



First International Conference Global Framework on Chemicals

16–20 November 2026 | Geneva, Switzerland

Implementation Programme

“Legal frameworks and institutional capacities for the sound management of chemicals and waste”

Workstream on IP1

Title of document: UNEP Leapfrogging Guidance on Chemicals Regulation

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About this document:

UNEP has prepared a “Leapfrogging Guidance on Chemicals Regulation” report to support countries in strengthening national chemicals legislation, institutional mechanisms and capacities, in line with Implementation Programme 1 (IP1) of the Global Framework on Chemicals (GFC), “to support and achieve the safe and sustainable management of chemicals throughout their life cycle.” (Strategic Objective A). It offers practical, operational pathways for policymakers, legislators, regulators and technical experts to design or reform legal and institutional frameworks on chemicals management across all chemicals and all sectors, including industrial chemicals, consumer chemicals, pesticides, and chemicals in products.

The guidance promotes a leapfrogging approach, meaning that countries can build effective chemicals management systems by relying on existing international knowledge, hazard classifications, assessments and regulatory experience, while progressively strengthening their own national capacities. . It promotes early protection by relying on existing international assessments, focusing on the most hazardous chemicals, strengthening transparency and industry responsibility, and progressively building national capacity over time.

This report builds on and complements existing international guidance, including UNEP’s LIRA Guidance, related tools on national authorities, chemicals control, risk

reduction and enforcement, the IOMC Toolbox, and the IOMC Building Blocks for National Systems for the Sound Management of Chemicals.

UNEP Leapfrogging Guidance on Chemicals Regulation

Working Draft for Pilot Implementation
Version 1.0 – June 2026
Living Document – Subject to Revision

This guidance is a working document developed by UNEP and partners to support discussion, testing and capacity-building on chemicals management legislation. It is intended as a practical resource for policymakers, legislators, regulators and other stakeholders and does not constitute legal advice.

The guidance has not been issued as a formal UNEP publication and remains subject to revision. It will be updated periodically to reflect lessons learned from pilot applications, evolving international practice and feedback from users.

The legislative provisions and examples contained in this document are illustrative only and should be adapted to national legal, institutional and policy contexts. Their inclusion does not imply endorsement of any particular legal approach by UNEP, the United Nations or participating organizations.

References to specific countries, laws, institutions or regulatory systems are provided for illustrative purposes and do not represent an assessment of their effectiveness or suitability for all jurisdictions.

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Introduction – *Why do we need this Guidance?*

1. Purpose of the Guidance

This report provides guidance to support countries in strengthening national chemicals legislation, institutional mechanisms and capacities, in line with Implementation Programme 1 (IP1) of the Global Framework on Chemicals (GFC), “*to support and achieve the safe and sustainable management of chemicals throughout their life cycle.*” (Strategic Objective A).

It offers practical, operational pathways for policymakers, legislators, regulators and technical experts to design or reform legal and institutional frameworks on chemicals management across all chemicals and all sectors, including industrial chemicals, consumer chemicals, pesticides, and chemicals in products.

2. Context and Challenges

The production, trade and use of chemicals continue to expand globally, often exceeding the ability of legal, administrative and institutional systems to adapt and respond. While chemicals play an essential role in modern economies, weak or fragmented systems can leave populations exposed to harmful substances and create uncertainty for the industry.

Despite the availability of certain guidance tools, many countries face challenges in translating such resources into concrete reforms. Existing tools often provide comprehensive technical guidance but limited support for operational decision-making, particularly in settings with limited resources. As a result, gaps and delays in legal and institutional responses can constrain timely and effective risk management.

3. Rationale and Conceptual Approach

This guidance addresses the above challenges by promoting practical, proportionate, and resource-efficient approaches to the design and implementation of legal, regulatory, and institutional frameworks for chemicals management. It supports countries in making informed decisions on key structural elements while remaining adaptable to different national contexts and capacities.

It is grounded in the objectives of the Global Framework on Chemicals (GFC), in particular the need to establish effective legal frameworks, institutional capacities and decision-making systems for the sound management of chemicals throughout their life cycle. It reflects core GFC principles, including prevention, transparency, access to information and a lifecycle approach.

A central premise is that countries can build on existing international knowledge, best practice, data, and regulatory experience instead of developing systems from first principles. The utilization of available hazard classifications, risk assessment mechanisms, and regulatory decisions can reduce duplication, catalyze implementation, and bolster the protection of human health and the environment.

It is in this context that the guidance promotes a **leapfrogging approach**, whereby countries establish functional and preventive systems by drawing on existing

international resources while progressively strengthening national capacity-building mechanisms.

The guidance is based on the following elements:

- **Preventive approaches:** prioritising early action to avoid harm;
- **Use of existing knowledge and information:** supporting decision-making based on available data and assessments;
- **Transparency and access to information:** ensuring access to relevant information for authorities, stakeholders and the public;
- **Proportionate and resource-efficient regulation:** focusing efforts where risks are greatest; and
- **Lifecycle perspective:** addressing chemicals throughout the entire lifecycle of their production, use and disposal, including in products and supply chains.

Together, these elements support the development of systems that are both protective and feasible, enabling early action while allowing frameworks to evolve over time.

4. Scope

The guidance covers the full lifecycle of chemicals and presents a wide range of legislative/regulatory approaches. It does not prescribe a single, one-size-fits-all model. It outlines options for:

- Defining legislative objectives and scope;
- Applying hazard-based and generic approaches;
- Using foreign data and regulatory reliance;
- Establishing listing systems;
- Ensuring transparency and the right to know;
- Securing sustainable financing, including cost recovery; and
- Strengthening institutional coordination mechanisms.

The focus is on key legal and institutional choices that determine how national systems function in practice, while remaining adaptable to diverse national contexts.

5. Relationship with Existing Instruments

This report builds on and complements existing international guidance, including UNEP's *LIRA Guidance*,¹ related tools on national authorities, chemicals control, risk reduction and enforcement,² and the IOMC Toolbox.³ It is designed to be interoperable with these resources and aligned with the GFC's modular approach.

¹ United Nations Environment Programme (UNEP) (2015). Guidance on the development of legal and institutional infrastructures and measures for recovering costs of national administration for the sound management of chemicals. Available at: <https://wedocs.unep.org/items/20ea9c63-4f70-46fc-94c3-8c7ce94379f1>

² <https://www.unep.org/resources/report/guidance-chemicals-control-contributing-national-progress-and-safety>.

³ **Inter-Organization Programme for the Sound Management of Chemicals (IOMC) (n.d.).** *IOMC Toolbox for Decision Making in Chemicals Management*. Geneva: IOMC. Available at: <https://www.iomctoolbox.org>

6. Key Deliverables

The guidance provides:

- **Practical options for legislative design** tailored to national capacities;
- **Approaches to reduce administrative and financial burdens**, including reliance on existing data and assessments; and
- **Illustrative provisions and model approaches** to support legal drafting and reform.

7. Expected Contribution

By promoting preventive, proportionate and adaptable approaches, this guidance supports countries in establishing legal and institutional systems capable of evolving over time while delivering **early and effective protection of human health and the environment**.

It also provides a basis for coordinated support by international partners and donors for **cost-effective and scalable reforms** aligned with national priorities and global commitments.

Part I — Why a Leapfrogging Approach Is Needed

1. Why regulate chemicals?

Chemicals play a central role in modern economies and societies. They are essential for industrial production, agriculture, health care, construction, electronics, and many other applications.⁴ At the same time, many chemicals pose significant risks to human health and the environment when produced, used, or disposed of without adequate controls.

Exposure to hazardous chemicals has been associated with a wide range of adverse health outcomes, including cancer, neurological disorders, reproductive and developmental effects, respiratory diseases, and endocrine disruption. Vulnerable populations such as children, pregnant women, workers and communities living near industrial activities may face elevated risks.⁵

Environmental impacts are also significant.⁶ Chemicals can contaminate air, water, soil, and food chains. Some substances persist in the environment for decades and accumulate in living organisms, affecting ecosystems, biodiversity and the services they provide to societies and economies.

The global chemicals sector is expanding rapidly, with production continuing to grow and an increasing share occurring in low- and middle-income countries. At the same time, many countries face significant challenges in managing chemicals safely. Legislative and regulatory frameworks may be incomplete or fragmented, institutional responsibilities dispersed, and access to data, expertise, and financial resources limited.

Inadequate chemicals management can result in substantial economic costs, including health care expenditures, productivity losses, environmental remediation and long-term damage to ecosystems and natural resources.

Strengthening national systems for the sound management of chemicals is therefore essential to protect human health and the environment, while supporting sustainable development, economic resilience, and social well-being. Effective chemicals legislation provides the foundation for such systems: it defines responsibilities for the public and private sector, establishes risk assessment and management, and creates mechanisms for enforcement and accountability.

2. What is chemical regulation?

Chemical regulation refers to the legal and institutional mechanisms governments use to ensure that chemicals are produced, imported, used, and disposed of in ways that minimise risks to human health and the environment. These mechanisms are typically

⁴ United Nations Environment Programme. (2023). Bonn Declaration for a Planet Free of Harm from Chemicals and Waste (ICCM5 outcome document), paragraph 4. Available at: <https://wedocs.unep.org/rest/api/core/bitstreams/965cfa50-5532-449e-9164-80a669891e60/content>

⁵ Ibid. para. 2.

⁶ Persson, L. et al. (2022). *Outside the safe operating space of the planetary boundary for novel entities*. Environmental Science & Technology. Available at <https://doi.org/10.1021/acs.est.1c04158>

established through legislation and implemented through regulations, administrative procedures and institutional arrangements.

These systems typically combine several elements, including requirements for information on chemical hazards and uses, mechanisms for assessing risks, regulatory tools for managing those risks, and enforcement measures to ensure compliance.

In many cases, regulatory systems focus on controlling the placement of chemicals on the market, requiring manufacturers or importers to generate and provide information on chemical hazards and uses.

In practice, chemical regulation involves balancing protection objectives with available regulatory capacity. Effective systems therefore aim to ensure that governments can take protective decisions while making efficient use of available scientific knowledge and regulatory resources.

3. Objectives of chemicals legislation

The primary objective of chemical legislation is to enable the use of chemical substances on the market while protecting human health and the environment from their adverse effects.

Achieving this objective requires regulatory systems capable of identifying hazardous substances, assessing potential risks, implementing appropriate risk management measures, and authorising specific allowed uses. Effective enforcement and monitoring mechanisms are also essential.

Regulatory systems must be designed to be feasible within national, institutional, and resource constraints. This is particularly important in low and middle-income countries where financial resources, technical expertise, and laboratory capacity may be limited. Systems that require extensive data generation, complex risk assessments, or large administrative structures may be difficult to implement effectively.

