Government Risk Management Approaches Used for Chemicals Management

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The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

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Executive Summary

Government chemicals management frameworks aim to enable the safe use of chemicals and ensure their proper management. The approaches used by governments to manage chemical risks are just one aspect of a larger risk management system with industry as a principal actor. They cover a spectrum of activities varying from a government regulatory response that is command-and-control in nature to policy approaches that aim to incentivise a shift in behaviour. The approaches can be responsive, to an identified existing risk, or proactive/pre-cautionary, aiming to minimise possible future risks. Also, the approaches can be used in combination.

This document provides a synthesis of the various risk management approaches and options that are used by OECD member country government chemical regulatory programmes to manage the risk of chemicals. The scope of the document focuses on the management of risks of industrial and consumer chemicals, i.e., chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals.

The synthesis can serve as a basis for future discussions of individual risk management approaches, either for particular types of chemicals or regarding particular risk management approaches and facilitate international alignment. It can also promote the identification of areas where governments can additionally support better chemicals management and serve as a resource for countries developing their chemicals management programmes.

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1. Introduction

Risk management is a key pillar of a government's framework for chemicals management. It is composed of action-oriented activities to reduce or eliminate risks to human health and the environment from chemical hazards. Traditionally risk management has often been seen as a step in the regulatory continuum for chemicals management: information gathering and screening; hazard identification and exposure characterisation; risk characterisation; and if an unacceptable risk is identified, the enactment of risk management activities by government. However, there are many elements of risk management that fall outside of this continuum that orient and increase robustness of chemical management frameworks and the actions of all stakeholders.

Government chemical risk management approaches are just one aspect of a larger risk management system and cover a range of activities varying from a government regulatory response to an identified health or environmental risk of a chemical to the provision of guidance to steer chemical stewardship (i.e., a spectrum of approaches from command-and-control approaches to policy approaches that aim to incentivise a shift in behaviour). The approaches can be responsive in nature, to an identified existing risk, or proactive/pre-cautionary in nature, aiming to minimise possible future risks. Also, the approaches can be used in combination.

This document provides a synthesis of the various risk management approaches and options that are used by OECD member country government chemical regulatory programmes to manage the risk of chemicals. The scope of the document focuses on the management of risks of industrial and consumer chemicals, i.e., chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals.

Given that each country or jurisdiction has enacted their own specific legislation for chemicals management, terminology varies amongst them. Hence, this document, in its description of approaches, aims to be generic and to minimise the use of terminology specific to certain legislation. A particular legislation may define (or label) a particular category in a slightly different manner than this document does and due to the spectrum of approaches, sometimes a particular example of an approach could in fact be categorised under different headings. The goal is not a perfect categorisation, nor a complete cataloguing of approaches, but aims to illustrate the myriad of types of risk management approaches. The examples may use more specific terms.

Being an overview document, the document can serve as a basis for future discussions of individual risk management approaches, either for particular types of chemicals or regarding particular risk management approaches. It can also facilitate the identification of areas where governments can additionally support better chemicals management. While the categorisation below appears to be simplistic, the decision to enact a particular measure is in fact a challenge due to the uncertainty involved in the decision-making process and its elements. Therefore, the majority of the approaches taken are done so in the face of uncertainty. The types of uncertainty will vary depending on the approach, but can include uncertainty in hazard or exposure assessments, uncertainty in the economic costs and benefits of a decision, uncertainty in the enforcement and effectiveness of the risk management approach selected and others. These uncertainties are best illustrated in specific scenarios.

This document can also serve as a resource for countries developing their chemicals management programmes, enabling them to identify the wide variety of risk management approaches that can be used. As described earlier, government chemical risk management approaches are one aspect of larger risk management systems. Increasingly there is also recognition of the need to consider a systems approach, and the influence chemical stewardship has on broader environmental and societal issues and vice-versa, even in the absence of government regulation. While the focus of this document is government action, the approaches and examples within serve the broader goal of risk management that applies to chemical stewardship across the whole life-cycle of chemicals and the choices that are made by industry – from their extraction and production, trade, use (industrial, commercial, consumer), release, and end-of-life management. This follows the notion of the notion of Responsible Business Conduct where "*enterprises should, within the framework of laws, regulations and administrative practices in the countries in which they operate, and in consideration of relevant international agreements, principles, objectives, and standards, take due account of the need to protect the environment, public health and safety, and generally to conduct their activities in a manner contributing to the wider goal of sustainable development*" (OECD, 2011[1]).

2. Risk Management Approaches

2.1. Regulatory bans

2.1.1. Ban manufacture, import, processing, commercialisation and use (including in products)

Description

A ban is a legal prohibition of all activity pertaining to a substance. This includes a ban on all activities ranging from manufacture, import, processing, commercialisation and use. In implementing a ban, some exemptions can be put into place. While regulatory restrictions (see Section 2.2) can also include prohibitions on certain activities, regulatory bans as denoted here would typically apply to all activities with narrow exemptions.

Type of hazard, exposure or risk?

Bans are typically reserved for substances of high hazard where limits on exposure or activities would not adequately control risk or where those limits are unlikely to be implemented fully. In some scenarios, bans are also applied to substances with combinations of particular properties such as persistence, bioaccumulative, hazard and/or long-range transport.

Applicability to particular life-cycle stage or sector?

A ban would apply to the entire life cycle of a chemical and across sectors. Implementation of a ban could be staggered across the life-cycle so that manufacturing or import are required to cease earlier than subsequent steps. Bans could also be implemented with phase-down timeframes.

Table 2.1. Examples of regulatory bans

Country/Jurisdiction	Description	Legislation	Reference
Canada	**Prohibition of Certain Toxic Substances Regulations, 2012 -** These regulations prohibit the manufacture, use, sale, offer for sale and import of certain toxic substances, and products containing them, with a limited number of exemptions.	Canadian Environmental Protection Act	LINK (Canada, n.d.[2])
International	**The Stockholm Convention on Persistent Organic Pollutants –** Substances listed on the global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment.	Stockholm Convention on Persistent Organic Pollutants	LINK (UN Environment, n.d.[3])
Japan	**Class I Specified Substances** – Persistent, highly bio-accumulative and chronically toxic substances that are prohibited (except for special uses)	Chemical Substances Control Law	LINK (Japan, n.d.[4])
Korea	**Prohibited Substances –** List of substances that are prohibited from manufacturing, importing, selling, storing, transporting or use for all purposes	Chemicals Control Act, Act on Registration and Evaluation of Chemical Substances	LINK (Korea, 2021[5])

2.2. Regulatory restrictions including prohibition of certain activities and regulatory limits

2.2.1. Restrict manufacture, import, export, processing, commercialisation or use (including in products)

Description

A restriction is narrower than a ban as it places limitations or prohibitions on certain activities. Restrictions can include elimination of, or limits on, certain sub-sets of activities or control the manner in which particular activities are carried out, or by whom they are carried out. Many of the examples that follow in 2.2.1 to 2.2.5 are examples of restrictions on specific types of activities.

