Women Any Effect, California Proposition 65: Reproductive;
- **Neurotoxicity:** According to the IRIS;
- **Use of children's products:** Reported as products intended for use by children in 2006 in the Inventory Update Rule (IUR), Washington State Children's List;
- **Biomonitoring (both human and environmental indicative of potential human exposure):** according to the National Report on Human Exposure to Environmental Chemicals (NHANES), Contaminants in Drinking Water, Fish Tissue Studies.

In this way, a total of 1,235 substances was reached, from which certain substances were excluded due to duplication, for being outside the scope of TSCA, or for being under a specific management measure. Likewise, metals and their compounds were grouped together. Through this process, a total of 345 substances were reached, which underwent a second process illustrated in Figure A3, in terms of their hazard, exposure, and potential for persistence and bioaccumulation. For the calculation of the score of the chemical substance, the highest value of the hazard ranking was taken, and the normalized value of exposure and properties of persistence and bioaccumulation that are added to obtain a total evaluation of the substance.

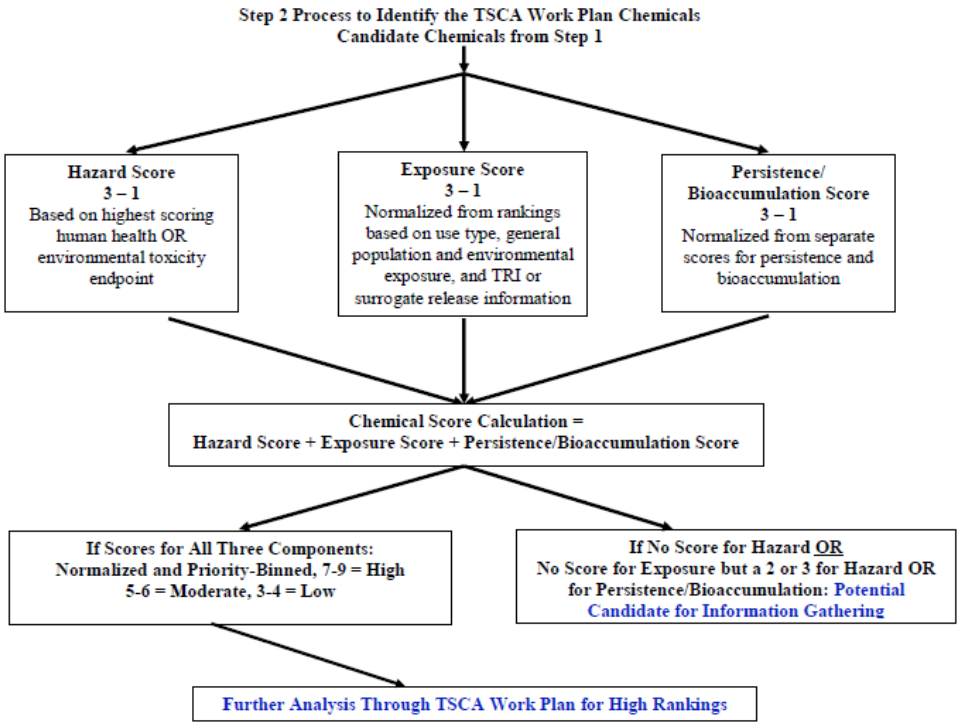


Figure A3. Second prioritization process carried out by the EPA, United States. Source: Own elaboration based on US EPA (2012).

hazard assessment

For the EPA, the hazard score included both human health and environmental toxicity concerns. Specific hazard classification criteria are based on EPA criteria, developed from recognized sources, including the GHS. To arrive at a harmonized classification, data was obtained not only from the inventory, but from other easily accessible sources such as IARC, the eChem Portal, and other national and international resources.

The danger score was determined based on 3 danger levels, and each danger level had a corresponding danger range (High-3, Moderate-2, and Low-1). The concentration ranges or characteristics that correspond to each level of danger are listed in Annex 4, which includes a comparison table with the criteria of the other case studies.

Exposure valuation

The exposure score was based on a combination of chemical use, general population and environmental exposures, and emissions and release data. The type of use score included: consumer product applications, industrial uses, and commercial uses that could result in widespread exposures. The general population and environmental exposure score included measured data on the presence of a chemical in biota and environmental matrices. The emissions and releases score was based on TRI data. For those not in TRI, the release score was calculated using inventory data (volume of production, number of exposure points, and type of use). All exposure category scores (type of use, population and environment exposure, emissions and releases) were summed and then normalized to an overall high-moderate-low scale.

Assessment of the potential for persistence and bioaccumulation

Chemicals were given a separate score to classify their potential for persistence and/or bioaccumulation. EPA New Chemicals program criteria were used. Separate persistence and bioaccumulation scores were then summed to produce a total score, which was normalized as high-moderate-low.

Final prioritization process, high and low priority substances

In 2016, the TSCA instrument was modified by the Lautenberg amendment of 2016. This modification determined that the EPA should designate, within a period of 9 to 12 months, high-priority chemical substances subject to subsequent risk assessment (20 in total), and of low priority for which, in principle, a risk assessment would not be guaranteed

(20 in total) [27]. The amendment designated the agency to have at least 20 high-priority substances in the risk assessment process by December 2019. For the prioritization process, EPA was required to have 50% of all high-priority substances removed of the 2014 work plan, giving preference to the following characteristics:

- Persistence and bioaccumulation (with a score of 3);
- Carcinogenic substances known; either,
- High acute or chronic toxicity.

For this process, in addition to legal requirements, EPA was given discretion to determine which chemicals to prioritize, so details as exhaustive as in previous processes have not been identified. In its communications, EPA describes that, to support a high or low priority designation, it evaluates the chemical under its conditions of use [28]against certain criteria specified in section 6(b)(1)(A) of the TSCA through the review of reasonably available information regarding:

- The hazard and exposure potential of the chemical;
- Persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage near significant sources of potable water;
- The conditions of use or significant changes in the conditions of use of the chemical substance; Y
- The volume or significant changes in the volume of the chemical manufactured or processed.

[27] A chemical designated as low priority indicates that a risk assessment is not warranted at this time, but this does not imply low or no risk. TSCA defines a high priority chemical as "a chemical that the Administrator concludes, without regard to cost or other non-hazardous factors, may present an unreasonable risk of harm to health or the environment due to a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the Administrator". On the other hand, a low priority substance is one that "if the Administrator concludes, based on information sufficient to establish, without taking into account costs or other factors that are not risk, that said substance does not meet the standard of [High priority]".