Legislation should therefore aim to achieve high levels of protection while remaining proportionate and implementable.

Preventive approaches are central to this objective. Rather than responding to harm after it occurs, legislation should enable risks to be identified and addressed at an early stage. Precautionary approaches may also support timely action where credible evidence indicates potential harm, even in the absence of full scientific certainty.

Early regulatory action can reduce long-term costs and prevent widespread exposure. This requires legal frameworks that allow authorities to make timely decisions using available information, including data and assessments developed in other countries or through international processes.

4. Limitations of traditional regulatory pathways

Traditional approaches to chemical regulation have often relied on the development of comprehensive national inventories of chemicals, followed by substance-by-substance assessment and control.⁷⁸

Under such approaches, regulators identify chemicals on the market, collect data on their hazards and uses, and assess risks on a substance-by-substance basis before introducing regulatory measures. While such systems can provide detailed information, they are often resource-intensive and time-consuming.

Experience from several jurisdictions shows that assessing chemicals individually may take many years, particularly when large numbers of substances are involved.⁹ For countries with limited regulatory capacity, these approaches can delay risk management actions and place significant demands on scientific and administrative resources.

In this context, alternative regulatory strategies that rely more extensively on existing international knowledge and streamlined decision-making processes may provide more practical pathways for strengthening protection.

5. What is “leapfrogging” in chemicals legislation

Experience from the development and implementation of chemicals legislation indicates that complex regulatory systems established in high-income countries are not always readily transferrable to countries with limited capacity. Frameworks based on extensive data generation, registration, and substance-by-substance assessment can be difficult to implement where resources are constrained and where most chemicals are imported, such as in low and middle-income countries.

In this context, a leapfrogging approach refers to the use of simplified, preventive and resource-efficient regulatory strategies that enable countries to establish functional systems more rapidly by building on existing international knowledge and regulatory experience.

Such approaches emphasize the use of hazard classifications, risk assessments and regulatory decisions developed in other jurisdictions, as appropriate. They also promote the allocation of responsibilities to producers, importers and suppliers, including for the generation of information and the coverage of regulatory costs.

For the purposes of this guidance, legislative/regulatory approaches may be considered “leapfrogging”, where they:

1. **Enable early protection:** Allowing regulatory action without requiring a complete system with inventories or national assessment build-out.
2. **Shift the responsibility on producers, importers and suppliers of chemicals and products containing chemicals,** for covering regulatory costs and provide

⁷ See https://www.nite.go.jp/chem/jcheck/list3.action?category=141&request_locale=en

⁸ Philippine Inventory of Chemicals and Chemical Substances, https://chemical.emb.gov.ph/?page_id=138

⁹ Lira Guidance, page 39.

reliable content information on the chemicals used, and the potential risks of their products

3. **Avoid duplication of scientific assessment:** Relying on existing international hazard classifications, data, and regulatory decisions in trusted jurisdictions.
4. **Reduce per-chemical decision-making burdens:** Through the use of grouping approaches, functional uses, or typical exposure scenarios, rather than substance-by-substance assessments.
5. **Remain adaptable:** Enabling systems to incorporate new knowledge without requiring frequent legislative amendments.
6. **Address chemicals in products and value chains,** focusing on supply-side obligations where enforcement is most feasible.
7. **Prevent regrettable substitution,** through grouping, hazard-class regulation, and essential-use logic.
8. **Align with a domestic enforcement capacity, where limited,** relying on documentation, declarations, and market-access controls.
9. **Support sustainable financing,** including through cost recovery, fees, or extended producer responsibility mechanisms.

Not all regulatory tools meet these leapfrogging criteria. Approaches that depend on long preparatory phases, extensive national data generation, or large technical infrastructures may remain valuable but are better suited as **complementary or later-stage options**, of system development.

Part II Guidance —Recommended Actions for Leapfrogging

The guidance below outlines key elements of an effective and preventive system for chemicals management, based on a leapfrogging approach. It presents a legislative model built around the following components:

- High-level **protective objectives** that enable authorities to take timely action to protect human health and the environment, including through restrictions, bans and placing the burden of proof on economic operators to demonstrate that decisions on chemicals are unfounded;
- An enabling **overarching chemicals framework law** including basic principles on the placing of chemicals on the market, and applying to substances not covered under sector-specific legislation;
- Effective implementation of **Occupational Safety and Health (OSH)** requirements, ensuring workers are protected from chemical hazards, through enforceable obligations on employers to provide safe and healthy working environment.
- Preferential use of **generic risk management measures**, particularly for hazardous chemicals where exposures cannot be reliably controlled, unless safety is demonstrated by economic operators;
- Explicit legal provisions for **reliance on internationally generated classifications, data, and risk assessment decisions**;
- Robust **information, disclosure, and right-to-know obligations** ensuring transparency across supply chains and access to relevant information for authorities, workers and the public;
- **Sustainable financing mechanisms**, including cost recovery fees and extended producer responsibility.
- **Effective institutional coordination mechanisms**, ensuring coherent implementation across relevant authorities and sectors.

1. Setting the level of protection and power for authorities to act

When drafting chemicals legislation, a critical first step is to define clear objectives and determine the level of protection the law aims to achieve. These elements establish the foundation of the legal framework, guiding its interpretation, implementation and enforcement.

The chosen level of protection reflects the policy priorities, including the extent to which the law prioritizes the protection of human health and the environment, potentially including recognition of the human right to a healthy environment, relative to other considerations such as economic activity. It also shapes the regulatory approach adopted, for example whether to rely on generic risk approach that is focused on the substitution of hazardous chemicals or to a more detailed substance-by-substance risk assessment.

Objectives in the legislation serve act as the compass for the system. They define the purpose and direction and influence how its substantive provisions are designed, applied and enforced. Objectives that establish a high level of protection, such as those referring to precautionary approaches (Stockholm Convention), the polluter-pays or the right to a healthy environment, can support timely and decisive action, including in situations of uncertainty that does not only seek to prevent “unreasonable risk.” By contrast, formulations that that emphasize balancing protection with economic interests may lead to more constrained regulatory action.

In practice, many legal systems anchor chemicals legislation in broader constitutional or treaty-based principles. For example, the European Union legislation emphasizes a high level of environmental protection and the precautionary principle.¹⁰ Several countries also recognize the rights to health or to a healthy environment in their constitutions, which may guide regulatory and judicial decision-making. The choice of objectives therefore has direct implications for how legislation is interpreted and applied.¹¹

Objectives should be drafted in a way that:

- Clearly states the purpose/ *what* the law is meant to achieve;
- Provides a basis for interpretation by regulators, courts and stakeholders;
- Guides the selection of regulatory tools (e.g., inventories, classification and labelling, restrictions, authorisation, supply-chain information obligations).

Recommendations for drafting

Regulators should select a formulation that aligns with national priorities and institutional capacities.

The level of protection defines *how far* the law intends to go in safeguarding human health and the environment, and it determines the types of regulatory tools that are appropriate. While no single model applies in all contexts, this guidance identifies several broad approaches, each with different implications for implementation.

Model A – Rights-based

“The purpose of this Act is to ensure a high level of protection of human health and the environment from the adverse effects of chemicals throughout their life cycle, in

¹⁰ The objectives of REACH and CLP Regulations are grounded in the Treaties: Article 191 of the Treaty on the Functioning of the European Union (TFEU) e, while Article 114 TFEU supports the functioning of the internal market.

¹¹ See Colombia, Constitución Política de Colombia de 1991. Article 79 Bogotá: Asamblea Nacional Constituyente, 1991. Available at: <https://www.constitucioncolombia.com>; Chile. Constitución Política de la República de Chile, Article 19(8). Santiago: Gobierno de Chile, 1980 (as amended). Available at: https://www.camara.cl/camara/doc/leyes_normas/constitucion.pdf; Constitution of the Republic of South Africa, 1996. Article 24. Pretoria: Government of South Africa, 1996; Constitution of Kenya, Article 42, Nairobi, 2010. Available at.: <https://www.justice.gov.za/constitution/SACConstitution-web-eng.pdf> https://www.parliament.go.ke/sites/default/files/2017-05/The_Constitution_of_Kenya_2010.pdf; Constitution of the Republic of Uganda, 1995. Article 39, Kampala, 1995. Available at: <https://faolex.fao.org/docs/pdf/uga132923.pdf>

accordance with the precautionary principle, the polluter pays principle, and the right to a healthy environment.”

Implications for drafting:

- favours upstream controls (bans, restrictions, generic risk approaches);
- strong transparency rules with narrow CBI exceptions;
- precautionary and preventive interpretation in case of uncertainty;

Model B – Preventive (Minimising risk)

Purpose clause template:

“This Act aims to prevent and minimize adverse impacts of hazardous chemicals on human health, property, and the environment by regulating their manufacture, import, use, and disposal, and by promoting safer alternatives.”

Implications for drafting:

- supports a risk based tools pragmatically with a focus on substitution, when technically and economically feasible;
- the burden of proof should be placed on the economic operators
- focuses on reducing hazardous chemicals;
- requires information generation and disclosure obligations.

Model C – Risk management based (Control of unreasonable risk)

Purpose clause template:

“The purpose of this Act is to protect human health and the environment against unreasonable risks from chemicals, while supporting sustainable industrial development, innovation, and trade through efficient, science-based regulation.”

Implications for drafting:

- favours detailed risk assessments and places the burden of proof on government;
- promotes substitution only as a last resort when alternatives are established and they are economically feasible;
- requires extensive data collection to regulate chemicals.

2. Legal architecture for chemical controls

Countries regulate chemicals through different legislative approaches. Some frameworks apply broadly to all chemicals placed on the market, while others regulate

specific products or uses such as pesticides, pharmaceuticals, consumer or industrial chemicals.

Comprehensive chemicals legislation typically establishes general obligations for manufacturers and importers, including requirements to provide information on chemical hazards and uses, and to comply with regulatory decisions adopted by competent authorities.

In parallel, many countries maintain sector-specific legislation to address specific product groups or uses (pesticides, pharmaceuticals, consumer products etc) where tailored rules are necessary.

UNEP recommends the establishment of an overarching framework law for chemicals control that applies across sectors and chemicals placed on the market. Such a law provides the legal backbone of the national system, by defining core principles, allocating responsibilities and establishing regulatory tools.

Within this architecture, **the framework law does not replace sectoral legislation** but complements it. It promotes coherence across regulatory regimes and helps prevent gaps in coverage.

This approach enables countries to strengthen chemicals management progressively while maintaining existing regulatory systems for specific product groups. The framework law provides a flexible foundation for phased implementation, without requiring comprehensive and detailed regulation of each chemical from the outset.