Type of hazard, exposure or risk?

Restrictions are generally applied to hazardous substances where risk has been identified for a certain activity with a substance but where this risk can be controlled via preventing or controlling the activity or eliminating a certain sub-set of activities. Restrictions on particular activities or uses would allow other activities or uses (which present less risk) to continue. Restrictions could also include a requirement for training or certification, so that use is limited only to certified or qualified users.

Applicability to particular life-cycle stage or sector?

Restrictions can be applied across different sectors and target aspects of the entire life cycle. Implementation of a prohibitions could be staggered through the life-cycle of a use in a particular sector so that manufacturing, import, or distribution are required to cease earlier than subsequent steps. Prohibitions or limitations could also be implemented with phase-down timeframes.

Table 2.2. Examples of regulatory restrictions

Country/Jurisdiction	Description	Legislation	Reference
European Union	**Arsenic compounds -** 1. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use to prevent the fouling by micro-organisms, plants or animals of: — the hulls of boats, — cages, floats, nets and any other appliances or equipment used for fish or shellfish farming, — any totally or partly submerged appliances or equipment. 2. Shall not be placed on the market, or used, as substances or in mixtures where the substance or mixture is intended for use in the treatment of industrial waters, irrespective of their use. 3. Shall not be used in the preservation of wood. Furthermore, wood so treated shall not be placed on the market. Some derogations are also foreseen (see LINK 1 & 2)	Annex XVII to REACH Legislation	LINK 1 (European Commission, 2009[6]) LINK 2 (ECHA, n.d.[7])
United States	**2,4,6-TTBP** - prohibits the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP at concentrations above 0.3% in any container with a volume of less than 35 gallons for any use, in order to effectively prevent the use of 2,4,6-TTBP as an antioxidant in fuel additives or fuel injector cleaners by consumers and small commercial operations (e.g., automotive repair shops, marinas). Also prohibits the processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP at concentrations above 0.3 percent by weight, for use as an oil or lubricant additive, regardless of container size.	TSCA 6(h) Regulation of Persistent, Bioaccumulative, and Toxic Chemicals	LINK (US EPA, 2021[8])

2.2.2. Regulatory limits on environmental releases

Description

Regulatory limits on environmental releases pertain to the delineation of the maximum levels of release permissible to air, water or soil.

Type of hazard, exposure or risk?

These maximal limits are typically applied to point-sources (single, identifiable locations of release) for substances in order to maintain exposure levels below an identified hazard threshold level.

Applicability to particular life-cycle stage or sector?

This type of risk management approach is most suitable for life-cycle stages where point-source releases to the environment could occur such as manufacturing, processing and end-of-life.

Table 2.3. Examples of regulatory limits on environmental releases

Country/Jurisdiction	Description	Legislation	Reference
Canada	**Pulp and Paper Mill Effluent Chlorinated Dioxins and Furans Regulations -** prohibit the release of 2,3,7,8-tetrachlorodibenzo-para-dioxin and 2,3,7,8-tetrachlorodibenzofuran in pulp and paper mill effluents	Canadian Environmental Protection Act	LINK (Canada, 2017[9])
European Union	**Emission limit values** are delineated for many chemical substances from different types of industrial facilities. Establishes the main principles for permitting and control of large industrial installations based on an integrated approach and the application of best available techniques (BAT).	Industrial Emissions Directive	LINK (European Commission, n.d.[10])
Japan	**Emission limit values** are delineated for many chemical substances from different types of industrial facilities. Most of the values are set in order to maintain exposure levels below an identified hazard threshold level. However, there are some exceptions such as mercury; the emission limit values of mercury to the air are based on the application of best available techniques (BAT). The details on air quality management policy in Japan are summarized in OECD Environment Working Papers. The purpose of Water Pollution Control Act is to prevent the pollution water in areas of public waters and in groundwater, thereby protecting the public health and preserving living. This act applies effluent standards to workplaces that have facilities those discharge certain polluted water or wastewater.	Air Pollution Control Act, Water Pollution Control Act, etc.	LINK (Botta and Yamasaki, 2020[11]) LINK (Japan, 2021[12])
England and Wales	**Environmental Permitting Regulations -** permits for chemicals come under "pollution" aspect of this whereby they put a requirement on permit holders to follow the conditions in the permit which tell the permit holder to prevent or minimise pollution. Pollution is any emission as a result of operations which may be harmful to human health or the quality of the environment, for example ecosystems on land or water	Environmental Permitting (England and Wales) Regulations 2016	LINK (United Kingdom, 2016[13])

2.2.3. Regulatory limits on environmental levels

Description

Regulatory limits on environmental levels pertain to the maximum level for the presence of a substance in a particular media (air, water, soil, sediment).

Type of hazard, exposure or risk?

These maximum levels are typically applied to the aggregate level of a substance in the environment from both point and non-point sources in order to maintain exposure levels below an identified hazard threshold level.

Applicability to particular life-cycle stage or sector?

Setting of limits on environmental media pertain to accumulation of sources from along the life cycle and releases from all sectors involved with the substance. They can be used for example in remediation scenarios (e.g., maximum levels remaining soil of contaminated sites following clean-up), setting of

maximal levels in drinking-water after treatment, and setting of ambient-air pollution limits for particular substances which may trigger risk management activities if reached. These limits align with identified hazard threshold levels.

Table 2.4. Examples of regulatory limits on environmental levels

Country/Jurisdiction	Description	Legislation	Reference
European Union	**List of Priority Substances** for which environmental quality standards (EQS) are set for the substances in surface waters. Measures in Member States must be taken to ensure that EQSs are met for priority substances. Also measures must be taken to reduce the emissions, discharges and losses of the priority substances and to phase out those of the most harmful.	Water Framework Directive 2000/60/EC and Environmental Quality Standards Directive	LINK (European Commission, n.d.[14])
United States	**Dust lead clearance levels** - Clearance levels indicate the amount of lead in dust on a surface following the completion of an abatement activity. Post-abatement dust-lead levels are evaluated against, and must be below, the applicable clearance levels.	TSCA section 402 and 403	LINK (US EPA, 2021[15])
Japan	**Environmental quality standards** are to be established respectively, which are recommended to be kept up, so as to protect human health and conserve the living environments. Environmental quality standards for water pollution are target levels for water quality that are to be achieved and maintained in public waters (rivers, lakes, seas, etc.) and groundwater. These standards are established to achieve two major goals the protection of human health and the conservation of the living environment. In especially, regarding the goal of the protection of human health, standards have been set for the concentration of 27 substances that can affect human health due to water pollution.	Basic Act on the Environment	LINK (Japan, 2018[16])

2.2.4. Regulatory limits on concentration in or releases from consumer products and articles

Description

For consumer products and articles, limits can be set on the maximal level of a substance in a product or article and on the maximal level of release of a substance from a product or article. The regulated entity would be the product or article formulator or manufacturer, not the consumer user or the distributor (retailer).

