Case Study of Canada's Chemicals Management Plan

For the **Inter-Organization Programme for the Sound Management of Chemicals** Toolbox for decision-making in chemicals management

Industrial Chemicals Management Scheme

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Environnement et Changement climatique Canada

Canada

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Overview

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) Toolbox for Decision-Making in Chemicals Management is an internet-based platform aimed at countries seeking to establish a chemicals management system or to address specific challenges related to chemicals management. The IOMC consists of nine participating organizations that promote the coordination of activities and policies internationally to achieve the sound management of chemicals to minimize their adverse impacts to human health and the environment. The IOMC Toolbox is hosted by the Organisation for Economic Co-operation and Development (OECD).

One of the key components of the IOMC Toolbox for Decision-Making in Chemicals Management, is its Industrial Chemicals Management Scheme. In 2021, the OECD Chemicals and Biotechnology Committee endorsed a proposal to enhance the utility of the IOMC Toolbox by adding country case studies to this scheme, using Canada's Chemicals Management Plan (CMP) as a pilot. The objective of this initiative is to assist countries developing chemicals management programs by offering real-world examples of technical and functional elements from existing systems.

For simplicity throughout this case study, the scheme will be referred to as the IOMC Toolbox for Industrial Chemicals Management or "the Toolbox".

The CMP is a Government of Canada (GC) program aimed at reducing the risks posed by new and existing substances to humans and the environment. Two federal departments, Environment and Climate Change Canada (ECCC) and Health Canada (HC), jointly administer the CMP.

Approach

This document provides an overview of how key functional and technical elements described in the IOMC Industrial Chemicals Management Scheme are applied in the context of Canada's CMP to identify, assess, and—if needed—manage industrial chemicals. Each program area of the CMP is mapped to one or more elements of the Industrial Chemicals Management Scheme, as illustrated in Figure 1. Throughout this overview, hyperlinks to publicly available information are included for further detail.

The information contained in this document does not supersede or modify any act, regulation or legal obligation, including an obligation to comply under any instruments referred to under the *Canadian Environmental Protection Act, 1999* (CEPA), including statutory or legislative instruments.

IOMC Toolbox Element		CMP Program Area
Legal and Institutional Framework **(New)**	→	Legal and Institutional Framework
Information / Data	→	Information Management
National Industrial Chemicals Registers **(New)**	→	Industrial Chemicals Lists
Hazard Assessment	→	Scientific Evaluation
Exposure Assessment		
Risk Characterization		
Risk Management	→	Risk Management
Awareness Raising	→	Engagement
Evaluation of the effectiveness of the system	→	Monitoring, Surveillance and Research
Compliance Monitoring	→	Compliance Verification
Enforcement of Obligations	→	Enforcement

Figure 1. Elements of the IOMC Industrial Chemicals Management Scheme versus Canada's Chemicals Management Plan program areas.

Legal and Institutional Framework

The Legal and Institutional Framework element of the IOMC Toolbox for Industrial Chemicals Management outlines the foundational components of a chemicals management system. It consists of four main sub-elements:

1. Organization of legislation and national administration
2. Government and industry responsibilities
3. Financing
4. Other aspects/considerations

Refer to the Industrial Chemicals Management Scheme and choose **Legal and Institutional Framework** under the Key functional elements selection list for more information.

In the Canadian context, the GC plays a key role in protecting human health and the environment from exposure to harmful substances. The *Canadian Environmental Protection Act, 1999* (CEPA) is the core federal statute to prevent and control all types of pollution. It provides the main legislative framework for a range of federal environmental and health protection programs, including the management of chemicals. Launched in 2006, the Chemicals Management Plan (CMP) follows a risk-based approach that aims to bring all federal actions for assessing and managing risks from new and existing substances under one comprehensive program. These substances include chemicals, polymers and animate products of biotechnology.

Evolution of chemicals management in Canada and the Chemicals Management Plan

In 1994, under the authorities of the original *Canadian Environmental Protection Act* of 1988, Canada began to screen all new substances for potential risks to human health and the environment before allowing their use or introduction into the Canadian market. However, thousands of existing substances were already in the market before that time, many of which had not been examined for their potential to pose a risk to the environment or human health. Risk assessments for 69 individual chemicals, classes of chemicals, and complex effluents or emissions were undertaken. These substances were identified as priorities for assessment based on recommendations from two multi-stakeholder expert advisory panels. As a result, they were added to the Priority Substances List(s) under the authorities of the original CEPA. These substances were assessed by government scientists over the course of 10 years and, where necessary, risk management instruments for them were developed.