1.3 Southeast Asia (from ACC-ASEAN guidance)

With the support of the American Chemistry Council (ACC), the ASEAN countries are in the process of evaluating prioritization mechanisms based on their latest advances in data collection through their inventories. In 2019 they prepared a document that explains the proposed process (ACC, 2019), which is briefly described below.

hazard assessment

In the same way as in the case of the United States, each of the GHS hazard classifications for the environment and human health is assigned a numerical value (score), with 1 being the lowest value and 4 being the highest. . The overall score is ultimately determined by the highest score. In the case of missing data that cannot be filled, this approach suggests that the chemical be ranked "medium high". By way of illustration, Table A1 shows the suggested criteria for scoring according to hazards.

Table A1. Hazard score according to ACC-ASEAN proposal.

Hazard score		
	Human health	Environment
1	Acute toxicity 3, 4, 5 Corrosive/Skin Irritation Serious eye damage/irritation Target Organ Toxicity Aspiration hazard No CMR, non-toxic for target organs	Not qualified
two	Acute toxicity 2 No CMR Target organ toxicant 2	Acute toxicity 3 Chronic toxicity 3 or 4 No data on aquatic or chronic toxicity
3	Acute toxicity 1 Respiratory or skin sensitizer 1	Acute toxicity 2 Chronic toxicity 2

[28]"Conditions of Use" is a term in TSCA that means "the circumstances, as determined by the Administrator, under which a chemical is intended, known or reasonably expected to be manufactured, processed, distributed in commerce, used or delete". For prioritization purposes, the Administrator may determine that certain activities fall outside the definition of "terms of use."

	CMR 2/ Effects due to lactation serious eye year/irritation Target Organ Toxicity 1 Insufficient information to classify	Insufficient information to classify
4	WRC 1A, 1B	Acute toxicity 1, chronic toxicity 1

Exposure assessment

To assess the exposure, three elements are proposed: the uses and patterns of use of the chemical (intermediate products, industrial use, commercial use, consumer use), the volume (of production or import) as a first step indicator of the relative potential emission/release characteristics, and persistence and bioaccumulation characteristics of the chemical. The use patterns were adopted from TSCA and are also consistent with REACH exposure scenarios. It should be noted that, under this approach, specific products for children do not differ from products for general consumption. By way of illustration, tables A2, A3 and A4 show the suggested criteria for obtaining the score according to exposure.

Table A2. Score of usage patterns according to the ACC-ASEAN proposal.

Use	Classification	Punctuation
Consumer	High	4
Commercial	medium-high	3
Industrial	Medium	two
intermediaries	Low	1

Table A3. Score of production/import volumes according to the ACC-ASEAN proposal.

Production/import volume	Classification	Punctuation
Greater than or equal to 1000 t/year	High	4
From 100 to 1000 t/year	medium-high	3
From 10 (inclusive) to 100 t/year	Medium	two
Less than 10 t/year	Low	1

Table A3. Persistence and bioaccumulation potential score according to the ACC-ASEAN proposal.

Persistence and bioaccumulation	Classification	Punctuation
Persistent and bioaccumulative	High	5
Persistent or bioaccumulative	Medium	3
Not persistent and not bioaccumulative	Low	1

Under this approach, persistence and bioaccumulation are considered indicators of exposure. The document acknowledges that persistence and bioaccumulation (BP) criteria are not globally harmonized and recommends values directed in particular at organic chemicals, suggesting different criteria for inorganic substances or metals.

Finally, the scores for each element (use pattern, production volume, and CP) are added to arrive at a total score that corresponds to a low to high exposure range (standardization process same as EPA's), see Table A4.

Table A4. Total exposure score according to the ACC-ASEAN proposal.

Total score (use pattern, volume and BP)	Exposure ranking	exposure score
11-13	High	5
9-10	Medium-High	4
7-8	Medium	3
5-6	Medium-Low	two
3-4	Low	1

Total Substance Score

The final score is obtained by adding the Hazard Score and the Exposure Classification Score, and finally the substances are grouped according to the matrix in Table A5.

The document highlights that the priority groups (high, medium or low) must be defined by each jurisdiction according to the available resources, such as funds, time, experience, employees. As a suggestion, the document recommends as a first step, designating 5-10% of the substances as high priority.

Table A5. Total exposure score according to the ACC-ASEAN proposal. Unofficial translation.

Exposure score		Total score				
Human health score	environmental score	1 combination of scores 3-4	2 combination of scores 5-6	3 combination of scores 7-8	4 combination of scores 9-10	5 combination of scores 11-13
1	1	2	3	4	5	6
2	2	3	4	5	6	7
3	3	4	5	6	7	8
4	4	5	6	7	8	9

Figure A4 shows an illustrative case of prioritization (high) carried out by Thailand for 5-10% of the substances, considering a total of 1000 evaluated substances [29].

Prioritiy group	Number of substances	Percentaje	
9	6	0.6%	8.6%
8	15	1.5%	
7	65	6.5%	
6	235	23.5%	72.7%
5	265	26.5%	
4	227	22.7%	
3	156	15.6%	18.7%
2	31	3.1%	
	Total = 1000	Total = 100%	

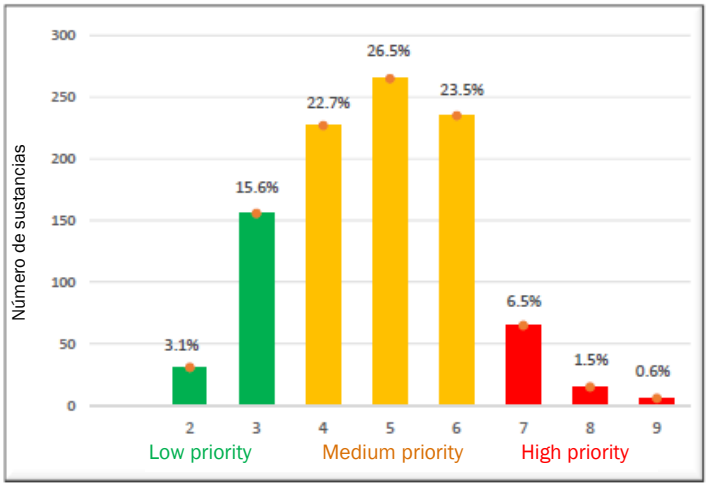


FIGURE A4. EXAMPLE OF PRIORITIZATION, CARRIED OUT BY THAILAND (2019-2020) BASED ON THE ACC TOOLKIT FOR ASEAN (2019).

[29] This process had the collaboration of 7 members of companies with a presence in the ASEAN States. The process culminated in a total of 66 chemicals (over 2 rounds) from 3 groups: Basic Chemicals, Specialty Chemicals, and Consumer Chemicals. The process was carried out concealing the identity of the substance. The data used were: the GHS classification, the European Union harmonized CLP classification, company data on other hazards, acute environmental toxicity, P&B, and patterns and ranges of use at the national level.