Recommendations for drafting

Article X – Scope and General Powers

This Law applies to the manufacture, import, and placing on the market of chemicals, except where specific uses are governed by other legislation. Where a specific use is governed by other legislation, this Law shall nonetheless continue to apply to the extent that the other legislation affords a lower level of protection to human health or the environment.

Chemicals may only be placed on the market if they do not pose unacceptable risks to human health or the environment, in accordance with the conditions set out by this Law and any applicable legislation. The burden of demonstrating that a chemical may be placed on the market, and that the applicable conditions are met, rests with the manufacturer or importer.

The competent authority may take necessary measures to prevent or minimise such risks, including implementing restrictions, conditions, or prohibitions, in accordance with this Law. The competent authority may take such measures, notwithstanding scientific uncertainty as to the nature or extent of the risk, where there are reasonable grounds for concern that a chemical may cause harm to human health or the environment.

3. Regulate chemicals across all sectors: occupational safety and health legislation.

No single regulatory framework typically covers the entire lifecycle of chemicals, from production and import to use, storage, and disposal, through a unified system of

market authorization and risk assessment. Instead, countries rely on a patchwork of sector-specific laws addressing different stages or categories, such as pesticides, pharmaceuticals, industrial chemicals, worker protection, or waste management.

Within this fragmented landscape, occupational safety and health (OSH) legislation plays a unique and essential role. It is one of the few frameworks that applies across all sectors and to all chemicals, with the objective of protecting workers from exposure and minimizing risks where exposure cannot be avoided.

At the international level, the **ILO Chemicals Convention, 1990** (No. 170)¹², and Recommendation No. 177¹³, provide a comprehensive framework for the safe management of chemicals in workplaces. The Convention establishes core obligations for suppliers and employers, including:

- Chemical hazard classification;
- Hazard labelling and communication;
- Provision of safety data sheets;
- Worker information (see International Chemical Safety Cards developed by ILO)¹⁴ and training; and
- Implementation of proper control measures to prevent harmful exposure.

These elements create a set of universal duties applicable to hazardous chemicals in workplaces and represent one of the few globally recognized systems of cross-cutting chemical control. However, their scope is limited to occupational exposure and does not extend to market approval, consumer use, environmental protection, transport, or waste management.

The **Globally Harmonized System of Classification and Labelling of Chemicals (GHS)** is the principal international standard for hazard classification and communication. It establishes harmonized criteria for classifying substances and mixtures based on their health, environmental and physical hazards, as well as standardized labelling and safety data sheet formats. Since its adoption in 2002, it has become a foundational tool for sound chemicals management across multiple sectors.¹⁵

Regional systems may build on the GHS to establish more detailed regulatory frameworks. For example, the European Union's Classification, Labelling and

¹² International Labour Organization, Convention Concerning Safety in the Use of Chemicals at Work (No. 170), June 25, 1990, 1650 U.N.T.S. 383. Available at: https://normlex.ilo.org/dyn/nrmlx_en/f?p=NORMLEXPUB:12100:0::NO::P12100_INSTRUMENT_ID:312315

¹³ International Labour Organization, Recommendation Concerning Safety in the Use of Chemicals at Work (No. 177), June 25, 1990. Available at: https://normlex.ilo.org/dyn/nrmlx_en/f?p=NORMLEXPUB:55:0::55:P55_TYPE,P55_LANG,P55_DOCUMENT,P55_NODE:REC,en,R177,/Document

¹⁴ <https://www.ilo.org/icsc>.

¹⁵ See also the United Nations. Plan of Implementation of the World Summit on Sustainable Development. paragraph 23 (c) Johannesburg, South Africa: World Summit on Sustainable Development, 2002, which aspired for the system to be fully operational by 2008. See para. 23(c). Available at: https://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf

Packaging (CLP) Regulation¹⁶ requires manufacturers and importers to classify and label substances and mixtures and, in certain cases, provides for harmonized classifications through a centralized process ensuring uniform hazard communication across the EU area.¹⁷ These harmonized classifications ensure consistent hazard communication and may trigger risk management measures for substances of concern.

The European Union also requires manufacturers and importers to notify the European Chemicals Agency (ECHA), which maintains a public classification and labelling inventory, which includes both harmonized classifications and information submitted by companies.¹⁸ This enhances transparency and provides a shared source of information for authorities, industry and the public.

While OSH frameworks and hazard communication systems such as the GHS provide essential cross-cutting controls applicable to all chemicals, they are not sufficient on their own to ensure comprehensive lifecycle management. Complementary legislative approaches are therefore required.

Recommendations for drafting

Article X – Duty of employers to prevent exposure

The most effective means to prevent exposure of workers to toxic substances is to eliminate them from the workplace. This is reflected in the good practice known as the hierarchy of hazard controls. In this context countries should implement provisions from the ILO conventions that prevent and control exposure to hazardous chemicals:

- Employers must assess, monitor and record the exposure of workers to hazardous chemicals and ensure that exposure limits are not exceeded.
- Employers must assess chemicals' risks and appropriately protect workers by their choices of chemicals, technology, control measures, working systems, working practices, hygiene measures and, if the foregoing are insufficient, must provide personal protective equipment to workers free of charge.
- Employers also must limit the exposure of workers to hazardous chemicals to a safe level and arrange for handling of emergencies and provision of first aid.

Article Y – Supplier duties: classification, labelling and safety data sheets

Country regulators must ensure that, as a minimum ILO instruments on chemical risk at work, in particular Convention No 170 of 1990 and its recommendation No. 177 are embedded into national legislation to ensure that:

- Suppliers of chemicals must ensure that they provide a Safety Data Sheet which includes the hazards and risks of the chemicals.

¹⁶ European Union 2008. *Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures*. Brussels: EU

¹⁷ The list of chemicals with their harmonised classification is available at: <https://chem.echa.europa.eu/obligation-lists/clhList>

¹⁸ See ECHA, Understanding CLP. Available at: <https://echa.europa.eu/regulations/clp/understanding-clp>; <https://echa.europa.eu/regulations/clp/cl-inventory>

- Employees must be provided with SDS for hazardous chemicals. The format and content of labels and SDS must be prescribed by the competent body.
- Chemicals have a classification and labelling according to the type and degree of their hazards, preferably in line with international standards. The labelling of hazardous chemicals must clearly explain their hazards.
- Employers must ensure that all chemicals are properly labelled and have SDS and that only chemicals for which a classification, labelling and SDS have been prescribed by the authority are used.

Article Z – Classification and labelling system

- While any system of classification and labelling of chemicals is suitable if the hazards and risks are clearly understood by employees, Country regulators are encouraged to apply existing international standards on classification, labelling and packaging on chemicals.
- It is crucial that, whatever system is used, the information is clearly understood by the workers and that the information is provided in the languages understood by workers.

4. Using Generic Risk Assessment approaches to support protective decision-making

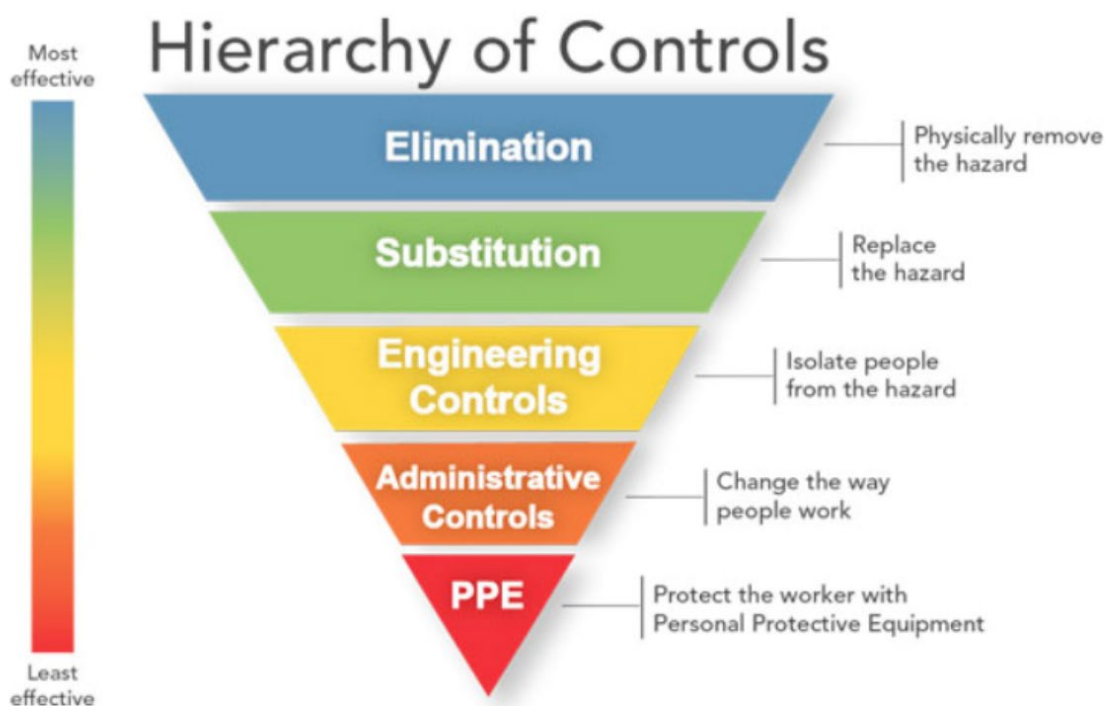
Chemicals legislation may rely on different approaches to regulatory decision-making. These approaches exist along a spectrum, differing mainly in the amount of information required and in how uncertainty is addressed. Rather than distinguishing between “hazard-based” and “risk-based” systems, it is more accurate to recognize that all regulatory systems assess risk, but apply varying levels of detail, data requirements and precaution depending on the context.

The “hierarchy of controls,” widely used in occupational safety, illustrates this continuum. Higher levels prioritize prevention of harm by eliminating or avoiding hazardous substances, while lower levels focus on managing exposure through engineering controls, administrative measures, or personal protective equipment.

The choice of approach depends on several factors, including:

- the **desired level of health and environmental protection**,
- the **hazard properties of the substance**,
- the **nature of exposure and affected populations**,
- the **degree of uncertainty**, and
- the **availability of scientific information and regulatory capacity**.

Importantly, not all decisions require detailed chemical-by-chemical risk assessments. Many jurisdictions routinely adopt legally robust measures based on **screening-level or generic risk assessments**, particularly where exposures are widespread or where vulnerable populations may be affected.



Source: US Center for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH). 2016. "Hierarchy of Controls". Viewed at <https://www.cdc.gov/niosh/hierarchy-of-controls/about/index.html> (13 October 2025)

Generic risk approaches

Generic risk approaches rely on **simplified assessments**, using hazard classifications, conservative exposure assumptions, or worst-case scenarios to support decision-making.

They are particularly appropriate where:

- exposure is widespread or difficult to quantify,
- vulnerable populations may be affected,
- substances have properties of particular concern, or
- timely preventive action is required.