Type of hazard, exposure or risk?

This approach can be used to limit the level of exposure to a substance from direct exposure to consumer products and articles through dermal, inhalation, mouthing (children) or via release of the substance from the product/article to the indoor environment leading to indirect exposure via e.g., indoor air, dust. This approach could be applied to limit exposures to below identified hazard threshold levels.

Applicability to particular life-cycle stage or sector?

Applicable to consumer products and articles with a focus on the product/article use stage of the life cycle. Typically, this approach does not account for products in the waste stage where release and pathway to environment might be different, especially if breakdown of products is involved.

Table 2.5. Examples of regulatory limits on concentration in or releases from consumer products and articles

Country/Jurisdiction	Description	Legislation	Reference
United States	**Formaldehyde Standards for Composite Wood Products -** Set formaldehyde emissions limits for certain composite wood products and established a third-party certification program for laboratory testing and oversight of formaldehyde emissions from manufactured and/or imported composite wood products.	TSCA Title VI	LINK (US EPA, n.d.[17])
Korea	**Formaldehyde or mixture containing 1% and above -** Manufacture, import, sales, storage, transport, and use of wood veneers for furniture, fabrics, baby products for age under 3, wallpaper adhesives, and leather softeners are prohibited.	Chemicals Control Act. Act on Registration and Evaluation of Chemical Substances	LINK (Korea, 2021[5])
Canada	**Concentration of Phosphorus in Certain Cleaning Products Regulations** limit the amount of phosphorus in laundry detergents, household dish-washing compounds (including hand dish-washing soap and automatic dish-washing detergents) and household cleaners that are manufactured in or imported into Canada.	Canadian Environmental Protection Act	LINK (Canada, n.d.[18])

2.2.5. Regulatory limits on occupational exposures

Description

Regulatory limits on occupational exposure pertain to setting maximum limits of exposure in work-place environments, principally for inhalation or dermal exposures. These limits could be applied to the general workplace environment, or relate to the setting of maximal limits in, or released from, products used in the workplace.

Type of hazard, exposure or risk?

These maximum levels are typically applied to the level of a substance in the workplace in order to maintain exposure levels below an identified hazard threshold level.

Applicability to particular life-cycle stage or sector?

Applicable to life-cycle stages where occupational handling or exposure to substances occur such as manufacturing, processing, industrial or commercial use and end-of-life processing.

Table 2.6. Examples of regulatory limits on occupational exposures

Country/Jurisdiction	Description	Legislation	Reference
European Union	**Indicative occupational exposure limit values** (IOELV) are health-based, non-binding values, derived from the most recent scientific data available and taking into account the availability of reliable measurement techniques. For any chemical agent for which an IOELV has been set at European Union level, Member States are required to establish a national occupational exposure limit value. They also are required to take into account the Union limit value determining the nature of the national limit value in accordance with national legislation and practice.	Directive 2019/1831 pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC	LINK (European Commission, 2019[19])
Australia	**Workplace exposure standards** (WES) is a list of hazardous chemicals and their maximum exposure limits. State or territory work health and safety authorities then implement these standards as laws.	Commonwealth, states and territories are responsible for implementing, regulating and enforcing workplace health and safety laws in their jurisdictions.	LINK (Australia, n.d.[20])
United Kingdom	**Workplace exposure limits** (WEL) requiring employers to control substances that are hazardous to health and currently includes more than 500 substances.	Control of Substances Hazardous to Health Regulations	LINK (United Kingdom, n.d.[21])

2.2.6. Regulatory requirements for training, certification, or conducting certain processes

Description

Regulatory requirements for training, certification, or carrying out certain practices may be used to limit occupational or environmental exposures or limit the sectors in which chemical substances may be used. These requirements could serve as a gatekeeping function or to reduce exposures to third parties as a result of commercial use or practices.

Type of hazard, exposure or risk?

These requirements are typically applied where training is likely to be successful in ensuring that worker behaviour following training can limit exposure such that there are limited or no risks to workers, bystanders, consumers, the general population, or the environment. These requirements are most successful when certification of training or experience with risk reduction practices can be achieved, and that certification can be verified by regulators or consumers.

Applicability to particular life-cycle stage or sector?

Applicable to life-cycle stages where occupational handling or exposure to substances of occur such as manufacturing, processing, industrial or commercial use, end-of-life processing, and clean-up or remediation.

Table 2.7. Examples of requirements for training and certification

Country/Jurisdiction	Description	Legislation	Reference
United States	**Lead-Based Paint Renovation, Repair and Painting (RRP) Rule** aims to protect the public from lead-based paint hazards associated with renovation, repair and painting activities. The rule requires workers to be certified and trained in the use of lead-safe work practices, and requires renovation, repair, and painting firms to be EPA-certified.	TSCA sections 402 and 403	LINK (US EPA, n.d.[22])

2.3. Generic risk management approaches

2.3.1. Generic risk management approaches as a default for certain hazard classes and uses

Description

As a default approach, substances with a particular hazard profile automatically trigger predetermined risk management measures. The potential exposures and risks are considered generically and embedded *a priori* in legislation.

Type of hazard, exposure or risk?

This approach has been used in scenarios which result in direct exposure to potentially vulnerable groups and in use scenarios which result in widely dispersive applications which result in a significant exposure of humans or the environment. This use profile is coupled with a particular hazard profile for severe adverse effects on human health or the environment.

Applicability to particular life-cycle stage or sector?

This approach aims to automatically and proactively ban particular uses of a substances and therefore is focused on the use life-cycle stage of the product across sectors resulting in the exposures of concern.