Second prioritization period

The document indicates that for some substances more data may be needed in order to be prioritized within the same group with similar characteristics. For this second process, it is recommended to use data from: biomonitoring and environmental monitoring, emissions and releases, risk management at the international level.

1.4 Canada

Since 2006, priorities for risk assessment of chemicals under the Canadian Environmental Protection Act (CEPA, 1999) have been based on the results of categorization from the Domestic Substances List (DSL) and New Substances Notifications.

The first prioritization process in 2006, called Categorization, consisted of the review of approximately 23,000 substances from the DSL (Figure A5). The health authority committed to categorizing substances with the highest potential for exposure of the general population (exposure of workers or vulnerable subpopulations was not considered), and persistent or bioaccumulative substances considered "inherently toxic" to humans. The environment portfolio identified substances that are persistent or bioaccumulative and "intrinsically toxic" to non-human organisms. Categorization decisions were made by substance, and some decisions were made based on substance class, and included commercial chemicals manufactured or imported into Canada of more than 100 kg/yr.

The exposure potential criterion was based on reported volumes and uses of substances in commerce in Canada between 1984 and 1986. Hazard and exposure information was compiled from a combination of publicly available literature searches and international assessments. Stakeholders were also encouraged to submit data, and when necessary, the Government of Canada generated new data. Substances associated with significant information gaps (e.g., no use or volume reporting, or uncertain PBT estimates) were not prioritized for evaluation. The final results on the 4,300 prioritized substances were posted online for public comment.

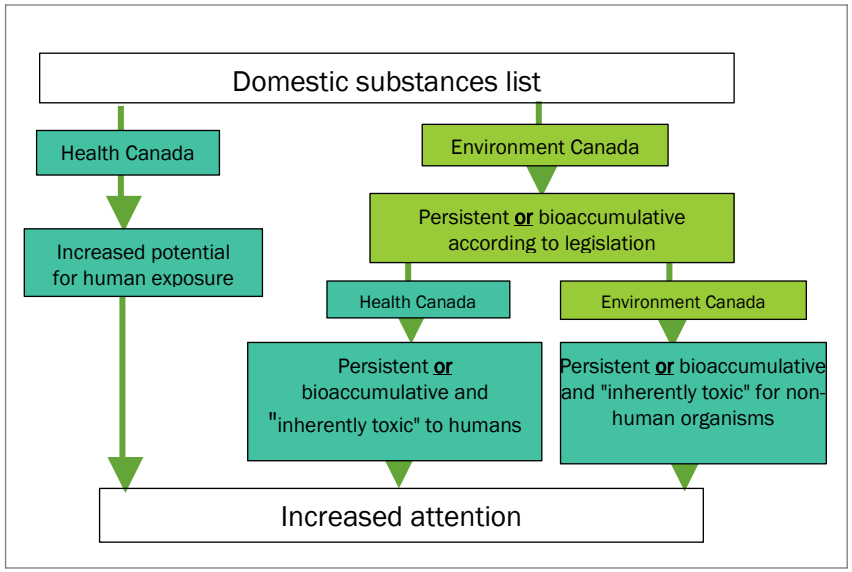


FIGURE A5. SUBSTANCE PRIORITIZATION PROCESS IN DLS, CANADA. SOURCE: OECD (2019)

A New Prioritization Approach: Identification of Risk Assessment Priorities (IRAP)

The approach to prioritization has been modified since 2014 in Canada, where an Identification of Risk Assessment Priorities (IRAP) process is now performed. [30]. The process is different from categorization, where each substance on the DSL is classified based on prescribed criteria. The objective is to selectively identify substances for which there are indications that suggest that the substance should be considered as a new priority for evaluation or future work. With the IRAP process, new information from a

[30]More information: https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=A10191AD-1

large number of sources is evaluated to determine the appropriate action for the substances involved.

There are 3 steps involved in identifying risk assessment priorities:

- **Acquisition:** active and passive collection of information relevant to the potential health and ecological risks of substances. The acquisition of new information occurs continuously, while the other two steps are usually performed at regular intervals.
- **Evaluation:** exclusion/inclusion of substances for which new information has been received. This evaluation requires expert judgment and consideration of the different types of information that may be available for any given substance.
- **Action:** type of activity that will be carried out on the substances identified as candidates for further work. These actions could include assessment, risk management, data collection, research and monitoring, generation of new data, etc.

After reviewing the relevant information sources for in-scope substances, the following categories of substances are determined for which:

- It is unlikely that further action is required at this time based on the available information (15,629 substances after evaluation in 2019),
- Additional data collection is likely to be required (443 substances after evaluation in 2019),
- Further scoping/issue formulation is likely to be required (85 substances after assessment in 2019 [31]),
- Monitoring of ongoing international activity (101 substances after evaluation in 2019) is likely to be required.

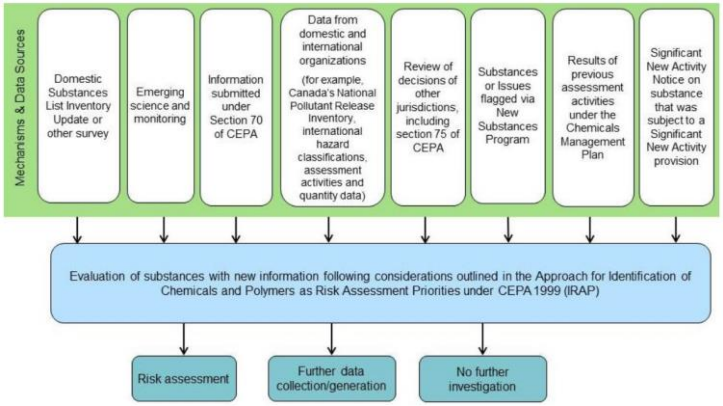


FIGURE A6. CANADA'S NEW PRIORITIZATION PROCESS (IRAP). SOURCE: HTTPS://WWW.CANADA.CA/EN/HEALTH-CANADA/SERVICES/CHEMICAL-SUBSTANCES/FACT-SHEETS/IDENTIFICATION-RISK-ASSESSMENT-PRIORITIES.HTML

1.5 Australia

's National Industrial Chemicals Assessment and Notification Scheme (NICNAS) established a prioritization process for substances in its national inventory with different tiers (IMAP). The scheme focuses on the identification of high and low priorities for risk assessment and management and takes into account the general population, consumers, workers and the environment. Prioritization applies to all chemicals for industrial use in the inventory that meet the selection criteria (including commercial chemicals, polymers, UVCBs, substances with endocrine disrupting potential, and chemical groups that group substances with structural or hazardous similarities or a similar use).

During the first stage, 3,000 chemical products were selected for evaluation and prioritization over a period of 4 years, a process that was repeated again. The fundamental criteria are three: 1) chemicals for which

[31]It was proposed that of the 85 substances recommended for further analysis, 21 individual substances and 4 groups of substances should be considered.