Because they rely on less detailed information, these approaches enable **faster and more preventive regulatory action**. However, they may lead to stricter controls than those resulting from more refined risk assessments. For this reason, they are often complemented by more detailed evaluations, where necessary.

Detailed risk-assessments approaches

Detailed risk assessments evaluate both **hazard and exposure** to determine whether a substance poses unacceptable risks under specific conditions of use. They allow more tailored and proportionate risk management measures and can help avoid unnecessary restrictions where exposure is limited or well controlled. Countries with a developed system tend to use this approach, at least for most chemical uses.

However, these approaches typically require significant data, technical expertise and institutional capacity. They may therefore be time-consuming and difficult to implement where information is limited.

In many low- and middle-income countries, constraints such as limited toxicological data, modelling capacity and technical expertise can make comprehensive risk assessments challenging. In such contexts, generic approaches based on existing hazard classifications, simplified exposure assumptions and internationally available assessments are often more practical. These approaches enable authorities to take protective action without requiring extensive national data generation.

Where more detailed assessments are needed, feasibility can be enhanced by allowing reliance on international data and assessments. Existing sources include GHS classifications, WHO/IPCS reports, OECD evaluations and assessments by established regulatory authorities, already used by many low- and middle-income countries.

Grouping approaches, which assess related substances collectively rather than individually, can further reduce effort.¹⁹ These may include class-based restrictions or the use of read-across and category-based reasoning.

Combining approaches

In practice, effective regulatory systems combine these approaches. **Generic approaches can provide an efficient starting point**, enable early action, and allowing authorities to take protective action using hazard classifications, internationally available data and simplified exposure assumptions. While more detailed assessments can be applied selectively where needed.

Approaches that reduce data requirements, make systematic use of existing knowledge and allow for gradual strengthening over time tend to be more feasible, particularly in resource-constrained settings. Incorporating grouping methods and ensuring compatibility with digital (including artificial intelligence) tools can further support progressive system development.

Designing regulatory frameworks that integrate these elements allows countries to strengthen chemicals management incrementally while maintaining effective protection of human health and the environment.

Recommendations for drafting

Article X – Restrictions for Pesticides and Biocides

“A pesticide active substance, safener or synergist shall not be approved if, on the basis of available scientific data and information, including a review of the scientific literature by the Authority, it is considered to have the hazard characteristics listed in Annex (X)

¹⁹ Organisation for Economic Co-operation and Development (OECD), Guidance on Grouping of Chemicals, Second Edition, OECD Series on Testing and Assessment No. 194 (2014), available at: https://www.oecd.org/en/publications/guidance-on-grouping-of-chemicals-second-edition_9789264274679-en.html

Article X+1 – Restriction on supply to the general public

Article X+2 – Restriction on supply of substances listed in Annex [1]

Substances that meet the characteristics specified in Annex 1 shall not be placed on the market or used for supply to the general public:

- as substances;
- as constituents of other substances; or
- in mixtures,
- at or above the concentration limits established under applicable legislation or, in the absence of such limits, at or above the generic concentration limits applicable to the relevant hazard class under the Globally Harmonized System of Classification and Labelling of Chemicals.

Substances or mixtures containing such substances may only be supplied to professional users.

Suppliers shall ensure that the packaging of such substances or mixtures is clearly and permanently marked:

“Restricted to professional users.”

Paragraph 1 shall not apply to products where regulated under other applicable legislation.²⁰

Annex hazard characteristics (to be updated as necessary):

- Carcinogen Category 1A or 1B according to the Globally Harmonized System for Classification and Labelling
- Mutagen Category 1A or 1B according to the Globally Harmonized System for Classification and Labelling
- Toxic for reproduction 1A or 1B according to the Globally Harmonized System for Classification and Labelling
- Persistent, Bioaccumulative and Toxic
- Very Persistent and very bioaccumulative
- Persistent, Mobile, and Toxic
- Very persistent and very mobile
- Endocrine Disrupting²¹

For hazard characteristics not yet covered by the Globally Harmonized System (e.g, endocrine-disrupting, persistent, mobile and toxic; and very persistent and very mobile properties), a substance shall be treated as meeting the relevant

²⁰ Exempted uses may include the following: medicinal and veterinary products; fuels and mineral oil products used in combustion systems; medical devices and more.

²¹ These hazardous characteristics are not covered, for now by the GHS but they are defined under the EU CLP Regulation that implements the GHS in the EU.

characteristic where it has been so classified or identified by a trusted jurisdiction specified in regulations.

5. Reliance on international data, classifications, and regulatory decisions

Many countries face significant challenges in generating the scientific data required for chemical hazard and risk assessments. Comprehensive assessments require substantial expertise, access to toxicological and exposure data, modelling capacity and laboratory infrastructure. At the same time, regulators must evaluate large volumes of information across many substances.

For countries with limited resources, producing and assessing such data can be difficult. However, a substantial body of scientific and regulatory work has already been developed internationally. Regulatory authorities in several jurisdictions routinely conduct detailed hazard and risk assessments, often based on internationally harmonized methodologies and made publicly available.

Making effective use of this existing information offers an opportunity to accelerate decision-making while reducing costs and duplication.

Use of Existing Studies and Assessments

A large volume of toxicological and environmental data has already been generated through regulatory processes, academic research and international cooperation. Assessments conducted by well-resourced authorities often include detailed evaluations of hazards, exposure scenarios and risk management measures.

Using such information, can support key regulatory functions, including:

- identification of chemicals of concern;
- prioritization of substances for further review;
- key information for national classification and labelling decisions;
- restrictions or bans on hazardous substances;
- development of national watchlists or priority lists.

In practice, many countries underutilise these resources. Authorities may seek to replicate full assessments even where robust evaluations already exist, leading to duplication, delays and inefficient use of resources.

Establishing clear legal mechanisms for reliance on foreign data and regulatory decisions can reduce inefficiencies and enable more timely risk management.

International Frameworks supporting Data Reuse

International cooperation has already established several mechanisms to facilitate the sharing and reuse of chemical safety information.

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) provides a common framework for hazard classification and communication, making classifications broadly comparable and usable across jurisdictions. For instance, the EU has developed a harmonized classification and labelling system rooted in rigorous

scientific methods, covering thousands of chemicals with legally binding classifications.²²

The **Organisation for Economic Co-operation and Development (OECD)** has developed internationally recognized **OECD Test Guidelines** and **Good Laboratory Practice (GLP)** standards. Under the OECD system of **Mutual Acceptance of Data (MAD)**, participating countries agree to accept test data generated in accordance with these standards, reducing duplication, including unnecessary animal testing, and promoting consistent hazard evaluation. While participation MAD, facilitates the acceptance of test data across jurisdictions, **reliance on foreign regulatory conclusions does not require formal participation in MAD**. Countries can use publicly available hazard assessments, risk assessments and regulatory decisions produced by other authorities even if they are not members of OECD frameworks.

Box 1. Reliance on assessments by trusted overseas regulators (Australia)²³

Australia has introduced a regulatory mechanism that allows authorities to rely on chemical safety assessments carried out by designated foreign regulators. Under the Industrial Chemicals Act 2019, the Australian Industrial Chemicals Introduction Scheme (AICIS) can recognise evaluations performed by appointed “trusted overseas regulators.”

If a chemical has already been evaluated by one of these recognised authorities listed in legislation, companies introducing the substance in Australia may rely on the existing assessment when assigning its regulatory category. This can allow certain introductions to proceed through simpler notification or exemption pathways, provided the conditions of use are similar and the assessment meets the required standards.

The system minimizes duplication of scientific assessments, enabling regulators to concentrate resources on chemicals that haven't been evaluated elsewhere. It also illustrates how national legislation can integrate international regulatory insights while still overseeing chemicals in the domestic market.

The legal framework for this approach is established in the **Industrial Chemicals Act 2019**, while the **Industrial Chemicals (General) Rules 2019** specify the regulatory categories and include a **list of recognised “trusted overseas regulators” whose assessments may be relied upon**, subject to defined conditions.

²² These EU classifications can serve as a foundation for other countries to adopt, especially for highly hazardous chemicals such as carcinogens, for which automatic safety measures, such as bans and restrictions, can be implemented to protect public health. See CLP Annex VI – harmonised classification and labelling for certain hazardous substances, Table 3, The list of harmonized entries in Table 3 of Annex VI to the CLP Regulation, containing those substances for which a specific harmonized set of classification and labelling data has been agreed at EU level by Member States. The harmonized classification and labelling of hazardous substances are updated regularly through “Adaptations to Technical Progress (ATPs)”, which are issued by the European Commission. Following the adoption of an opinion on the harmonised classification and labelling of a substance by the Committee for Risk Assessment (RAC), the European Commission takes a decision and publishes the update in an ATP. Available at: <https://chem.echa.europa.eu/obligation-lists/clhList>

²³ Australia (2019). *Industrial Chemicals Act 2019*, No. 82, 2019; Australia (2019). *Industrial Chemicals (General) Rules 2019*, Schedule 2 (Trusted overseas regulators).

Recommendations for drafting

Legislation should provide a clear basis for the use of international data, classifications and regulatory decisions, supported by robust safeguards. Key considerations include:

1. **Legal Basis:** Laws should explicitly authorize companies, competent authorities and relevant stakeholders trigger the procedure to recognise hazard or risk assessments conducted by designated trusted foreign or international bodies. These provisions should make clear that recognition is subject to defined criteria and that the authority may adopt, adapt, or reject foreign conclusions as appropriate. To give recognition operative effect rather than leaving each case to a discretionary national process, legislation should provide a default rule: a substance banned or severely restricted by at least two trusted jurisdictions for reasons of human health or environmental protection is provisionally restricted nationally, pending review by the competent authority. Where the conclusions of trusted jurisdictions diverge, the authority shall apply the more protective conclusion unless it gives reasons for departing from it.
2. **Designation of Trusted Bodies:** Legislation should provide for the identification of trusted authorities whose assessments may be recognised. This can be done through regulations, schedules, or ministerial notices. Trusted bodies typically include regulators or scientific agencies with established, transparent, and evidence-based assessment processes.²⁴
3. **Equivalence Criteria:** Recognition should be limited to situations where core elements are comparable, including:
 - substance identity;
 - intended uses and exposure conditions;
 - assessment scope and methods;
 - data quality and transparency.
 - Where local uses differ (e.g. informal sector applications, climatic conditions), adjustments may be required.
4. **Periodic Review:** Mechanisms should allow authorities to revisit recognised foreign assessments periodically and to revise or withdraw reliance where new information or updated evaluations become available. Reliance on foreign assessments should operate as a floor, not a ceiling. National legislation should make clear that recognition does not prevent the competent authority from adopting more protective national measures where warranted by national conditions of use or policy priorities.
5. **Identification of trusted jurisdictions:** Criteria for identifying trusted bodies may include:
 - **Alignment with national protection objectives:** Its level of precaution, public-health focus, and environmental protection objectives are consistent with the country's chosen policy priorities.