Table 2.8. Examples of generic risk management approaches

Country/Jurisdiction	Description	Legislation	Reference
New Zealand	**Group Standards** are approvals for a group of hazardous substances of a similar nature, type or use. A group standard sets out conditions that enable a group of hazardous substances to be managed safely.	Hazardous Substances and New Organisms Act	LINK (New Zealand, n.d.[23])
European Union	**Generic Approach to Risk Management** - Potential exposures and risks are considered generically, prior to the adoption of legislation. A 'generic approach to risk management' is an automatic trigger of predetermined risk management measures (e.g., packaging requirements, restrictions, bans, etc.) based on the hazardous properties of the chemical and generic considerations of their exposure (e.g., widespread uses, uses in products destined to children, difficult to control exposure). It is applied in a number of pieces of legislation on the basis of specific considerations (e.g., characteristics of the hazard, vulnerability of certain population groups, non-controllable or widespread exposure).	Various including REACH, Cosmetic Products Regulation and Toys Directive	LINK 1 (European Commission, 2020[24]) LINK 2 (European Commission, 2019[25])

Japan	**Hazardous Air Pollutants (HAPs) -** Taking potential exposures and risks into consideration, HAPs are ranked into three groups; Group A (Substances that may be classified as HAPs), Group B (Priority Substances), and Group C (Designated Substances). Countermeasures of HAPs are considered for each rank. Reducing of emission of HAPs is regarded not as regulation but as voluntary control of business. When the policy for HAPs first began, emission reductions were promoted by having industry groups prepare voluntary control plans based on the "Guidelines for the Promotion of Voluntary Control of Hazardous Air Pollutants by Businesses" for substances whose concentrations in the atmosphere were high and for which emission control measures were evident to a certain degree, and by having the Central Environment Council conduct checks and reviews. Currently, MOEJ focuses on Group B, especially on arsenic and ethylene oxide. MOEJ also explores each emission source of them and promotes voluntary control of industry groups by businesses.	Air Pollution Control Act	LINK (Japan, n.d.[26])
United Kingdom	**Recommendation that for carcinogens** which do not show a threshold for effect, exposure should be as low as reasonably practicable.	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)	LINK (UK Committee on Carcinogenicity of Chemicals, 2018[27])

2.4. Regulatory prohibitions or restrictions at the end-of-life stage

2.4.1. Regulatory prohibitions or restrictions on the manner or method of disposal, recovery/reuse, recycling

Description

At the end-of-life stage a chemical (or chemical in a product/article) can be disposed (e.g., landfill, incineration), recovered for reuse or recycled. Prohibition or restriction of certain activities at end-of-life can be put into place to minimise impacts at disposal or if the chemical/product is recovered or recycled.

Type of hazard, exposure or risk?

Risk management activities at end of life are most often associated with high hazard substances (often legacy substances) in order to avoid environmental releases or re-circulation into new use scenarios that may result in new risks. In addition, incineration of some types of substances can lead to harmful by-products.

Applicability to particular life-cycle stage or sector?

Applicable to end-of-life stage and the waste management sector.

Table 2.9. Examples of regulatory prohibitions or restrictions at the end-of-life stage

Country/Jurisdiction	Description	Legislation	Reference
United States	**Storage and disposal of PCBs -** Regulations for the way in which materials and liquids containing PCBs above certain concentrations must be stored and disposed of at end-of-life.	TSCA section 6(e)	LINK (US EPA, n.d.[28])
United Kingdom	**Handling of hazardous waste -** Business must ensure that hazardous waste produced or handled by the business causes no harm or damage. This includes classification of chemical waste and determining if it meets hazardous waste criteria.		LINK (United Kingdom, n.d.[29])

2.5. Regulatory authorisations for use

2.5.1. Authorisation or exclusion from regulation for existing, new or expanded use

Description

Authorisation regulations, or exclusions from regulation, can be used to require approval for continuing or expanding an existing use or implementing a new use of a substance. An authorisation approach essentially limits the activities with a substance but allows for requests for approval for particular activities. Authorisations or exclusions may be time-limited or permitted only under special circumstances. Unreasonable or other significant risks would be recognized, but the use could be allowed to continue under certain conditions, such as for a limited time or with specified exposure or risk reduction measures in place.

Type of hazard, exposure or risk?

There are different scenarios when authorisation could be used. In situations where new or expanded uses may lead to additional risk from a substance, a regulator can request that the new or expanded activity be notified and assessed prior to being permitted. In addition, authorisation or exclusion from regulation can be used to allow for the continuation of existing uses in scenarios where a substance has been identified to be of high concern. These could be uses where exposure is adequately controlled, where work is on-going to shift to safer alternatives or where uses are considered 'essential' or 'critical' to society.

Applicability to particular life-cycle stage or sector?

Depending on the activity being approved, authorisation or exclusions from regulation can apply to the manufacturing, processing or use stages of a substance, across sectors. It is likely most relevant to public health, critical infrastructure, or national defence sectors.

Table 2.10. Examples of regulatory authorisations for use

Country/Jurisdiction	Description	Legislation	Reference
European Union	**REACH Authorisation -** REACH allows companies to apply for an authorisation to continue or start using and placing substances included in the Authorisation List (Annex XIV of REACH) on the market. The authorisation process aims to ensure that substances of very high concern (SVHCs) are progressively replaced by less hazardous substances or technologies where technically and economically feasible alternatives are available.	REACH	LINK (ECHA, n.d.[30])
United States	**Significant New Use Rules (SNUR) -** If a chemical subject to a SNUR will be used in a significantly new way, industry must notify the EPA. This obligates EPA to assess risks that may be associated with the significant new use, including risks to potentially exposed or susceptible subpopulations identified as relevant by EPA under the conditions of use; make a determination under the statute; and, if appropriate, regulate the proposed activity before it occurs. The approach is applied, for example, to new substances or discontinued uses of asbestos.	Toxic Substances Control Act	LINK (US EPA, n.d.[31])
Canada	**Significant New Activity Notifications -** The significant new activity (SNAc) provisions trigger an obligation for a person to provide the Government of Canada with information about a substance when proposing to use, import or manufacture the substance for a significant new activity. The government then assesses the substance for potential risks to human health and/or the environment. If risks are identified, the government may impose management measures. The SNAc provisions are applied when a substance has been assessed and there is a suspicion that new activities may pose a risk to human health and/or the environment.	Canadian Environmental Protection Act, 1999	LINK (Canada, n.d.[32])

2.6. Information dissemination

2.6.1. Supply-chain communication (warnings and instructions)

Description

Requirements for supply-chain communication can be put into place in the form of elements such as safety data sheets, labelling based on the Globally Harmonised System of Classification and Labelling (GHS) (UNECE, 2021[33]), providing instruction for safe handling and use along the supply-chain. This should also consider handlers at end-of-life. This may be described as downstream notification. To note that where GHS has been implemented in national legislation, it can apply in certain sectors and not others.

Type of hazard, exposure or risk?

Hazard communication in the supply chain is often based on the hazard classification of a substance under GHS (if adopted within national legislation).

Applicability to particular life-cycle stage or sector?

This approach would apply to manufacture, import, processing, use, end-of-life of a substance/mixture/product across sectors, but in particular is used in occupational settings where the substance/mixture/product is handled or distributed further across the supply chain.