In 1999, CEPA was reformed and provided the GC with new prescriptive measures on how to address existing chemicals (known as legacy chemicals), including measures for categorizing and conducting screening assessments of substances. CEPA 1999 established that, within seven years, the 23,000 "existing substances" on the Domestic Substances List (DSL) would be "categorized" as to whether they were a priority for assessment. The DSL is a list of substances manufactured in, or imported into, Canada on a commercial scale. These existing substances included those in Canadian commerce between January 1984 and December 1986. Using available information from industry, external partners, academic and government research, and other countries, government scientists worked with partners to apply a set of rigorous tools to categorize each of these existing substances.

The categorization process for existing substances was completed in September 2006 and resulted in the identification of approximately 4,300 priority substances that required further assessment under CEPA. The information from this categorization was used to focus attention on chemical substances of highest priority for assessment.

The CMP brought together various federal chemicals programs under a single strategy to assess existing substances identified as a priority and those not yet introduced into the Canadian market, and to take action on those substances found to be harmful. ECCC and HC jointly deliver the CMP, with the support of stakeholders and partners.

The CMP had an initial goal of assessing the approximately 4,300 priority substances by 2020–2021. This work was carried out in three phases:

- **Phase 1** (CMP1, 2006–2011): ~1,100 substances
- **Phase 2** (CMP2, 2011–2016): ~1,650 substances
- **Phase 3** (CMP3, 2016–2021): ~1,550 substances

Since 2006, Canada has published risk assessment reports for the large majority of these prioritized existing substances, and implemented over 200 risk management actions to address 500 substances found to be toxic under CEPA.

In 2021, the GC renewed its commitment to the CMP through to 2024. Originally designed to be completed in three distinct phases, the CMP continues to provide a transparent approach to protecting people and the environment from harmful substances, and a stable and predictable regulatory environment for industry. The program consists of several core activity streams: Risk Assessment; Risk Management; Compliance Promotion and Enforcement; Research; Monitoring and Surveillance; Engagement and Outreach; and Policy and Program Management.

In 2023, amendments to CEPA modernized many of its provisions with respect to chemicals management and introduced a requirement that the GC publish a Plan of Chemicals Management Priorities by June 2025. This new requirement replaces the completed DSL categorization exercise.

For more information, visit the Chemicals Management Plan website.

1. Organization of legal requirements and national administration

Overview of the *Canadian Environmental Protection Act, 1999* (CEPA)

CEPA provides the main legal underpinning of the CMP, including the assessment and management of substances to prevent, reduce, or control the environmental and human health impacts of:

- New and existing substances (including animate products of biotechnology)
- Freshwater and marine pollution
- Emissions from vehicles, engines and equipment
- Fuels
- Hazardous wastes
- Environmental emergencies, including accidental spills

The Minister of the Environment and Climate Change is primarily responsible for administering CEPA and jointly administers provisions on chemicals management with the Minister of Health. This includes the task of assessing and managing the risks associated with toxic substances. For more information, visit the Understanding the *Canadian Environmental Protection Act* website.

On June 13, 2023, Bill S-5, *Strengthening Environmental Protection for a Healthier Canada Act* received Royal Assent. Bill S-5 amended CEPA in two main ways: by introducing a right to a healthy environment under the Act and by strengthening Canada's chemicals management regime. For more information on CEPA, including the amendments in Bill S-5, visit the *Canadian Environmental Protection Act* Registry.

Other key federal laws

There are a number of specialized Acts involved in protecting human health and the environment that complement efforts taken under CEPA to manage risk from harmful substances, including:

- *Canada Consumer Product Safety Act* — addresses or prevents dangers to human health or safety that are posed by consumer products.
- *Hazardous Products Act* — requires suppliers of hazardous products to communicate the hazards associated with their products through product labels and Safety Data Sheets as a condition of sale and importation for workplace use.

- *Food and Drugs Act* — contributes to ensuring the safety of, and preventing deception in relation to food, drugs, cosmetics and medical devices, by governing their sale and advertisement.
- *Pest Control Products Act* — regulates products used to control of pests through a pre- and post-market evaluation program to prevent unacceptable risks.
- *Fisheries Act* — provides broad protections for fish and fish habitat throughout Canada.
- *Feeds Act* — regulates the manufacture, sale and import of livestock feeds to ensure they are safe to livestock, humans, and the environment.
- *Seeds Act* — helps ensure that seeds sold in, imported into, and exported from Canada meet established standards for quality, are labelled so that they are properly represented in the marketplace, and are registered prior to sale in Canada.
- *Fertilizers Act* — helps ensure that all fertilizers and supplement products sold in Canada are safe for humans, plants, animals, and the environment.
- *Health of Animals Act* — helps to protect animals and animal health in relation to diseases or substances that may affect terrestrial and aquatic animals or that may be transmitted by animals to people.