²⁴ In Australia, a list of trusted bodies is included in section 6 of the Industrial Chemicals (General) Rules 2019.

- **Scientific integrity:** The body applies transparent, peer-reviewed, and evidence-based methodologies consistent with international standards.
- **Institutional independence:** It operates free from conflicts of interest.
- **Transparency:** Assessment methods, rationales, and conclusions are publicly available or accessible to regulators.
- **Regulatory credibility:** The body has an established record of high-quality, science-based decision-making recognized by other competent authorities.
- **Participation in international** cooperation and information sharing networks: It participates in international networks (e.g. OECD, WHO, UNEP, ECHA) and facilitates access to complete assessment reports for national authorities.

The list of recognized bodies should be regularly reviewed to ensure continued compliance and equivalence with these principles.

6. Preventing the import of banned, severely restricted and unapproved substances of concern

Many substances that have been **banned, severely restricted, or refused approval in one country continue to be produced and exported to other countries**. This reflects a key limitation of national systems: restrictions on use do not necessarily prevent production and international trade, particularly where importing countries have limited regulatory capacity.

This issue is especially visible in the global pesticide trade. Significant volumes of pesticides containing substances banned in highly regulated jurisdictions continue to be exported, often to low- and middle-income countries. Similar concerns arise for other chemicals, including industrial substances and lead compounds, which remain in circulation despite well-documented risks to human health and the environment. Apart from pesticides, similar concerns exist for industrial chemicals, lead compounds, and lead-based paints.

Strengthening controls on the import of such substances is therefore an important component of national chemicals legislation. It helps ensure that domestic regulatory objectives are not undermined by the continued availability of substances already recognized elsewhere as posing unacceptable risks.

Building on existing MEAs to increase protection

International agreements can support national efforts to address these risks.

The **Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade**, promotes transparency in international trade by requiring exporting countries to notify importing countries when certain hazardous chemicals are banned or severely restricted domestically. Importing countries may decide whether to permit or refuse imports.

However, the Convention currently covers **a limited number of chemicals**, and many substances banned or restricted at national level are not listed. In addition, reporting

obligations are not always consistently implemented. As a result, hazardous chemicals may continue to be traded without being subject to the Convention's procedures.

The **Basel Convention** and the Bamako Convention at the regional level address the transboundary movement of hazardous wastes and can complement national controls where chemicals are classified as waste. The Ban amendment under the Basel Convention (into force since 2019) prohibits developed countries from exporting hazardous waste to developing countries. The Bamako Convention, goes further by treating certain banned or withdrawn substances as hazardous waste.²⁵

These frameworks provide useful tools, but they do not replace the need for comprehensive national legislation. Countries should therefore establish their own legal mechanisms to restrict or prohibit the import of substances that have been banned, severely restricted or refused approval elsewhere. African countries that are parties to the Bamako Convention may notify the Basel Secretariat of the waste definition, as outlined in Article 3 of the Basel Convention.

Recommendations for drafting

The following elements may be considered when designing legal provisions to prevent the import of hazardous chemicals (in **pesticide, industrial chemicals, or general chemicals management laws**).

Import of substances banned in the country of export	No person shall import a chemical substance, pesticide, mixture, or product containing such substance if the substance has been banned, prohibited, or refused approval in the country of manufacture or export, or in any jurisdiction designated as trusted in regulations, for reasons relating to human health or environmental protection.
Regulatory information in safety data sheets	The Safety Data Sheet must include authorized uses, details on bans, restrictions, or refusals of approval applicable to the substance in the country of manufacture or export.
Mirror ban based on foreign regulatory decisions	The competent authority may prohibit or restrict the import, of a chemical where the substance has been banned or severely restricted by one or more trusted regulatory authorities specified in regulations . An importer shall declare the regulatory status of the chemical, including any ban, restriction or refusal of approval in the country of export or in a trusted jurisdiction, at the point of import. The competent authority shall make the relevant prohibition, restriction, and watch lists available to the customs administration to enable verification at the border.
Waste definition from	The following substances shall be "hazardous wastes" for the purposes of this convention:

²⁵ *Bamako Convention on the ban on the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa, Article 2(1)(d)*

the Bamako Convention	a) Wastes that belong to any category contained in Annex I of this Convention; b) Wastes that are not covered under paragraph (a) above but are defined as, or are considered to be, hazardous wastes by the domestic legislation of the State of export, import or transit; c) Wastes which possess any of the characteristics contained in Annex II of this Convention; d) Hazardous substances which have been banned, canceled or refused registration by government regulatory action, or voluntarily withdrawn from registration, in the country of manufacture, for human health and environmental reasons. Wastes which, as a result of being radioactive, are subject to any international control systems, including international instruments, applying specifically to radioactive materials, are included in the scope of this Convention. Wastes which derive from the normal operations of a ship, the discharge of which is covered by another international instrument, shall not fall within the scope of this Convention.
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7. Using negative lists and watchlists to promote substitution

Lists of substances are a central tool in chemicals legislation. Unlike inventories of chemicals that primarily document the chemicals on the market (either imported or manufactured), lists provide direct regulatory control by identifying chemicals that are **prohibited or restricted (negative lists), approved or exempted (positive lists), and subject to monitoring, transparency measures (watch lists), or prioritized for substitution**. These lists can be tailored to national capacities and policy objectives.

The distinction between the two is functional rather than formal. An inventory is descriptive in nature, as it catalogues and records the substances that are present on the market and the quantities in which it is present. The inventory imposes no obligation and confers no permission on any parties involved in the lifecycle. On the other hand, a list is prescriptive as it attaches legal consequences (such as prohibition or restriction if on the negative list, enhanced monitoring and substitution planning if on the watch list, and permission to market if on the positive list) to the substances it names. The two are complementary, as an inventory provides the factual baseline of what is in circulation, against which listing decisions are taken and enforced, whereas lists give that baseline regulatory effect. A country may, therefore, institutionalize an inventory devoid of a list (based on mere visibility of the market), but a list operates most effectively where it can be cross-checked on a real-time basis against an inventory.

Negative lists (prohibition or restriction lists) identify substances that may not be manufactured, imported, placed on the market or used, either generally or for specific applications. They represent the highest level of control, consistent with eliminating at the top of the hierarchy of controls.

Examples of negative lists at the international level (global or regional) include:

- The **Stockholm Convention** Annex A (elimination) and Annex B (restriction), which require the prohibition or restriction of POPs (PCBs, PFOS, some brominated flame retardants, and recently added substances like PFHxS and dechlorane Plus);
- EU REACH Annex XVII (EC 1907/2006), which restricts or prohibits the manufacture, placing on the market or use of listed substances, mixtures, or articles;
- **EU RoHS Directive (2011/65/EU)**, which restricts lead, mercury, cadmium, hexavalent chromium, and several brominated flame retardants in electrical and electronic equipment, including through time-limited exemptions.

At the national level, many countries maintain similar systems. For example, several jurisdictions operate consolidated lists of prohibited, restricted or controlled substances, while others use priority lists to identify chemicals of concern requiring further action.²⁶

By contrast, **positive lists** identify substances that are permitted for use, either generally (inventories) or for specific applications (in agriculture/pesticides, cosmetics, etc). While such lists can provide a high level of control, they are typically resource-intensive to maintain, as they require continuous evaluation and updating of all listed substances. For this reason, their use should be carefully targeted.

Examples include:

- **Canada's** Domestic Substances List (DSL) is an inventory (positive list) of substances manufactured in, or imported into Canada on a commercial scale without notification. The DSL is amended, on average, 12 times per year to add, update or delete substances and currently contains more than 28 000 substances. If imported or manufactured over certain threshold, prior notification and assessment is required to determine if they are toxic or could become toxic.
- **Japan's** Chemical Substances Control Law (CSCL) maintains a positive list of existing and newly evaluated substances approved for manufacture or import. New substances are assessed for persistence, bioaccumulation, and toxicity to ensure that only substances meeting safety standards enter the market. The system functions as a national authorization list for responsible management of industrial chemicals.
- **EU's** REACH includes a positive list (Annex IV) of substances deemed to present minimum risk because of their basic properties (e.g. water, nitrogen), and a list

²⁶ In Vietnam, legislation (Law on Chemicals (2007) and its implementing regulation Decree 113/2017/ND-CP, as amended by Decree 82/2022/ND-CP) establishes five lists that include a structured negative and conditional use system; in Argentina, Resolución 504/2022 – *Listado Nacional de Sustancias y Productos Químicos Existentes, Controlados, Restringidos y Prohibidos* establishes a unified national list of controlled, restricted and prohibited substances, as the country's main negative list; In the Philippines, the priority chemicals list includes existing and new chemicals that the Department of Environment and Natural Resources – Environmental Management Bureau (DENR-EMB) has identified as potentially presenting an unreasonable risk to public health, workplaces, or the environment, https://chemical.emb.gov.ph/?page_id=52.

of substances (Annex V) exempted from registration because registration is deemed inappropriate or unnecessary.

Positive lists are commonly used in sector-specific legislation, such as for pesticides, biocides, food contact materials and cosmetics, where more stringent pre-market controls are required.

Box 2 – Argentina/MERCOSUR: cosmetics restrictions adopted following EU CMR classification

ANMAT published Disposition 2820/2026 on May 15, 2026, incorporating MERCOSUR Resolution GMC 27/25 into Argentine national law. The measure adds two substances to the regional list of components prohibited in personal hygiene products, cosmetics, and perfumes:

Trimethylbenzoyl diphenylphosphine oxide (INCI: trimethylbenzoyl diphenylphosphine oxide, CAS 75980-60-8)

N,N-dimethyl-p-toluidine (CAS 99-97-8)

Both are photo-initiators and chemical accelerators used in gel nail and UV-cured nail products. Both were banned in the EU on September 1, 2025, due to their classification as carcinogenic, mutagenic, or toxic to reproduction (CMR). That EU ban triggered an immediate cascade across Latin America — Costa Rica, Chile, Colombia, and Peru all took action within weeks, and Brazil formally banned both substances in October 2025.

Argentina’s action through MERCOSUR now formalizes the regional prohibition at the bloc level. Companies with products already holding NSO authorization in Argentina have 60 days from publication to update formulations and registrations.