Table 2.11. Examples of supply-chain communication (warnings and instructions)

Country/Jurisdiction	Description	Legislation	Reference
European Union	**Extended Safety Data Sheets -** Safety data sheets include information about the properties of the substance or mixture, its hazards and instructions for handling, disposal and transport and also first-aid, fire-fighting and exposure control measures. The format and content follow the rules for safety data sheets of the Globally Harmonized System (GHS) and contain further elements specific to the European Union such as the inclusion of relevant exposure scenarios in an annex. The detailed requirements are specified in REACH. A safety data sheet should be provided to downstream users for substances or mixtures with particular hazard properties.	Annex II to REACH	LINK (ECHA, n.d.[34])
Japan	**GHS Labels and Safety Data Sheet -**. In Japan, Japanese Industrial Standards (JIS Z 7252 (classification method) and JIS Z 7253(SDS, Label)) corresponding to GHS are established as a means for transmitting hazard information when chemical substances are transferred or provided between businesses. In addition, under the Industrial Safety and Health Law, Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement and the Poisonous and Deleterious Substances Control Law, the business operator obligated delivering SDS and labeling (labeling is obligatory to make efforts, under the Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement). It is recommended to incorporate JIS when creating SDS.	National standard JIS Z 7253:2019 and JIS Z 7253:2019 Industrial Safety and Health Law Act on the Assessment of Releases of Specified Chemical Substances in the Environment and the Promotion of Management Improvement Poisonous and Deleterious Substances Control Law	LINK (Japan, n.d.[35])
Many countries	A summary of GHS implementation in countries has been summarized by the UNECE.		LINK (UNECE, n.d.[36])

2.6.2. Consumer communication (warnings and instructions)

Description

Requirements for consumer risk communication can be put into place in the form of elements such as labelling based on the Globally Harmonised System of Classification and Labelling (UNECE, 2021[33]) (GHS) and providing instruction for safe handling and use. This allows the consumer to better manage their chemical risks.

In addition, governments can consider consumer behaviour coupled with the dissemination of information on chemicals and associated alternative choices, to minimise chemical use more generically or shift to safer alternatives or practices.

Type of hazard, exposure or risk?

Typically, hazard classifications under GHS are made available.

Applicability to particular life-cycle stage or sector?

Applies to products available to the consumer but can be targeted at different parts of the value chain-end-users or intermediary businesses who buy products for use/res-sale.

Table 2.12. Examples of consumer communication (warnings and instructions)

Country/Jurisdiction	Description	Legislation	Reference
Canada	**Chemicals Management Plan information sheets** are a series of short fact sheets about chemical substances and micro-organisms that are being (or have been) assessed in Canada for their possible risks to human health and the environment.		LINK (Canada, n.d.[37])
European Union	**Classification, Labelling and Packaging (CLP) Regulation** is based on the GHS. It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market. The identified hazards must be communicated to other actors in the supply chain, including consumers. CLP also sets detailed criteria for the labelling elements and general packaging standards to ensure the safe supply of hazardous substances and mixtures.	(CLP) Regulation ((EC) No 1272/2008)	LINK (ECHA, n.d.[38])

2.6.3. Public right to know

Description

Public right to know is embedded in The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (The Aarhus Convention (UNECE, 1998[39])) which establishes a number of rights of the public with regard to the environment. This includes access to environmental information, participation in environmental decision-making and access to justice pertaining to these rights.

Information is empowering. Access to information provides the public with the ability to make informed decisions for themselves and can incentivise positive chemical management through public scrutiny.

Type of hazard, exposure or risk?

Public right-to-know is not limited to any particular hazard, exposure or risk. Public right-to-know is rooted in the premise that people have the right to know about chemical-related activities that could impact their quality of life or adversely impact the environment. Chemical-related activities include, for example: the chemicals that are manufactured or used in one's community; the chemicals and quantities thereof that are released to air, water or land from industrial facilities following routine business operations; the chemicals that are used in household products. However, public participation in chemical risk management decision-making requires prior dissemination of information on hazard, exposure and/or known or anticipated risk to the public.

Applicability to particular life-cycle stage or sector?

Public right-to-know is not limited to any particular hazard, exposure or risk.

Table 2.13. Examples of implementation of public right-to-know

Country/Jurisdiction	Description	Legislation	Reference
Many (Global Inventory on Pollutant Releases)	**Pollution release and transfer registries (PRTRs) -** At least 50 countries have in place PRTRs which are publicly accessible databases or inventories of chemicals or pollutants released to air, water and soil and transferred off-site for treatment. It brings together information about which chemicals are being released, where, how much and by whom.		LINK (OECD, n.d.[40])
European Union	**Consumer right to know -** Obligation by industry to answer a consumer inquiry about the presence of a substance of very high concern in an article, within 45 days. Consumers can play an active role by taking an interest in the safety of the products they buy.	REACH	LINK (European Commission, n.d.[41])
United States	**Toxics Release Inventory -** In 1986, with the enactment of the Emergency Planning and Community Right-to-Know Act (EPCRA), the Toxics Release Inventory (TRI) was established as the first national Pollutant Release and Transfer Register (PRTR) in the world. Since then, environmental agencies in other countries have implemented their own PRTR programs modeled after the TRI Program. In addition to annually collecting release and other waste management quantities on more than 800 chemicals from over 20,000 facilities, the TRI also collects information on newly implemented source reduction practices. All of the information collected is required to be disclosed.	Section 313 of the Emergency Planning and Community Right-to-Know Act	LINK (US EPA, n.d.[42])

2.7. Information gathering and record keeping

2.7.1. Requirement of record keeping or reporting

Description

Requirements for record keeping (with potential requirements for reporting to regulatory agencies) are typically in place for all substances manufactured, imported or used, so that companies will be able to fulfil specific regulatory reporting requirements in addition to meeting enforcement and implementation needs. Record keeping alone can also be used as an administrative approach for risk management of lower risk chemicals that are exempt from notification to an authority.

Type of hazard, exposure or risk?

Substances for which a record keeping administrative approach is applied can vary. Record keeping or reporting may be used to supplement additional risk management approaches for high risk substances; record keeping alone may apply to typically low risk substances that are not notified to government. Some examples include low-volume substances, exempt substances, or substances for research and development.

Applicability to particular life-cycle stage or sector?

Could be applied across manufacture, import or use of a substance and also support communication across life-cycle stages.