NICNAS has exposure data, 2) chemicals identified as a concern for which action has been taken abroad, and 3) chemicals detected in international studies that analyse present presence in the umbilical cords of babies. Then, the 3,000 identified chemicals were compared with criteria for hazards to human health, the environment, and exposure. This comparison determined three categories of substances, Tier I (those not expected to present an unreasonable risk, Tier II (those requiring regulatory controls for safe use), and Tier III (and those requiring evaluation). additional).

In 2021 the Australian government announced a series of national reforms for the use, management and disposal of industrial chemicals that will help provide more consistent regulation [32]. The new legislation establishes the Industrial Chemical Environmental Management Standard (IChEMS). Substances will be listed in IChEMS according to their level of concern for the environment, and risk management measures will also be prescribed. This scheme is based on the work carried out by AICIS, using a risk-based approach. By the end of 2022, it is expected to have the Principles of Environmental Management of Industrial Chemicals, which will establish the technical prioritization criteria. According to the official website of the Australian government [33], the programming could consider: substances proposed for inclusion in international conventions; controlled substances in countries with comparable safety standards; substances of interest to support a safe circular economy; alternatives for the substances of interest; opportunities to classify broad groups of chemicals; Group chemicals based on their use.

1.6 China (People's Republic of)

The HJ 1229-2021 standard specifies the principles, procedures and technical requirements for the detection of chemical substances for priority evaluation and applies to the screening of chemical substances for environmental risk evaluation. The process is described in Figure A7.

[32]Source: https://www.industrialchemicals.gov.au/news-and-notices/new-national-chemicals-management-standard

[33]Source: https://www.dcceew.gov.au/environment/protection/chemicals-management/national-standard#our-scheduling-strategy

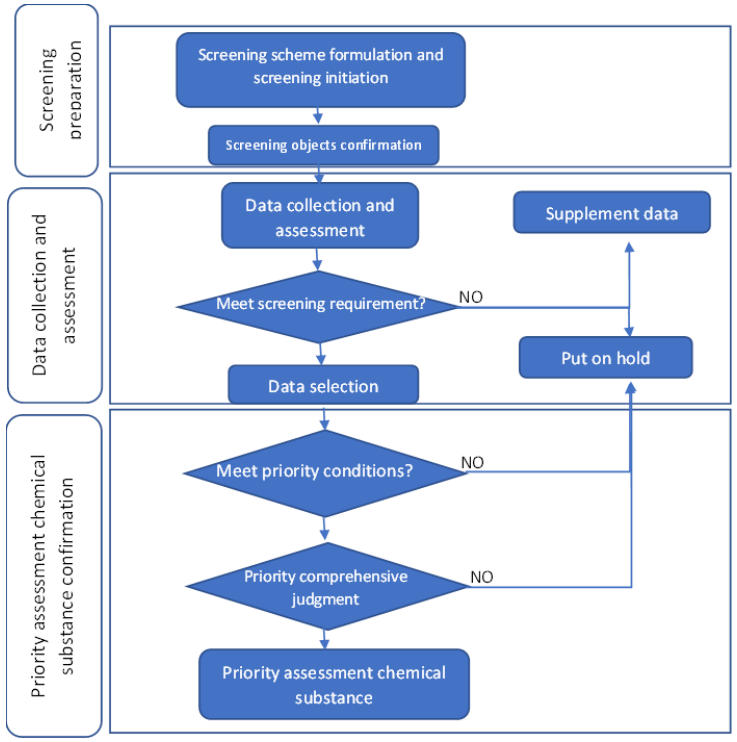


FIGURE A7. SELECTION PROCESS OF CHEMICAL SUBSTANCES FOR PRIORITY EVALUATION IN CHINA. SOURCE: STANDARD HJ 1229-2021 UNOFFICIAL TRANSLATION.

1. In the first stage of screening, a prioritization plan is formulated, determining the objectives and requirements;
2. During the data collection and evaluation stage, data on chemical hazards and exposures should be comprehensively collected and their validity assessed;
3. At the stage of determining chemical substances for priority evaluation, the chemical substances will be examined according to the selection conditions, and the evaluation priority will be comprehensively considered to determine the chemical substances.

According to the standard, the scheme must give priority to the following chemicals:

a) According to GB/T 24782, those persistent, bioaccumulative and toxic substances (PBT) or substances of high persistence and high bioaccumulation) or substances of high persistence and high bioaccumulative (vPvB);

b) Chemicals with carcinogenicity, mutagenicity or reproductive toxicity, focusing on GB 30000.23, GB 30000.22, GB 30000.24 standards, substances classified as Class 1A or 1B carcinogenic, mutagenic or toxic for reproduction, substances that are near carcinogenic, mutagenic or toxic for reproduction;

c) Chemicals with persistence and toxicity or bioaccumulation and toxicity, whose toxicity approach is based on GB 30000.23, GB 30000.22, GB 30000.24, GB 30000.26, GB 30000.28 or classified as carcinogenic, mutagenic, toxic for reproduction, or under the category of repeated exposure to specific target organs or long-term aquatic hazards with a standard classification of more than 2 classes;

d) Other Highly Hazardous Chemicals for Priority Attention: Endocrine disruptors, highly suspected PBT or vPvB substances, reproductive toxicants, long-term aquatic hazards or repeated exposure to specific target organs;

e) Chemicals for which there is evidence showing that there has been environmental exposure, such as detection of environmental media, or in vivo detection of chemicals that have evidence of environmental exposure;

f) Chemicals with potential environmental exposure that should be given priority attention, such as chemicals with high production or annual use, widely dispersed use, widely dispersed use in many branches, or in many scattered places, or in daily public life.

1.7 European Union[34]

By 2019, the "chemical universe" under REACH comprised approximately 19,000 substances. On the basis of available knowledge, each of these substances was assigned to one of the following groups:

- High priority for regulatory risk management;
- High priority for data generation and evaluation;
- Low priority for the adoption of new regulatory measures.

Substances that have not yet been examined and for which very little information is available are currently in an uncertain zone. Until now, the authorities have focused their activities on substances registered above 100 tons per year.