Link to Disposition:

<https://www.boletinoficial.gob.ar/detalleAviso/primera/342011/20260515?busqueda=1>

Watchlists are dynamic tools used to flag substances that may pose risks but require further evidence or assessment. Inclusion typically triggers enhanced monitoring, disclosure obligations and targeted inspections,

Examples include the **EU REACH Candidate List** of Substances of Very High Concern, the EU **Water Framework Directive watch list**, and systems such as California’s Proposition 65. Similar monitoring and priority-pollutant lists exist in Latin America and Asia, including Chile’s RETC (Registro de Emisiones y Transferencia de Contaminantes), which tracks pollutants released into air, water and soil.

List type	Core purpose	Regulatory effect
Positive list	Authorizes placing on the market and use of listed substances	Pre-market authorization; defines substances allowed in specific sectors
Negative list	Prohibits or restricts manufacturing, import used in some or all applications in	Legal certainty; compliance and enforcement focus
Watch list	Flags emerging concerns for monitoring or substitution	Early warning; supports innovation and transparency

Listing chemicals for risk management serves several regulatory purposes:

- **Prioritization** — identifies substances requiring early or urgent action
- **Transparency** — signals to industry that a substance is under consideration
- **Supply-chain communication** — requires downstream users to assess alternatives
- **Legal clarity** — lists provide explicit reference points for compliance
- **Resource efficiency** — allows regulators to focus on the substances of highest concern

Establishing Lists based on foreign assessments

UNEP recommends the use of **watchlists** as an entry point for controlling hazardous chemicals. Watchlists identify substances of concern based on existing international knowledge and can later serve as the basis for inclusion in negative lists. They signal future regulatory expectations and encourage industry to plan for substitution with safer alternatives. Their effectiveness depends on clear criteria, transparency and a credible prospect of regulatory action.

Recommended approach for establishing watchlists:

- **Review existing authoritative sources:** draw lists from trusted jurisdictions and international bodies (e.g., CMRs, endocrine disruptors, PBT/vPvB substances).
- **Define clear entry criteria,** including hazard classes or monitoring evidence.
- **Leverage international decisions:** include chemicals already identified elsewhere, where protection objectives are comparable.
- **Prioritize high-exposure uses:** focus on sectors such as cosmetics, detergents, electronics, and food-contact materials.²⁷
- **Engage stakeholders:** collect information on uses, exposures, risk management practices, and availability of alternatives.

²⁷ See “ADDRESSING CHEMICALS OF CONCERN IN ELECTRICAL AND ELECTRONIC EQUIPMENT, TOYS, AND THE BUILDING AND CONSTRUCTION SECTOR, Key messages and lessons learned”, SAICM Secretariat, February 2024, Available at: <https://saicmknowledge.org/sites/default/files/resources/ADDRESSING%20CHEMICALS%2026-1%20WEB.pdf>

- **Establish monitoring mechanisms:** where feasible, use tools such as PRTR²⁸ system or environmental quality standards for specific substances.
- **Promote substitution:** use listing to drive supply chain engagement and transition planning for safer alternatives.
- **Ensure periodic review:** update lists regularly to reflect new evidence or changing priorities.
- **Promote regional cooperation:** Share data and methodologies through regional platforms (e.g. African PRTR Network, ASEAN Working Group on Chemicals, CARICOM,) to reduce costs and enhance consistency in prioritization.

Negative lists provide **legal certainty** by identifying substances that are prohibited, restricted, or subject to specific conditions of use. They are a primary tool for eliminating known hazards and aligning national practice with MEAs (e.g. Stockholm, Rotterdam, and Minamata Conventions.) **Advantages include a strong protective effect and clear compliance requirements, making implementation relatively straightforward, particularly where similar measures have already been adopted in other jurisdictions. This approach also supports public trust and enhances enforcement clarity.**

- **Build on international obligations:** incorporate substances listed under relevant MEAs into national annexes or schedules.
- **Use foreign regulatory decisions for sector-specific bans:** consider substances banned/restricted in other jurisdictions (e.g. in electronics, cosmetics, detergents, pesticides, biocides, food packaging), particularly where safer alternatives are available.
- **Consolidate regulated substances:** maintain unified lists across sectors to improve clarity and compliance.
- **Apply risk- or hazard-based triggers:** rely on international classifications or risk assessment outcomes, as appropriate (e.g. substances listed based on intrinsic hazard (e.g. CMR, PBT).
- **Provide for regular review:** update lists periodically, including through grouping approaches where relevant (substances with similar structure and characteristics).
- **Link watchlists and negative lists:** allow substances to transition from watchlists (monitoring) to negative lists (restriction) when the market is prepared for substitution. To avoid arbitrariness, legislation should specify the criteria triggering this transition. For example, a watch-listed substance shall be moved to the negative list where suitable safer alternatives are available, or where it has been prohibited or severely restricted by [two] trusted jurisdictions, and require that the transition follow stakeholder consultation and a reasoned regulatory and policy decision.

²⁸ A PRTR is an environmental database or inventory of potentially hazardous chemical substances and/or pollutants released to air, water and soil and transferred off-site for treatment or disposal. See <https://prtr.unece.org/about-PRTR>

- **Ensure enforceability:** make lists accessible and usable by customs and other enforcement agencies.

Recommendations for drafting

The following provisions illustrate how countries may formulate in the national legislation provisions to facilitate the creation of these lists.

Watchlist definition (i.e. chemicals of concern list)	“Watchlist” means a list of substances of concern identified by the competent authority, including those with hazardous properties such as carcinogenic, mutagenic, reproductive toxicity, persistent, bioaccumulative, toxic, or endocrine-disrupting properties, as identified through classification and labelling systems, including the Globally Harmonized System (GHS), and, where appropriate, based on classifications or regulatory determinations adopted by trusted jurisdictions specified in regulations, to trigger transparency, monitoring, substitution planning, and potential regulatory action, including restriction or phase-out.
Watchlist of chemicals known to be hazardous to human health and the environment	1) The competent authority shall establish and maintain a national watchlist of substances of concern. 2) The initial watchlist shall be established within [12 months] of the entry into force of this Act. 3) For the purpose of establishing the watchlist, the competent authority shall: a) identify substances on the basis of hazardous properties, including those classified under the Globally Harmonized System (GHS); b) take into account classifications, assessments, or regulatory actions adopted by trusted jurisdictions specified in regulations; c) consider information from international conventions, scientific bodies, and monitoring programmes; and d) prioritize substances for which there is evidence of exposure or potential risk to human health or the environment. 4) Prior to the inclusion of a substance on the watchlist, the competent authority shall: a) publish a proposal for listing, including the reasons for concern; b) provide an opportunity for public and stakeholder consultation within a specified period; and c) take into account the comments received in its final decision. 5) The competent authority shall publish and update the watchlist at least once per year and may adopt simplified procedures for updates based on new scientific or regulatory information.

Obligations related to the watchlist	Any person who manufactures, imports, distributes, or uses a substance included on a national watchlist shall: a) notify the competent authority of the manufacture, import, and uses of the substance, including quantities and conditions of use; b) ensure that the substance is accompanied by a Safety Data Sheet indicating its watchlist status; c) implement appropriate risk management measures to minimise exposure and releases; and d) where feasible, identify and assess safer alternatives, including the preparation of a substitution plan, and provide such information upon request. The competent authority shall: a) ensure that non-confidential information submitted under this provision is made publicly available in an accessible format, in line with the principle of the public’s right to know; and b) review substitution plans and other information submitted, and, where appropriate, propose further risk management measures, including restrictions or phase-out of the substance. Any person subject to this provision shall pay an annual contribution for substances included on the watchlist, as determined by the competent authority, to support inventory maintenance, monitoring, and regulatory actions.
Substances to be included in the watchlist	The inclusion of substances in the watchlist shall be informed by reviewing the following lists, as specified and updated in regulations (for example):²⁹ - Annex XVII of EU REACH Regulation - Annex VI of EU CLP Regulation - Canada’s Toxic substances list under the Canadian Environmental Protection Act - EU Candidate list of substances of very high concern
Negative list	The competent authority may prohibit or restrict the import of a chemical where the substance has been banned or severely restricted by one or more jurisdictions.

8. Enabling transparency on chemicals data and chemicals in products

Transparency is a core principle of the GFC and an essential element of the right to a clean, healthy, and sustainable environment. It enables informed decision-making, strengthens accountability and supports early action on hazardous substances. Two areas are critical:

²⁹ The lists are provided solely as examples.

- access to information on hazards, risks and regulatory decisions; and
- information on chemicals in products across the value chain (including through labelling)

Access to information is one of the most effective and low-cost regulatory tools available. Publicly available information improves compliance, supports stakeholder engagement and reduces reliance on resource-intensive enforcement. Transparency throughout the regulatory process, including access to draft decisions, final measures and their rationale, enhances trust, accountability and the quality of decision-making. At the same time, confidentiality claims should be strictly limited: information necessary to protect human health and the environment should not be withheld.

Significant gaps remain in relation to chemicals in products, where information often does not flow along supply chains. This limits the ability of workers, consumers, recyclers and waste handlers to assess risks, particularly in informal settings. Improving traceability and communication across value chains is therefore essential.

Addressing these challenges does not require complex systems. Countries can build on existing international information, establish basic communication obligations and ensure public access to non-confidential data. This supports substitution, strengthens waste management and promotes safer production and consumption.

In line with international commitments on access to information,³⁰ national legislation should include the following elements:

Access to information and right to know

- Ensure public access to information on chemical hazards, risks, regulatory status and risk management measures without requiring a demonstration of interest;
- Require publication of draft decisions, public consultations, and final decisions, including their rationale, in accessible formats;
- Strictly limit confidential business information claims, excluding hazard and risk information and requiring justification, time-limited and review;
- Disseminate information through accessible channels using clear and understandable language.

Chemicals in products and supply chains³¹

³⁰ Principle 10 United Nations (1992), *Rio Declaration on Environment and Development*, adopted at the United Nations Conference on Environment and Development, Rio de Janeiro, 14 June 1992; United Nations Economic Commission for Europe (UNECE) (1998), *Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention)*, Aarhus, Denmark, 25 June 1998; United Nations (2018), *Regional Agreement on Access to Information, Public Participation and Justice in Environmental Matters in Latin America and the Caribbean (Escazú Agreement)*, Escazú, Costa Rica, 4 March 2018.

³¹ See the Chemicals in Products (CiP) GEF SAICM project <https://www.unep.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/chemicals-products/chemicals-products-cip>

- Require suppliers to communicate information on hazardous chemical content in products throughout the value chain, including to downstream users, consumers and waste managers;
- Allow the use of information already generated in other jurisdictions to reduce duplication and administrative burden;
- Promote public access to non-confidential information on chemicals in products to support substitution and informed decision-making.
- Encourage regional cooperation to harmonize approaches and share data on chemicals in traded products.

Recommendations for drafting

The following provisions illustrate how countries may formulate legislative measures to facilitate transparency. Where feasible, countries should also consider becoming parties to regional instruments that guarantee access to information.