Table 2.14. Examples of implementation of record keeping

Country/Jurisdiction	Description	Legislation	Reference
Australia	**Record-keeping obligations for introduced chemicals -** Depending on the risk-based categorisation of the chemical being introduced, industry must keep certain records and report certain information. For some categories of chemicals, information does not need to be submitted to the government, but records must be maintained.	Australian Industrial Chemicals Introduction Scheme	LINK (Australia, n.d.[43])
United States	**Mercury Inventory –** Requires reporting from manufacturers (including importers) of mercury or mercury-added products, or persons who otherwise intentionally use mercury in a manufacturing process. The information collected will be used to develop future inventories of mercury supply, use, and trade in the United States. Based on the inventory of information collected, the EPA will identify any manufacturing processes or products that intentionally add mercury and recommend actions to achieve further reductions in mercury use.	Toxic Substances Control Act	LINK 1 (US EPA, n.d.[44]) LINK 2 (US EPA, 2018[45])
United States	**Chemical Data Reporting -** Requires manufacturers (including importers) to provide EPA with information on the production and use of chemicals in commerce. Under the CDR rule, EPA collects basic exposure-related information including information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. The CDR database constitutes the most comprehensive source of basic screening-level, exposure-related information on chemicals available to EPA, and is used by the Agency to protect the public from potential chemical risks.	Toxic Substances Control Act	LINK 1 (US EPA, n.d.[46]) LINK 2 (United States, 2011[47])

2.7.2. Requirement for monitoring

Description

Requirements for monitoring the level of a substance in the environment or occupational setting can be put into place to support regulatory limits placed on a substance (see section 3.2). When levels are approached or exceeded, immediate risk management can be triggered.

Type of hazard, exposure or risk?

Requirements for monitoring are typically put into place for substances for which restrictions have been put into place due to their hazard or risk, and environmental or workplace levels must be kept below specified thresholds.

Applicability to particular life-cycle stage or sector?

Typically used during manufacture and use phases but can also apply to end-of-life releases.

Table 2.15. Examples of implementation of monitoring requirements

Country/Jurisdiction	Description	Legislation	Reference
Canada	**Environmental Code of Practice for Base Metals Smelters and Refineries -** Defines requirements for air emissions and water effluent monitoring and their associated standards.	Canadian Environmental Protection Act	LINK (Canada, n.d.[48])
United Kingdom	**Workplace Exposure Limits -** Exposure measurements are required in workplaces to check that relevant exposure limits are not exceeded.	Control of Substances Hazardous to Health Regulations	LINK (United Kingdom, n.d.[21])
United Kingdom	**Lead exposure -** Employers are required to monitor potential lead exposure to workers.	The Control of Lead at Work Regulations 2002	LINK (United Kingdom, 2002[49])
Japan	**Continuous Monitoring of the Air Pollutants -** Municipalities continuously monitor the air pollution status such as PM2.5, NO2, SO2, etc. These results are immediately posted on the website of MOEJ. **Measurement of State of Pollution of Effluent -** The person who established the specific facility measures the pollution level of the Effluents discharged from that workplace. **Water Quality Monitoring in public water area -** Local governments continuously monitor the state of water pollution in public water areas and report the results to the nation.	Air pollution Control Act, Water Pollution Control Act	LINK 1 (Japan, n.d.[50]) LINK 2 (Botta and Yamasaki, 2020[11]) LINK 3 (Japan, n.d.[51])

2.7.3. Requirement for testing

Description

Testing requirements can be included in regulations that outline minimum information requirements for notification/introduction of commercialisation. The testing requirements typically increase with increasing tonnage bands of manufacture and import, to ensure more robust information is available for higher tonnage chemicals.

Type of hazard, exposure or risk?

The testing requirements are used to probe hazard properties which expand with the volume of commercialisation of a substance. The typically apply across all substances that are subject to the specific legislation.

Applicability to particular life-cycle stage or sector?

Testing requirements are usually introduced during the commercialisation (manufacture and/or import) of a substance. But also at later stages of expansion of the use of the substance.

Table 2.16. Examples of requirements for testing

Country/Jurisdiction	Description	Legislation	Reference
EU	**Information requirements for registration -** Standard information requirements on intrinsic properties of a substance are those which are required as a minimum to meet the registration obligations. They depend on the quantity of the substance that is manufactured or imported into the EU/EEA. Registrants first need to evaluate all available data on the intrinsic properties of a substance. Only when this data is not adequate to meet the requirements of REACH, may additional testing be needed. However, before testing on vertebrate animals, use of alternative methods and all other options must be considered. Testing on vertebrate animals shall be undertaken only as a last resort.	REACH	LINK 1 (ECHA, n.d.[52]) LINK 2 (European Commission, n.d.[53])
Japan	**New Chemical Notification -** For normal (not low volume) notification and evaluation of new chemicals, standard test requirements are in place for biodegradation, bioaccumulation, toxicity and eco-toxicity.	Chemical Substances Control Law	LINK (Japan, n.d.[54])

2.7.4. Registration/Notification for Commercialisation

Description

Most chemical legislation requires the registration or notification for commercialisation of a substance. This could be an initial registration of all substances when robust chemical legislation is introduced or notification of individual new substances as they are commercialised. This allows for a country to understand the types of substances in their country and forms the basis of a chemicals management framework.

Type of hazard, exposure or risk?

Registration/notification is typically not dependent on the type of hazard or risk of a substance but related to its commercialisation. However, countries that are just beginning to establish their chemical management frameworks may start with a registration process of very hazardous substances being manufacture or imported.

Applicability to particular life-cycle stage or sector?

Registration/notification occurs at the commercialisation (manufacture and/or import) of a substance.

Table 2.17. Examples of registration/notification for commercialisation

Country/Jurisdiction	Description	Legislation	Reference
Japan	**Existing and New Chemical Substances -** There are ~28 000 existing chemicals that were either notified as already being manufactured/imported when the CSCL was published in 1973 or were added after new chemicals evaluation. New chemicals must go through a notification process. Annual reporting manufacture/import volume and usage is mandatory for existing chemicals.	Chemical Substances Control Law	LINK (Japan, n.d.[54])
Australia	**Pre-introduction report -** A pre-introduction report is a once-off report that all industrial chemical importers or manufacturers must submit for chemical introductions that are authorised under a reported category. Introductions under the reported category are considered low risk to human health and the environment. It is required to submit the report before introducing the chemical.	Australian Industrial Chemicals Introduction Scheme	LINK (Australia, n.d.[55])
United States	**Pre-manufacture Notice** - Anyone who intends to manufacture (including import) a new chemical substance for a non-exempt commercial purpose is required to submit a pre-manufacture notice (PMN) at least 90 days prior to the manufacture of the chemical. A new chemical is one that is not already on the TSCA Inventory of Chemical Substances, which includes chemicals in commerce in 1975, and those authorised new substances added since. Under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA in 2016, EPA must review and make a determination on the PMN.	Toxic Substances Control Act	LINK (US EPA, n.d.[56])
Canada	**New Substances Notification** - New substances (chemicals, polymers or living organisms) must undergo ecological and human health assessments before being introduced into the Canadian marketplace at high volumes. The acceptability of test data provided by notifiers largely depends on whether the conducted tests comply with the practices set out in the Principle of Good Laboratory Practice and the applicability of the methods to the substance under investigation. Evaluation of these substances can result in risk management measures if the substance is concluded toxic or may become toxic.	New Substances Notification Regulations	LINK (Canada, n.d.[57])

2.8. Voluntary Agreements

Description

In lieu of, or to complement, regulatory risk management activities, voluntary agreements between a government and an industry sector or company can be put into place to work towards a particular risk management objective. These types of agreements could be used, for example, where industry is already actively working towards a specific objective (e.g., phase-out of a use of a substance) and a mutually agreeable time-frame and objectives can be identified. This is complementary to agreements and commitments within particular industry sectors that occur without the intervention of government.