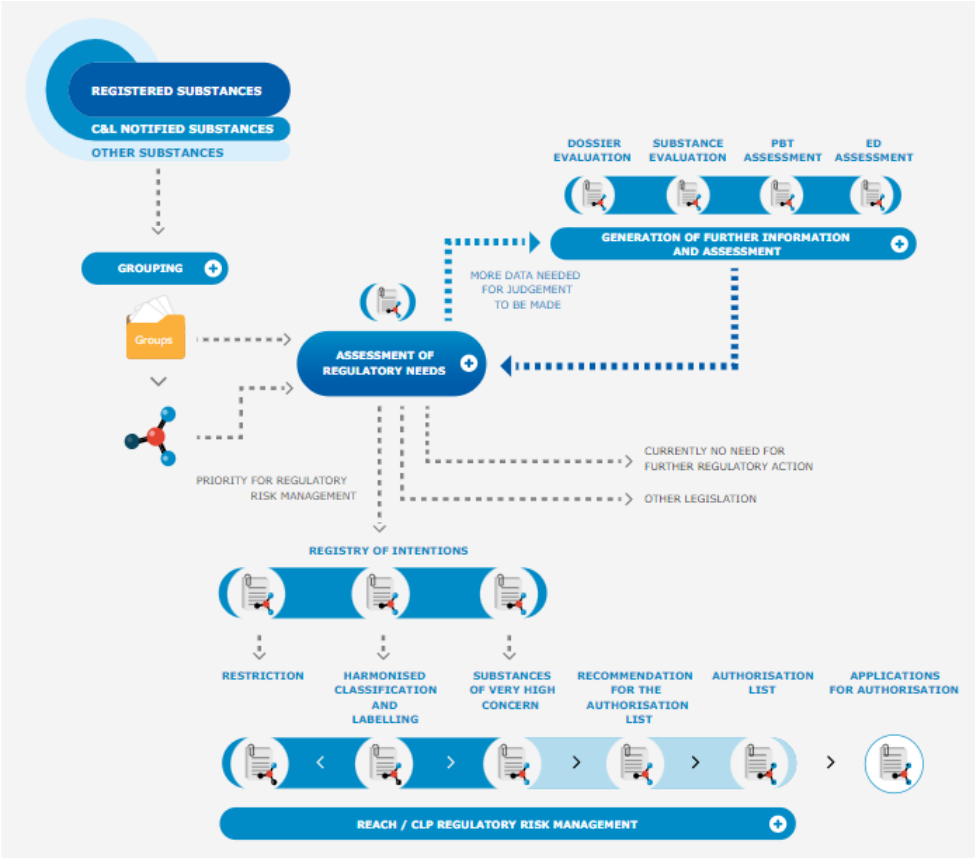


FIGURE A8. NEW INTEGRATED METHODOLOGY FOR THE ANALYSIS OF THE EU CHEMICAL UNIVERSE. SOURCE: HTTPS://ECHA.EUROPA.EU/ES/IRS-INFOGRAPHIC

Group work[35]

According to ECHA, working with groups helps determine what data needs to be generated or further evaluated for a given substance. For several years, authorities have attempted to address groups of structurally similar

[34] Main source for this section: ECHA (2019). Mapping the chemical universe to address substances of concern. Integrated Regulatory Strategy Annual Report. Access: https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2018_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425

[35] More information on the ECHA website: https://echa.europa.eu/en/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Assessment+of+regulatory+needs

substances rather than individual substances. This approach has been progressively introduced through the Common Assessment and, since 2017, groups of substances of potential concern have been the main starting point for work. Clustering is mainly done through computer algorithms. Substance groups are formed mainly on the basis of: (i) structural similarity, using substance identity information in registration dossiers and CLP notifications, and (ii) read-across and categories, using information received in industry registration dossiers and external sources.

Substances of Very High Concern (SVHC)

ECHA prioritizes substances on the Candidate List to determine the order in which substances should be included in the authorization list contained in Annex XIV of the REACH Regulation. Substances that meet the SVHC criteria are included on the candidate list for eventual inclusion on the authorization list. They are:

- Substances that meet the criteria to be classified as carcinogenic, mutagenic or toxic for reproduction, category 1A or 1B, according to CLP.
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances according to REACH annex XIII.
- Substances, on a case-by-case basis, that produce an equivalent level of concern as CMR or PBT/vPvB substances.

Substances that have the highest priority are recommended for inclusion first. All substances not recommended, as well as substances recently added to the Candidate List, will be considered in future rounds. Priority is normally given to substances with PBT or vPvB properties, wide dispersive use or high volumes. Prioritization is carried out mainly on the basis of information from registration dossiers. However, information from the public consultation on the identification of SVHC is also considered, as well as other information from REACH/CLP.

Properties		Volume (t/year)		Use	
C **or** M **or** R **or** similar effects	1	0-100	6	INDUSTRIAL	5
OF	7	100-1000	9	PROFESSIONAL	10
PBT **or** vPvB	13	1000-10000	12	CONSUMPTION	fifteen
PBT **or** vPvB **and** another prop .	fifteen	>10000	fifteen		

FIGURE A9. ASSIGNMENT OF SCORES FOR THE PRIORITIZATION OF SVHC SUBSTANCES. SOURCE: ECHA (2020)

Since 2008, 197 substances have been identified as SVHC and placed on the Candidate List.