Principle of transparency	Transparency and access to information shall guide the implementation of this Act, in order to protect human health, the environment, and the right of all persons to a clean, healthy, and sustainable environment.
Right of access to information on chemicals	Any person shall have the right to access information on chemicals on the market, including information on hazards, risks, uses, regulatory status, and risk management measures, without the need to demonstrate an interest, subject only to limitations foreseen by the law. Any refusal of access must take place within [one month] and in writing. The refusal shall state the specific ground relied upon, and it shall be subject to administrative review and the right to judicial appeal before national forums, subject to provisions of national law. Where countries have a Right to Information (RTI) legislation (such as India³²), such RTI legislation shall prevail.
Restrictions to the right to Access	Confidential business information shall not apply to information necessary to protect human health or the environment, including: a) hazard properties and classification; b) information on risks and exposure; c) regulatory decisions, restrictions, or risk management measures; and d) information necessary for safe handling, use, and disposal. Claims of confidentiality shall be justified, time-limited, and subject to review by the competent authority. A person asserting confidentiality shall do so at the time the

³² The Right to Information Act, 2005, Act No. 22, Acts of Parliament, 2005 (India).

	information is submitted and shall state the grounds relied upon. The competent national authority shall adjudicate the claim within [60 business days, with the term “business days” defined as per national law] and shall reject any claim that is unsubstantiated or that relates to information falling within paragraphs (a) to (d). Decisions on confidentiality claims are subject to administrative review. While legitimate commercial confidentiality is protected, this does not apply to information on hazards, risks, or safe use.
Communication of information in the value chain	Any person who manufactures, imports, or places a product on the market shall ensure that information on hazardous chemicals contained in the product is communicated throughout the supply chain, including to: a) downstream users; b) workers; c) consumers, where relevant; and d) waste operators and recyclers.
Labelling requirements for products containing hazardous chemicals of concern	The competent authority may require that products containing listed chemicals of concern be accompanied by a label providing information necessary to protect human health and the environment. Such labels shall: a) be clear, accurate, and understandable to the general public; b) include information on hazards, safe use, and disposal, as appropriate; c) be provided in all official languages of the country; and d) where appropriate, include pictograms or digital tools, such as QR codes or electronic labels, to facilitate access to additional information. The competent authority may adopt regulations specifying the format, content, and categories of products subject to labelling requirements

9. Recovering the costs of chemicals regulation from economic operators

Cost recovery should be the central instrument for chemicals management. Legislation should provide competent authorities with clear powers to **levy, revise, index and enforce fees**, and to retain revenues. Given varying administrative capacities, systems should be **simple at the outset but scalable over time**.

A practical starting point is a single annual registration fee for manufacturers and importers placing chemicals or products containing chemicals on the market. This

provides a predictable revenue stream to support administrative functions. As capacity develops, systems can evolve to include differentiated annual fees based on volume or number of substances, as well as service-based charges for activities such as technical evaluations, dossier reviews, authorizations, inspections, and renewals. Import fees or licensing charges for hazardous chemicals can further support cost recovery and improve oversight of high-risk chemical flows.

Fee structures should reflect the actual costs of administration, including staff time, information technology systems, interministerial coordination, and overhead. Fee schedules should be publicly available and reviewed periodically to ensure transparency and predictability. More advanced approaches, such as tiered or modulated fees linked to risk or incentivizing substitution, can be introduced progressively.

Taxes and Levies, and Tax Incentives for Substitution

Once cost-recovery systems are established, countries may complement them with **taxes and levies** to finance broader public functions. Levies on chemical imports or chemical-intensive products are particularly practical in low- and middle-income countries, as they can be collected through existing customs systems.

Fiscal instruments can also support substitution, by applying higher rates to hazardous substances (e.g. carcinogens, PBTs, or chemicals under international treaties) and reduced rates or exemptions for safer alternatives. This approach also creates market incentives. Legislation should empower relevant authorities to set and adjust rates and allocate revenues to chemicals and waste management, remediation or innovation programs.

Countries with limited capacity may begin with broad environmental levies and progressively adopt more targeted instruments as data and monitoring systems improve.

Extended Producer Responsibility (EPR)

EPR shifts the financial burden of managing products with hazardous substances at end-of-life from consumers to producers. Legislation should define priority product categories, require producers to establish or participate in producer responsibility organizations (PROs), and set performance standards for collection, recycling, and environmentally sound management. EPR schemes should also include provisions on the identification of substances of concern in products and measures to prevent contaminated materials from re-entering supply chains.

Recommendations for drafting

Some key considerations are as follows:

- Clearly define what costs are recovered, who pays and how revenues are generated;

- Provide legal authority to levy, adjust and enforce charges, and to retain revenues;
- Ensure transparency in fee-setting and the use of revenues;
- Design systems progressively, starting with simple instruments and expanding over time;
- Incorporate incentives to promote substitution and safer alternatives;
- Combine instruments (fees, levies, EPR) to ensure a stable and predictable financing system.
- Establish fee structures (e.g. annual registration fees, service-based charges);
- Provide for differentiated or risk-based fees where capacity allows;
- Enable the introduction of levies and taxes on chemicals or products;
- Define legal requirements for EPR schemes, including obligations on producers and performance standards;
- Include enforcement provisions for non-payment or non-compliance.

Financing and Cost Recovery	Importers, manufacturers of chemicals and of products containing chemicals shall bear the costs associated with the administration, implementation and enforcement of this Law. The competent authority may establish and collect charges or other financial mechanisms for that purpose, in accordance with applicable international trade obligations. Charges shall be proportionate to the costs of the services, functions and activities they finance. The schedule of charges shall be made publicly available [annually or as amended]. This requirement does not apply to taxes or general levies imposed under this Law.
Powers to Set and Use Financial Instruments	The competent authority may determine, revise and enforce the financial instruments established under this Law. Revenues generated under this Law shall be retained [in a dedicated fund] and used to support its implementation, including administration, monitoring, enforcement and risk reduction.
Producer Responsibility and Recovery Targets	Producers and importers placing products containing chemicals on the market shall ensure, in accordance with requirements set by the competent authority, the environmentally sound management of such products at end-of-life. The competent authority may establish requirements, including minimum targets for collection, recycling and recovery.

10. Creating a national coordination mechanism

Effective coordination among national institutions is essential for sound chemicals management. In most countries legislation can be fragmented along the chemicals lifecycle, with responsibilities distributed across multiple ministries and agencies

(including environment, health, labour, industry, agriculture, trade and customs)
Without effective coordination, this can lead to further fragmentation, duplication and regulatory gaps. Coordination arrangements vary widely in terms of legal basis, scope, institutional participation and degree of influence. In practice, most countries combine formal and informal mechanisms, adapted to their legal and administrative context

National coordination mechanisms can be broadly grouped into four models:

- **Legally mandated mechanisms:** Established through legislation or decree, with defined mandates and responsibilities. These provide the strongest institutional basis and continuity.³³
- **Consultative multi-stakeholder platforms:** Bringing together government, industry, academia and civil society to support policy alignment. While often advisory, they play an important role in shaping national strategies.³⁴
- **Hybrid institutional-technical mechanisms:** Combining formal coordination with scientific and enforcement capacity to support implementation.³⁵
- **Informal or ad hoc arrangements:** Offering flexibility and rapid coordination, but often with limited authority and sustainability.

Countries may combine elements of these models depending on national needs and capacity.

BOX – The Brazilian example of CONASQ

Brazil's National Commission on Chemical Safety (CONASQ), formally established through Decree No. 11.686/2023,³⁶ is a national coordination body bringing together government ministries, technical agencies, industry, workers, academia, and civil society. CONASQ provides a platform for dialogue, policy alignment, and technical coordination, including working groups on risk assessment, GHS implementation, and MEA obligations. Since the early 2010s, CONASQ has functioned as a multi-stakeholder coordination body, originally set up through administrative and policy frameworks related to SAICM implementation. In 2023, it was officially re-established and reinforced via Presidential Decree No. 11.686/2023, which solidified its legal authority and ensured its institutional longevity.

CONASQ's primary functions are coordination, consultation, and stakeholder engagement. Regulatory authority remains with individual ministries and agencies

³³ See National Advisory Committee, Government of Canada (1999), *Canadian Environmental Protection Act (CEPA 1999)*, S.C. 1999, c. 33, section 6; Government of Costa Rica (2006), *Decreto Ejecutivo No. 33104 – Creación de la Secretaría Técnica de Coordinación para la Gestión de Sustancias Químicas*, San José.

³⁴ Brazil, Decreto nº 11.686, de 5 de setembro de 2023, Institui a Comissão Nacional de Segurança Química – CONASQ. Diário Oficial da União, 6 Sept. 2023. Available at: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/d11686.htm

³⁵ Government of the Czech Republic, Národní centrum pro toxické látky (National Centre for Toxic Substances) and national coordination system for chemicals management, including implementation of EU chemicals legislation.

³⁶ Brazil, Decreto nº 11.686, de 5 de setembro de 2023, Institui a Comissão Nacional de Segurança Química – CONASQ. Diário Oficial da União, 6 Sept. 2023. Available at: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2023/decreto/d11686.htm

(e.g., ANVISA, IBAMA). CONASQ represents a comprehensive but advisory mechanism supporting policy coherence and cross-sectoral engagement.

Consultation on Brazil's Industrial Chemicals Bill ("REACH-like" Law) through CONASQ

CONASQ has played a central role in shaping Brazil's draft industrial chemicals management framework, widely referred to as the country's "REACH-like" law. The Commission convened government authorities (Environment, Health/ANVISA, Labour, Industry, Foreign Affairs, Science and Technology, Agriculture), alongside industry associations, labour unions, academia and civil society, to assess proposed elements such as the establishment of a national inventory, notification procedures, priority lists, data requirements, confidentiality protections, and risk management instruments. Working groups under CONASQ examined policy models from the EU (REACH), Canada (CMP), and OECD member countries, comparing registration obligations, hazard communication systems, and the feasibility of national risk evaluation structures.

This iterative consultation process led to successive refinements of the proposal, including alignment of the inventory with Brazil's industrial profile, adaptation of data submission requirements to national capacity, clarification of roles of ANVISA, IBAMA and the Ministry of Industry, and incorporation of principles already practiced under GHS implementation. When the Executive submitted the current legislative draft (PL 6120/2019) to Congress,³⁷ CONASQ continued to serve as the forum for **ongoing technical dialogue** and **national positioning**, particularly in relation to international conventions, coordination needs between ministries, and the balance between regulatory ambition and administrative feasibility. Although CONASQ does not hold regulatory authority, its inclusive structure and broad representation made it the primary mechanism through which Brazil collectively evaluated and shaped its future chemicals management law.³⁸

Core functions of a coordination mechanism

Regardless of the model, coordination mechanisms should be able to:

- **Map and clarify mandates** of different relevant authorities in chemicals and waste;
- **Facilitate exchange information** on chemicals, regulatory decisions, inspections and incidents;
- **Align national priorities**, including implementation of MEAs;
- **Review draft policies and legislation** relating chemicals management;

³⁷ See proceedings relating to this Proposal (PL 6120/2019) at <https://www.camara.leg.br/proposicoesWeb/fichadetramitacao?idProposicao=2230281&fichaAmigavel=nao>

³⁸ Brazil, Ministry of the Environment. Comissão Nacional de Segurança Química - CONASQ. Brasília: MMA.