Type of hazard, exposure or risk?

This approach can apply in different scenarios, but ideally where there is a specific risk that has been identified that can be addressed with an agreement with a particular sector/company. More general, wide-spread exposure or risk will not likely be amenable to this approach.

Applicability to particular life-cycle stage or sector?

Best suited if focused on a particular substance or sector that can define the parameters of the voluntary agreement to control the risk identified.

Table 2.18. Examples of implementation of voluntary agreements

Country/Jurisdiction	Description	Legislation	Reference
United States	**PFOA Stewardship Program -** In 2006, EPA invited eight major leading companies in the per- and polyfluoroalkyl substances (PFASs) industry to join in a global stewardship program with two goals: • To commit to achieve, no later than 2010, a 95 percent reduction, measured from a year 2000 baseline, in both facility emissions to all media of perfluorooctanoic acid (PFOA), precursor chemicals that can break down to PFOA, and related higher homologue chemicals, and product content levels of these chemicals. • To commit to working toward the elimination of these chemicals from emissions and products by 2015.		LINK (US EPA, n.d.[58])
Canada	**Bisphenol A in paper recycling mill effluents (2013 to 2017) -** Risk management objectives for paper recycling mills to minimize the risk of environmental impacts from their effluent releases of Bisphenol A (BPA) to the greatest extent practicable.		LINK (Canada, n.d.[59])
United Kingdom	**Code of practice setting a concentration limit in rubber infill material manufactured by Sports Pitch Construction Association (SAPCA) members -** The aim is to reduce the use of infill material that is non-compliant with the concentration limits set by the EU restriction. SAPCA continues to work closely with the UK government on this issue. The effectiveness of existing restrictions on PAHs and the precautionary measures taken by the sports sector means this is not a priority for government action at this time.		LINK 1 (United Kingdom, n.d.[60]) LINK 2 (SAPCA, n.d.[61])
Canada	**Code of Practice for Certain Methylenediphenyl Diisocyanates in Low-Pressure Two-Component Spray Polyurethane Foam Products -** The code of practice aims to reduce exposure of the general population to MDIs resulting from the use of low-pressure two-component spray polyurethane foam (SPF) products containing MDIs that are available to consumers by setting elements of best practices and recommendations for any person who manufactures, imports, or sells low-pressure two-component SPF products containing MDIs available to consumers.	Canadian Environmental Protection Act, 1999	LINK (Canada, 2017[62])
Multijurisdictional	**Cyanide Code –** The international cyanide management code for the manufacture, transport, and use of cyanide in the production of gold is a voluntary certification program of best practices for gold and silver mining companies and the companies producing and transporting cyanide used in gold and silver mining. According to the developers and participants in the code, it provides a mechanism of assurance for enhancing protection of human health and reducing the potential for environmental impacts.		LINK (International Cyanide Management Institute, n.d.[63])

2.9. Economic Instruments

Description

Economic instruments include elements such as taxes, fees and charges, subsidies and tradable permits. Many chemical management frameworks include fees and charges for the registration/notification of chemicals or to off-set activities such as risk assessment by authorities. Other economic instruments, such as taxes, have seen much less use in chemicals management but are available tools.

Type of hazard, exposure or risk?

Economic instruments such as taxes can be used to incentivise a shift in the market for substances not targeted by regulation, or to go further than regulatory expectations. Other types of instruments such as fees or charges can apply across substances that are considered in regulatory frameworks.

Applicability to particular life-cycle stage or sector?

Depending on the type of instrument, these instruments could apply along the life-cycle and across different sectors.

Table 2.19. Examples of implementation of economic instruments

Country/Jurisdiction	Description	Legislation	Reference
United States	**Fees for Administration of the Toxic Substances Control Act -** Fees are collected from chemical manufacturers and importers to help defray up to 25% of the costs associated with TSCA implementation efforts. Payment of fees is required for eight different categories of activities or fee-triggering events including test orders, new chemical notifications, exemption notifications, risk evaluations etc.	Toxic Substances Control Act	LINK (US EPA, n.d.[64])
Australia	**Cost recovery model -** The cost of regulatory activities is recovered through fees and charges. Fees are associated with various regulatory activities such as registration, early listing on the inventory, assessment, authorisation and protection of confidential information.	Australian Industrial Chemicals Introduction Scheme	LINK (Australia, n.d.[65])
Denmark	**Pesticide Tax -** The current pesticide tax will be restructured so that the plant protection products most harmful to health and the environment are subject to the highest taxes, whilst less harmful plant protection products are subject to relatively lower taxes.		LINK (Denmark, n.d.[66])
Sweden	**Excise duty on chemicals in certain electronic goods -** A tax has been levied on chemicals in certain electronic goods since 1 July 2017. The aim is to reduce the occurrence and spread of, and exposure to, dangerous flame retardants in people's homes.		LINK (Sweden, n.d.[67])

2.10. Additional Proactive Voluntary Risk Management Tools

Description

There are many additional voluntary risk management tools that can be used to nudge actors towards better proactive chemicals management and steer chemical stewardship. This includes the development of guidance for industry such as guidance on substitution (OECD, 2021[68]) (ECHA, 2018[69]), guidance on sustainable design (OECD, 2021[70]) (European Commission, n.d.[71]) (OECD, 2020[72]), criteria and certification schemes for safer or more ecologically friendly products (USEPA, 2009[73]), awareness raising campaigns of dangerous substances in the workplace (EU OSHA, 2018[74])information dissemination for existing chemicals (ECHA, n.d.[75]) (OECD, n.d.[76]), making available predictive hazard identification models for industry screening (ECHA and OECD, n.d.[77]), supporting the development of faster, more-efficient toxicological testing as a few examples. These approaches provide information, tools and guidance to industry to improve stewardship choices at an advanced stage of product development in order to proactively reduce chemical risks and can be applied across life-cycle stages and sectors.