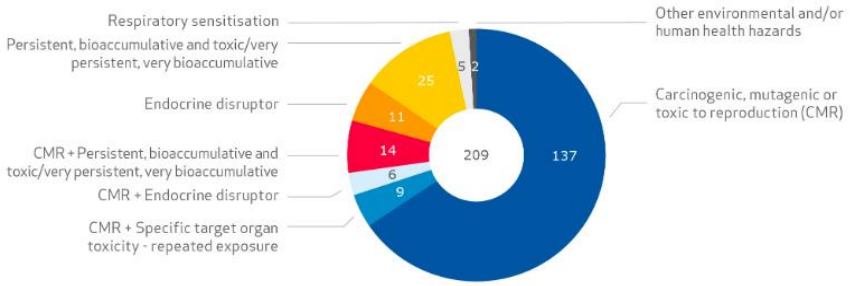
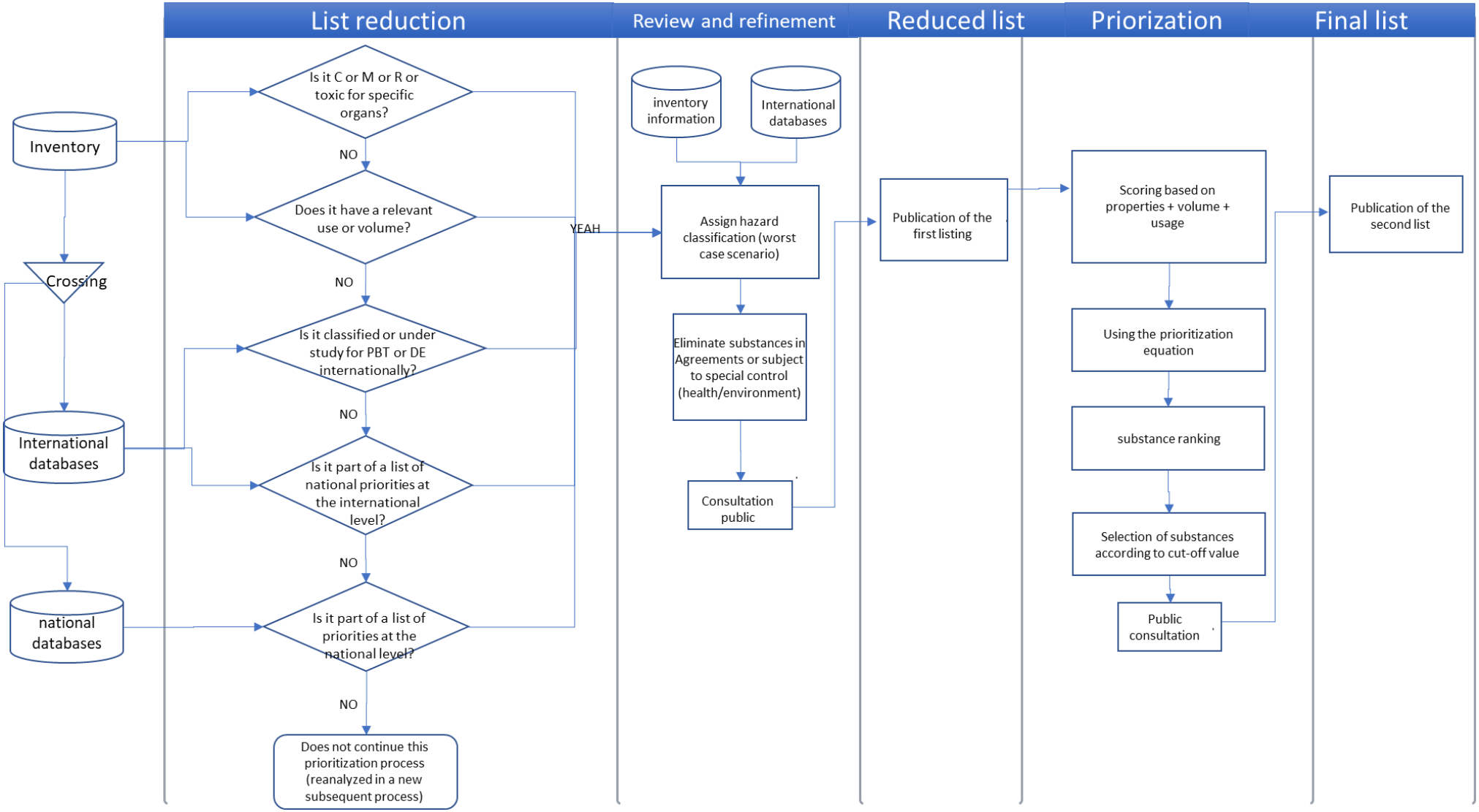


FIGURE A10. SUBSTANCES ON THE CANDIDATE LIST BASED ON THEIR PROPERTIES. SOURCE: ECHA (2019).

ANNEX 2. DETAILED FLOW CHART FOR THE PRIORITIZATION STAGES[36]



[36] This Annex has not yet gone through a formal translation process, so it could present errors and inconsistencies.

ANNEX 3. EXTERNAL SOURCES OF INFORMATION: INTERNATIONAL LISTS AND OTHER DATABASES[37]

- List of substances under EU regulatory needs assessment. LINK
- List of substances under EU dossier review. LINK
- List of substances in the CoRAP (Community Action Plan) of the EU. LINK
- EU list of substances under review for PBT properties. LINK
- EU list of substances under review for endocrine disruption. LINK
- List of substances with evaluations in progress or under public consultation in Australia. LINK
- List of prioritized substances in the Canadian Chemicals Management Plan. LINK
- List of substances subject to risk assessment of the United States. LINK

Data for prioritization can also be collected from a variety of different sources, generally publicly available, such as peer-reviewed scientific literature, grey literature. For example, multiple agencies have reported to the OECD on the use of IUCLID to collect hazard data or extract data from dossiers prepared for REACH. Another relevant source for obtaining data on substances regulated in other countries is the Rotterdam Convention, which informs countries about substances and formulations, including pesticides and industrial chemicals, that are prohibited or severely restricted by their States Parties. Additionally, this instrument has a tool called CIA (Chemical Information Assessment) that allows extracting physicochemical and toxicological data from the notifications of final regulatory measures that have been presented in the Convention and that supported the prohibition in the countries [38].

On the other hand, approximately half of the schemes studied by the OECD use New Approach Methodologies (NAM) to generate new information. Interestingly, there is no consensus on the definition of the term NAM (OECD, 2020), but for the purposes of this document, it is understood as all the technologies, methods, information resources and strategies that serve to minimize the study in animals for the purposes of to obtain information on chemical hazards and risks [39]. Software such as (Q)SAR [40], ToxCast results [41], or extrapolation between analogous substances are generally used when there are inconsistencies in the experimental data.

The use of databases or specialized data extraction software does not seem to be a trend. To collect and process data, most of the agencies consulted by the OECD manually extract information from the literature and databases, and use tools such as spreadsheets for data compilation. A minority have specialized tools for data extraction and/or processing. Some examples are RISCTOX, ChemBioOffice , Risk21, and Cognos Analytics [42].

[37] This Annex has not yet gone through a formal translation process, so it could present errors and inconsistencies.

[38] Official website of the Convention: http://pic.int . Information on the CIA Tool: http://www.pic.int/Implementation/FinalRegulatoryActions/FRAEvaluationToolkit/CIATool/tabid/4991/language/en-US/Default.aspx

[39] More information is available in the document "Overview of Concepts and Available Guidance related to Integrated Approaches to Testing and Assessment (IATA)." OECD Series on Testing and Assessment, No. 329, Environment, Health and Safety, Environment Directorate, OECD (2020).

[40] The OECD QSAR Toolkit is free software designed to support hazard assessment of chemicals, increasing knowledge about chemicals in a cost-effective manner. It is intended for use by governments, the chemical industry, and other interested parties. More information at: https://qsartoolbox.org/about/

[41] toxicity Forecaster (ToxCast) is a set of data and models of thousands of chemical substances from the United States Environmental Agency (EPA), which through analysis methods and computational toxicology allows prioritizing chemical substances. More information at: https://www.epa.gov/chemical-research/toxicity-forecasting

[42] https://iuclid6.echa.europa.eu/ , https://risctox.istas.net/en/ , http://www.cambridgesoft.com/solutions/details/?fid=188 , https://risk21 .org/ , https://www.ibm.com/products/cognos-analytics

ANNEX 4. TABLES OF ASSESSMENT OF HAZARDS, USES AND VOLUMES BASED ON CASE STUDIES[43]