Available at: <https://www.gov.br/mma/pt-br/assuntos/meio-ambiente-urbano-recursos-hidricos-qualidade-ambiental/seguranca-quimica/comissao-nacional-de-seguranca-quimica-conasq>

- **Enable stakeholder participation** (workers, industry, civil society, academia, indigenous peoples);
- **Support coordinated responses** to accidents and emerging issues.

To function effectively, coordination mechanisms should:

- **Designate a lead authority:** assign a ministry (often environment or health) to chair the mechanism and provide a basic secretariat function;
- **Define roles and procedures in writing:** establish clear terms of reference, also by way of a decree, covering membership, decision-making and links to policy processes;
- **Ensure inclusive participation:** involve relevant ministries as well as stakeholders, including workers' associations, industry, civil society, academia and, where relevant, indigenous peoples.
- **Keep structures practical:** focus on operational coordination starting with a small group for instance that meets regularly and focuses on concrete tasks (shared workplans, joint positions, review of draft laws) rather than creating complex bureaucratic arrangements;
- **Secure sustainable resources:** identify needs (meeting costs, minimal secretariat time, documentation, stakeholder outreach) and provide predictable funding, including through integration into existing budgets; and
- **Cover the full life cycle:** Ensure representation of authorities responsible for production, import, occupational safety, product regulation, waste and pollution.

Recommendations for drafting

The model provisions below endeavour to distil the central elements common to existing national coordination mechanisms, including the institutional model,³⁹ consultative multi-stakeholder model,⁴⁰ and the hybrid institutional–technical model.⁴¹ The draft clauses are drafted in neutral terms for the purposes of simple adaptation for a wide variety of national legal and administrative contexts. The bracketed text indicates options or values to be determined by the drafter depending on their national legal and policy scenarios. The provisions may be enacted through primary legislation, decree or regulation, and in accordance with national practice. The establishment of such provisos through progressive legislation or decrees provides the strongest foundation for continuity across political cycles.

Core elements to address include:

³⁹Canadian Environmental Protection Act, 1999, S.C. 1999, c. 33, § 6 (Can.); Decreto Ejecutivo No. 33104 de 2006, Creación de la Secretaría Técnica de Coordinación para la Gestión de Sustancias Químicas, San José (Costa Rica).

⁴⁰Decreto No. 11.686, de 5 de Setembro de 2023, Diário Oficial da União [D.O.U.] de 6.9.2023 (Braz.) (establishing the Comissão Nacional de Segurança Química (CONASQ)).

⁴¹Ministry of the Environment of the Czech Republic, Statute of the Council of the National Centre for Toxic Substances, arts. 1–7 (effective Jan. 1, 2022) (Czech).

- Establishment, legal basis and purpose of the mechanism;
- Functions and mandate, including the relationship with the regulatory authorities, such as individual ministries and agencies;
- Composition, chairing arrangements and stakeholder participation;
- Appointment procedures, terms of membership and alternates;
- Meetings, quorum and decision-making procedures;
- Working groups, including coordination of enforcement;
- Secretariat arrangements, status of members and rules of procedure.

Article 1 – Establishment and purpose	(1) A National Coordination Mechanism for Chemicals Management (“the Mechanism”) is hereby established [within the ministry responsible for the environment]. (2) The purpose of the Mechanism is to promote integrated and coherent action among all authorities with responsibilities for the management of chemicals throughout their life cycle, with a view to protecting human health and the environment and avoiding duplication of regulatory activity. (3) Regulatory authority shall remain with the competent ministry/ies and agency/ies. The Mechanism shall exercise coordinating, advisory and consultative functions. (4) Ministry/ies and/or agency/ies are strongly urged to consult the Mechanism before adopting a measure that materially affects the management of chemicals. A failure to consult shall not invalidate the measure, however, the Mechanism may record and publish its observations and voice its grievances and concerns.
Article 2 – Functions	The Mechanism shall: (a) coordinate the development of national strategies and priorities for the sound management of chemicals and their wastes, and monitor and evaluate the implementation thereof; (b) advise the competent authority/ies on draft legislation, regulations and policies affecting chemicals management, and propose their elaboration, revision and harmonization; (c) support national participation in the negotiation of international instruments related to chemicals, and monitor the implementation of obligations arising under multilateral environmental agreements; (d) facilitate the exchange of information among authorities on chemicals, regulatory decisions, inspections and incidents; (e) promote the integration of chemical safety into sectoral public policies;

	(f) identify needs for training, capacity-building and public information, and encourage scientific and technological development relevant to chemical safety; and (g) foster cooperation among the public sector, the private sector and civil society, at the national and subnational levels, in the coordinated implementation of risk management measures.
Article 3 – Guiding principles	In carrying out its functions, the Mechanism shall apply the precautionary principle [and the other principles set out in this Law]. ⁴²
Article 4 – Composition	(1) The Mechanism shall consist of: (a) one representative of each ministry and agency with responsibilities relating to chemicals, including the authorities responsible for environment, health, labour, agriculture, industry and trade, foreign affairs, finance and customs, [transport, mines and energy, science and technology] and relevant technical and enforcement agencies; (b) [where relevant,] representatives of subnational governments [and of indigenous peoples and local communities]; and (c) [number] representatives of non-governmental sectors, including industry, workers’ organisations, the academic and scientific community and civil society. (2) The Mechanism shall be chaired by the ministry/ies responsible for [the environment]. (3) Each member shall have an alternate, who shall replace the member in his or her absence. (4) The Chair may invite experts and representatives of other public or private bodies to participate in meetings as observers, without the right to vote.
Article 5 – Appointment and terms	(1) Members representing public bodies, and their alternates, shall be nominated by the heads of the bodies they represent and appointed by act of the [Minister responsible for the environment]. (2) Members representing non-governmental sectors shall be selected through a transparent public process [coordinated by the chairing ministry], for a term of [two] years[, renewable once].⁴³

⁴²See Canadian Environmental Protection Act, 1999, S.C. 1999, c. 33, § 6(1.1) (Can.) (requiring the National Advisory Committee to apply the precautionary principle in its advice and recommendations).

⁴³See Decreto No. 11.686, de 5 de Setembro de 2023, D.O.U. de 6.9.2023, art. 3, § 7 (Braz.) (non-governmental members chosen through a public selection process); Ministry of the Environment of the Czech Republic, Statute of the Council of the National Centre for Toxic Substances, art. 3(7) (effective Jan. 1, 2022) (nomination rights for industry and non-governmental organisations).

	(3) In the event of a vacancy, the alternate shall serve for the remainder of the term.
Article 6 – Meetings and decision-making	(1) The Mechanism shall meet in ordinary session at least [three] times per year and in extraordinary session upon convocation by the Chair, with a minimum notice of [fifteen] days. (2) The quorum for meetings shall be [an absolute majority of members; on second convocation, one third of members]. (3) The Mechanism shall decide by consensus or, where consensus cannot be reached, by a simple majority of the members present. In the event of a tie, the Chair shall have a casting vote. (4) Meetings may be held in person or by videoconference.
Article 7 – Working groups and enforcement coordination	(1) The Mechanism may establish permanent or temporary working groups to assist it in the performance of its functions. Working groups shall be coordinated by members representing public bodies. (2) The Mechanism shall establish a working group on enforcement, composed of representatives of the supervisory, inspection, customs and public health authorities, to exchange information on enforcement activities and coordinate joint control actions. The working group shall report to the Mechanism on the main outcomes of its meetings.⁴⁴
Article 8 – Secretariat, status of members and rules of procedure	(1) The secretariat of the Mechanism and of its working groups shall be provided by the [chairs ministry/ies]. (2) [Participation in the Mechanism shall be considered a relevant public service and shall be unremunerated]. Members shall maintain the confidentiality of information where so required. (3) The Mechanism shall adopt its rules of procedure within [ninety] days of [the entry into force of this Law / its first meeting].

Legal instrument: Where a formal instrument is not immediately feasible, terms of reference adopted at ministerial level may serve as an interim measure, with formalization at a later stage.

Scope of mandate: The provisions above confer coordinating and advisory functions while preserving the regulatory authority of individual ministries and agencies. Drafters wishing to confer decision-making functions on the Mechanism should ensure consistency with the allocation of powers under the wider legal framework.

Proportionality: In lower-capacity settings (LDCs, LMICs, SIDs) the structure should remain fairly basic. A small group meeting regularly, a part-time secretariat hosted by

⁴⁴See Ministry of the Environment of the Czech Republic, Statute of the Council of the National Centre for Toxic Substances, art. 6 (effective Jan. 1, 2022) (establishing a National Enforcement Forum of supervisory, customs and public-health authorities as an affiliated group of the Council).

the lead ministry, and resourcing integrated into existing ministry budgets. Working groups may be added progressively as needs arise.

Life-cycle coverage: Composition should ensure representation of authorities responsible for production, import, occupational safety, product control, waste and pollution, so that the Mechanism can take the whole life cycle of chemicals into account, including in the implementation of the Basel, Rotterdam, Stockholm and Minamata Conventions.

11. Conclusion

This guidance supports countries in translating international knowledge into practical and effective national chemicals legislation. Its primary objective is to promote timely and meaningful action, including in resource-constrained settings, through flexible approaches that build on existing tools and experience.

There is no single pathway for implementation. Countries may start from different starting points depending on their legal systems, institutional capacity and priorities. Some measures, such as transparency, access to information and worker protection, can be introduced relatively quickly. Others, including reliance on foreign assessments, classifications and regulatory decisions, can significantly improve efficiency and reduce costs, though they may require additional legal and institutional development.

A central principle of this guidance is the shared responsibility of industry. Economic operators are expected to generate information, comply with regulatory requirements and contribute to the financing of regulatory systems, helping ensure their sustainability.

By integrating various approaches and leveraging international cooperation and existing global resources, countries can establish chemicals management systems that are both practical and resilient. This guidance thus promotes a pragmatic path: **act where feasible, adapt where necessary and strengthen systems gradually.**

Ultimately, effective chemicals management relies on coordinated action among governments, industry, workers, civil society, and affected communities. With clear roles, appropriate tools and sustained engagement, countries can achieve lasting improvements in protecting human health and the environment.