2.11. Product Liability Laws

Description

Product liability litigation is a further mechanism to control chemical risks. Products liability refers to the liability of any or all parties along the chain of manufacture of any product for damage caused by that product. Legal action may be taken under such legislative approaches against companies producing or using chemicals, by those who are suffering toxic effects or who are being exposed through their environment, workplace, or consumer products. Compensation can be claimed for damages and costs, including for intangibles such as pain and suffering. The possibility of such legal actions may incentivise companies to ensure the chemicals and products that they manufacture are less toxic, as well as ensuring appropriate accountability for the production and use of toxic chemicals by industry.

Type of hazard, exposure or risk?

Claims usually arise in the context of occupation exposures where industrial workers are exposed to toxic substances; exposure in the home due to inhalation or ingestion of toxic substances; and consumer products where their use has caused unintended illness. Claims can also arise in the context of environmental land contamination.

Applicability to particular life-cycle stage or sector?

Consumer products, emissions and releases, and end of life (legacy) substances.

Table 2.20. Examples of product liability laws

Country/Jurisdiction	Description	Legislation	Reference
European Union	**The Environmental Liability Directive** applies to operators carrying out occupational activities, including with chemical substances, that cause environmental damage or the imminent threat of such damage	Directive 2004/35/CE on environmental liability with regard to the prevention and remedying of environmental damage	LINK (European Commission, 2004[78])
European Union	**The Product Liability Directive** applies to any product marketed in the European Economic Area (EEA), that is defective and causes physical damage to consumers or their property: the producer has to provide compensation irrespectively of whether there is negligence or fault on their part.	Directive 85/374/EEC on liability for defective products (Product Liability Directive)	LINK (European Commission, 1985[79])
European Union	**The General Product Safety Directive** applies to products to be placed on the market or intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers. It establishes a general safety requirement and imposes an obligation for the assessment of conformity of a product with the criteria designed to ensure that requirement	Directive 2001/95/EC on general product safety (General Product Safety Directive)	LINK (European Commission, 2001[80])
United States	**Comprehensive Environmental Response, Compensation, and Liability Act**, known also as Superfund ("CERCLA"). CERCLA's major emphasis is on the cleanup of inactive hazardous waste sites and the liability for cleanup costs on arrangers and transporters of hazardous substances and on current and former owners of facilities where hazardous substances were disposed.	Comprehensive Environmental Response, Compensation, and Liability Act of 1980 and Superfund Amendments and Reauthorization Act of 1986 (SARA)	LINK (US EPA, n.d.[81])

3. Effectiveness of risk management measures

3.1. Importance of enforcement of measures

While not a focus of this report, enforcement is key to successful risk management where the government risk management measure is requesting another party to undertake the activity. If the measures described above are not enforced, they are likely to be implemented to varying degrees by the responsible actors creating an unlevel playing field and not addressing the risk identified.

Governments implement enforcement through various measures such as information campaigns, inspections, requests for information, fines and even criminal proceedings in more extreme cases.

How to enforce the various risk management measures most effectively is an area of potential discussion and sharing amongst countries.

3.2. Importance of measuring effectiveness of measures

The above descriptions of risk management approaches do not provide information on their effectiveness. However, this is something that governments should aim to measure in order to understand the value of the measures that have been implemented, if they are addressing the risk management concern adequately, if further complementary measures should be implemented and to better understand future implementation of similar approaches.

Regarding retrospective evaluation of chemical regulations, (Dudley, 2017[82]) summarised the following:

> *OECD countries rely on regulatory tools to manage potential risks from exposure to targeted chemicals. Ex-ante regulatory impact assessment has a long tradition in many OECD countries, with established analytical steps and oversight as well as opportunities for public engagement to hold governments accountable for conducting analysis before regulations are issued. But ex-ante analyses necessarily depend on unverifiable assumptions and models of how the world would look absent the regulation, and how responses to regulatory requirements will alter those conditions. In essence, ex-ante analyses are hypotheses of the effects of regulatory actions.*
>
> *Better ex-post regulatory evaluation would allow agencies and others to test those hypotheses against actual outcomes. This would not only inform decisions related to the cost-effectiveness of existing policy, but would provide feedback that would improve future ex-ante analyses and future policies. However, ex-post analysis also poses challenges, especially when it comes to chemical risks. Once a regulation is in place, it is not always obvious what the world would have looked like without it. Measuring opportunity costs is not easy, and measuring regulatory benefits is often harder. Furthermore, once a regulation is in place, neither regulators nor regulatory entities have strong incentives for examining its actual impact.*

> *As a result of these methodological and incentive challenges, while ex-post evaluation has a long tradition in other areas (particularly in programmes financed through the fiscal budget), it has received little attention (and even fewer resources) in the regulatory arena, despite government guidelines requiring it.*

As an example, since 2017, the European Chemicals Agency (ECHA) has been monitoring the use of developers on the EU thermal paper market – and in particular the replacement of bisphenol-A (BPA) with bisphenol-S (BPS) and other alternatives – at the European Commission's request and following adoption of a restriction on BPA. In its latest report (ECHA, 2020[83]) ECHA reports on the effectiveness of the restriction. While the substitution process was considerably advanced even long before the end of the transition period, the majority of BPA uses has been replaced by the use of BPS which most likely has a very similar risk profile. This ex-post regulatory evaluation helps to inform and refine risk management approaches in the future.

4. Summary and Conclusions

There are many chemical risk management approaches available to government authorities, both regulatory and non-regulatory in nature. The challenge lies in their implementation in the face of the uncertainty of the identified or potential risk to human health and environment of the chemical(s) and the potential effectiveness of the measure that is selected to address that risk. These approaches can be used in combination to strengthen a risk management response.

As each risk management scenario is ultimately different in terms of the hazards, exposures and risks involved and the legislative construct within which the authority operates, it is challenging to harmonise risk management taken across countries. However, sharing knowledge, insights, approaches and lessons learned can lead to best practices and further align approaches internationally. This document outlining the myriad of approaches available forms a basis for this dialogue.

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Government chemicals management frameworks aim to enable the safe use of chemicals and ensure their proper management. They cover a spectrum of activities varying from a government regulatory response that is command-and-control in nature to policy approaches that aim to incentivise a shift in behaviour. The approaches can be responsive or proactive/pre-cautionary and can be used in combination.

This document provides a synthesis of the various risk management approaches and options that are used by OECD member country government chemical regulatory programmes to manage the risk of chemicals. The scope of the document focuses on the management of risks of industrial and consumer chemicals, i.e., chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals.

The synthesis can serve as a basis for future discussions of individual risk management approaches and facilitate international alignment. It can also promote the identification of areas where governments can additionally support better chemicals management and serve as a resource for countries developing their chemicals management programmes.

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