Table A6. Hazard assessment comparison table according to ICCA, EPA and ASEAN models

hazard class	Numerical assignment to hazard level	4 (tall) *For US EPA it is 3 *For ICCA it is 1	3 (Medium-high) *For US EPA it is 2 *For ICCA it is 2	2 (Medium low) *For US EPA it is 1 *For ICCA it is 3	1 (bass) *For US EPA does not count *For ICCA it is 4
Human health hazards					
Acute toxicity (dermal, ingestion, or inhalation)	ASEAN	-----	Category 1 GHS	Category 2 GHS	Categories 3, 4 and 5 SGA
	US EPA (2012 and 2014 method)	Oral LD50≤ 50 - 300 Dermal LD50≤ 200 - 1000 inhalation (gas) LC50 ≤ 2 - 10 Inhalation (dust) LC50 ≤ 0.5 – 1.0	Oral LD50≤ >300 – 2000 Dermal LD50>1000 - 2000 Inhalation (gas) LC50 >10 - 20 Inhalation (Dust) LC50 >1.0 - 5	Oral LD50>2000 Dermal LD50>2000 Inhalation (gas) LC50 >20 Inhalation (dust) LC50 >5	-----
	ICCA Guide (2011)	Category 1 GHS	Categories 2 and 3 SGA	Category 4 GHS	Category 5 GHS
Skin corrosion/irritation	ASEAN	---	-----	corrosive substance	irritant substance
	US EPA (2012 and 2014 method)	---			
	ICCA Guide (2011)	Category 1 A/B/C GHS	Category 2 GHS	Category 3 GHS	Not classified
Serious eye damage/eye irritation	ASEAN	----	-----	serious eye injury	irritant substance
	US EPA (2012 and 2014 method)	---			
	ICCA Guide (2011)	Category 1 GHS	Category 2A GHS	Category 2B GHS	Not classified
Sensitization (respiratory/ cutaneous)	ASEAN	-----	----	Category 1A/1B (respiratory and skin) GHS	-----
	US EPA (2012 and 2014 method)	Category 1A/1B	------	No evidence to prove	------
	ICCA Guide (2011)	Category 1A/1B (respiratory) GHS	Category 1A/B (cutaneous) GHS	Not classified	Not classified
Germ cell mutagenicity/ Carcinogenicity	ASEAN	Category 1 A/B GHS	Category 2 GHS	Not classified	Not classified
	US EPA (2012 and 2014 method)	Category 1 A/B and Category 2 GHS	Limited to animals (carcinogenicity)	Negative	--

[43] This Annex has not yet gone through a formal translation process, so it could present errors and inconsistencies.

hazard class	Numerical assignment to hazard level	4 (tall) *For US EPA it is 3 *For ICCA it is 1	3 (Medium-high) *For US EPA it is 2 *For ICCA it is 2	2 (Medium low) *For US EPA it is 1 *For ICCA it is 3	1 (bass) *For US EPA does not count *For ICCA it is 4
			Positive in vivo or in vitro (mutagenicity)		
	ICCA Guide (2011)	Category 1 A/B GHS	Category 2 GHS	Not classified	Not classified
Specific target organ toxicity - repeated exposures (dermal route, ingestion, inhalation)	**ASEAN**	----	Category 1 GHS	Category 2 GHS	no effects found
	US EPA (2012 and 2014 method) <u>Neurotoxicity (mg/kg/day)</u> Orally 13 weeks Oral 40-50 days Orally 4 weeks Dermal 13 weeks Dermal 40-50 days Dermal 4 weeks	< 10 < 20 < 30 < 20 < 40 < 60	10 – 100 20 – 200 30 – 300 20 – 200 40 – 400 60 – 600	> 100 > 200 > 300 > 200 > 400 > 600	------
	ICCA Guide (2011)	Category 1 GHS	Category 2 GHS	300 < NOEL ≤1000 mg/kg/d (not SGA, but ICCA guide criteria)	No effects found with the highest test dose (1000 mg/kg/d) (not SGA, but ICCA guideline criteria)
Reproductive and developmental toxicity (dermal route, ingestion, inhalation)	**ASEAN**	Category 1 A/B GHS	Category 2 GHS	Not classified	Not classified
	US EPA (2012 and 2014 method)	Oral (mg/kg/day) <50 Skin (mg/kg/day) <100 Inhalation (gas/vapour) <1 (mg/L/day) Inhalation (mist/dust) (mg/L/day) <0.1	Oral (mg/kg/day) < 50-250 Skin (mg/kg/day) < 100-500 Inhalation (gas/vapour) <1 (mg/L/day) Inhalation (mist/dust) (mg/L/day) <0.1 -0.5	Oral (mg/kg/day) >250 Skin (mg/kg/day) >500 Inhalation (gas/vapour) >2.5 (mg/L/day) Inhalation (mist/dust) (mg/L/day) >0.5	-----

hazard class	Numerical assignment to hazard level	4 (tall) *For US EPA it is 3 *For ICCA it is 1	3 (Medium-high) *For US EPA it is 2 *For ICCA it is 2	2 (Medium low) *For US EPA it is 1 *For ICCA it is 3	1 (bass) *For US EPA does not count *For ICCA it is 4
	ICCA Guide (2011)	Category 1 A/B GHS	Category 2 GHS	100 < NOEL ≤1000 mg/kg/d (not SGA, but ICCA guide criteria)	No effects found with the highest test dose (not SGA, but ICCA guideline criteria)
Environmental Hazards					
Short-term (acute) hazard to the aquatic environment	**ASEAN**	Acute 1 SGA	Acute 2 SGA	Acute 3 GHS, acute non-toxic	Not classified
	US EPA (2012 and 2014 method)	(LC50 or EC50) (mg/L) <1.0 – 10	(LC50 or EC50) (mg/L) > 10 - 100	(LC50 or EC50) (mg/L) > 100	------
	ICCA Guide (2011)	Acute 1 SGA	Acute 2 SGA	Acute 3 SGA	Not classified
Long-term (chronic) hazard to the aquatic environment	**ASEAN**	Chronic 1 SGA	Chronic 2 SGA or insufficient information to classify	Chronic 3 SGA, Chronic 4 SGA or no data	Not classified
	US EPA (2012 and 2014 method)	(NOEC or LOEC) (mg/L) < 0.1 – 1	(NOEC or LOEC) (mg/L) > 1 - 10	(NOEC or LOEC) (mg/L) > 10	------
	ICCA Guide (2011)	Chronic 1 SGA	Chronic 2 SGA	Chronic 3 SGA	Chronic 4 SGA
Physical hazards (not GHS classifications, but criteria)					
Flammability (gases and liquids)	**ICCA Guide (2011)**	Flash Point ≤23°C and initial boiling point ≤35°C	Flash Point ≤23°C and initial boiling point > 35°C	23°C < Flash Point ≤ 60°C	60°C < Flash Point (FP) ≤93°C
Reactivity	**ICCA Guide (2011)**	Detonates or explodes rapidly and decomposes under normal conditions of temperature and pressure	Unstable. Detonating. Reacts with water.	Unstable when heated or under pressure (does not react with water)	no reactivity

Table A7. PB property valuation comparison table according to ICCA, EPA and ASEAN models

Property	Numerical Assignment to Property	4 (tall) *For US EPA it is 3	3 (Medium-high) *For US EPA it is 2	2 (Medium low) *For US EPA it is 1	1 (bass) *For US EPA does not count
Persistence	**ASEAN**	**Non-volatile organic substances (Vapor pressure ≤ 1000Pa) are non-persistent if:** 1) They are rapidly biodegradable (OECD 301) 2) Inherently biodegradable (OECD 301, 302, 306) 3) Demonstrated by extrapolation or measurements 4) There is a level equivalent degradation (e.g. >20% in 28 days) via abiotic degradation, such as			

Property	Numerical Assignment to Property	4 (tall) *For US EPA it is 3	3 (Medium-high) *For US EPA it is 2	2 (Medium low) *For US EPA it is 1	1 (bass) *For US EPA does not count
		photolysis (OECD 316) or hydrolysis (OECD 111) 5) Simulated in soil, water, sediment (e.g. OECD 308 /309) with a half-life < 180 days 6) Evaluation by the BIOWIN model (Epi Suite v 4.11) **Volatile organic substances (Pvap> 1000Pa) are not persistent if:** half-life <2 days			
	US EPA (2012 and 2014 method)	Half-life > 6 months	Half-life≥ 2 months	Half-life < 2 months	--------
	ICCA Guide (2011)	Half-life in seawater and freshwater > 60 days median pathway in sediments > 180 days	half-life in seawater > 60 days, Half-life in fresh water > 40 d Half-life in sea sediment > 180 d, Half-life in soils> 120 d	Does not apply	Not considered a persistent substance
Bioaccumulative potential	**ASEAN**	**Organic substances are considered bioaccumulative if:** - Trophic magnification factor (TMF) in field < 1 - Laboratory biomagnification factor (BMF) < 1 - Bioconcentration factor (BCF) in fish, laboratory study < 5000			

Property	Numerical Assignment to Property	4 (tall) *For US EPA it is 3	3 (Medium-high) *For US EPA it is 2	2 (Medium low) *For US EPA it is 1	1 (bass) *For US EPA does not count
		- Estimated BCF < 5000 (BCFBAF model in Epi Suite v 4.119)			
	US EPA (2012 and 2014 method)	BCF or BAF > 5000	BCF or BAF ≥ 1000	< 1000	--------
	ICCA Guide (2011)	BCF > 5000 L/kg	BCF > 2000 L/kg	Does not apply	It is not considered a bioaccumulative substance

Table A8. Use valuation comparison table according to ICCA and EPA models

Numerical Assignment to Exposure Level	4 (high) for ICCA *For US EPA it is 3	3 (Medium-high) for ICCA *For US EPA it is 2	2 (Medium low) for ICCA *For US EPA it is 1	1 (low) for ICCA *For US EPA does not count
Exposure scenarios for workers and consumers	**Use for general consumption** Control measure: Product design, instructions for use	**Professional use (for example, craftsmen)** Control measures: Personal protection elements, organizational management measures	**Industrial use** Control measures: specialized equipment, technologies, personal protection elements, organizational management measures	**Closed (isolated) systems**
Exposure scenarios for the environment	**Professional use and for general consumption**	**Professional use and for general consumption** Emission of substances:	**industrial operations.** Emission control: end-of-process technologies, organizational	**industrial operations** Emission control: closed or

	Emission of substances: intentional. E.g., personal care products, cleaning, agricultural use, etc.	unintentional. For example, adhesives and paints.	management measures	strictly controlled systems.

Other examples from the scientific literature on exposure criteria are described in Shin S. et al. (2014) and Winnebeck K. et al (2012). The former, based on a prioritization analysis for the occupational sector, assigned higher relative weights to the characteristics of carcinogenicity, mutagenicity and toxicity (Table A9). The latter propose a series of volume thresholds within the framework of a system designed for the United States industry.

Table A9. Assignment of relative scores for the different hazard classifications in occupational safety contexts. Source: Shin S. et al. (2014)

danger feature	class 1		class 2	class 3	class 4	No data	Unrated	Does not apply
Acute toxicity (oral, dermal)	6		4	two	1	6	0	0
Acute (respiratory) toxicity	5		3	two	1	5	0	0
Irritation (dermal, eye)	6		4	-	-	6	0	0
Sensitization (dermal, eye)	9		-	-	-	9	0	0
Inhalation hazard	5		3	-	-	5	0	0
mutagenicity	twenty	16	12	-	-	twenty	0	0
reproductive toxicity	twenty	16	12	-	-	twenty	0	0
carcinogenicity	twenty	16	12	-	-	twenty	0	0
Target Organ Toxicity	9		7	-	-	9	0	0

Table A10. Priorities according to the range of volume produced/imported. Source: Winnebeck K. et al (2012).

Produced/imported volume range	Priority	Punctuation
Greater than or equal to 100,000,000 pounds (50,000 tons)	high	4
Between 1,000,000 and 100,000,000 pounds (500 and 50,000 tons)	High average	3
Between 25,000 and 1,000,000 pounds (12.5 and 500 tons)	Half	two
Less than 25,000 pounds (12.5 tons)	Short	1

ACRONYMS

ACC	American Chemistry Council
ASEAN	Association of Southeast Asian Nations
CEPA	Canadian Environmental Protection Act
CMR	Carcinogenic, mutagenic and toxic for reproduction
CAS	Chemical Abstract Services
DSL	Canada Domestic Substances List
EPA	United States Environmental Protection Agency (US EPA)
SMC	Sound Management of Industrial Chemicals
ICCA	International Council of Chemical Associations
LARCF	Latin American Regulatory Cooperation Forum
vPvB	Very persistent and very bioaccumulative
NICNAS Australian	National Industrial Chemicals Assessment and Reporting Scheme
NDSL	Canada Non-Domestic Substances List
OECD	Organization for Economic Cooperation and Development
WTO	World Trade Organization
PBT	Persistent, bioaccumulative and toxic to the aquatic environment (T) – chronic or acute
UNEP	United Nations Environment Program
REACH	Registration, evaluation, authorization and restriction of chemical substances of the European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
STOT	Specific Target Organ Toxicity, Single Exposure or Repeated Exposure
SVHC	Substances of Very High Concern
TSCA	United States Toxic Substances Control Act
UVCB	Substances with unknown or variable composition, complex reaction products, and biological materials
VWG-SMC-LA	Virtual Working Group for the Sound Management of Industrial Chemicals in Latin America

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