Implementing regulations for chemicals management

In Canada, regulations are the rules used to carry out the intent of Acts and have the force of law. CEPA provides the authority to enact regulations on various aspects of chemicals management, such as the notification of new substances (sections 89 and 114) to the New Substances Program and risk management measures on toxic substances (section 93).

Some of the regulations that support the administration and implementation of chemicals management under CEPA include:

- *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)] — Outlines the information requirements for assessing new living organisms before they are imported into or manufactured in Canada.
- *New Substances Notification Regulations (Chemicals and Polymers)* [NSNR (Chemicals and Polymers)] — Outlines the information requirements for assessing new chemicals and polymers before they are imported into or manufactured in Canada.
- *Persistence and Bioaccumulation Regulations* — Describes the criteria to be used in determining whether a substance is persistent or bioaccumulative.
- *Prohibition of Certain Toxic Substances Regulations* — Prohibits the manufacture, use, sale, offer for sale, and import of certain toxic substances, as well as products containing them, with a limited number of exemptions.

A full list of current, proposed and repealed regulations under CEPA can be found in the *Canadian Environmental Protection Act* Registry.

2. Government and industry responsibilities for chemicals management

Key government responsibilities

In Canada, every level of government plays a part in protecting against risks from harmful substances. At the federal level, the Government of Canada:

- Collects scientific data and commercial activity information from a variety of sources (e.g., industry, journal articles, databases, safety data sheets).
- Conducts research and collects scientific data through monitoring and surveillance activities.
- Assesses and manages, as needed, new substances before they are imported into or manufactured in Canada.
- Identifies, prioritizes, and assesses existing substances that may pose a risk.
- Implements risk management measures on substances where risk has been determined, including making regulations and developing guidelines and objectives within the CMP that apply across the whole country.
- Measures performance of risk management measures and strategies.
- Enforces federal laws and regulations related to chemicals management and promotes compliance.
- Conducts outreach with the public and engages with industry and non-governmental organizations or civil society along with the public, academia and Indigenous partners.
- Engages in bilateral and multilateral cooperation for the global sound management of chemicals and waste.
- Reports to Parliament and conducts evaluations of the CMP program.

Industry/Business responsibilities

Among other responsibilities, industry and businesses must:

- Remain current with the laws and regulations in place to govern chemicals.
- Provide all mandated information and scientific data, notably on applications for new substances, as per the NSNR (Chemicals and Polymers) and the NSNR (Organisms).
- Submit information and data to the program as mandated under CEPA, through information gathering provisions.
- Communicate the hazards associated with their products through product labels and Safety Data Sheets for workplace use, as per the *Hazardous Products Regulations*.
- Comply with risk management measures, including non-regulatory and regulatory restrictions, and ensure that no prohibited substances are produced, imported, or placed on the market.

3. Financing chemicals management

National budget allocation

Canada's chemicals management activities are supported by a combination of fixed-term funding from the Canadian federal budget and annual supplemental allocations within departmental budgets. This funding allows the GC to administer the CMP and carry out CEPA-mandated activities relating to chemicals management. During the three phases of the CMP, the program received approximately $600 million CAD over five years in the first phase (2006–2011). During the last two phases (2011–2016 and 2016–2021), it received approximately $500 million CAD for each phase, for a total of $1.6 billion over all three phases. In the 2021 Federal Budget, the GC funded the program at $296 million CAD over three years (2021–2024).

Staffing structure

Since ECCC and HC jointly deliver the CMP, the program's staffing structure is spread across the two federal departments. In its first year, the CMP employed approximately 158 Full Time Equivalent (FTE) employees, gradually increasing staff to meet growing program requirements, and culminating with approximately 396 FTEs in the last year of CMP Phase 1. During CMP Phase 3, the program maintained a consistent level of staff at 434 FTEs, reflecting the evolution and growing complexity of the program. This staffing level is consistent today.

Cost recovery mechanisms

Section 328 of CEPA grants the Minister of Environment and Climate Change and the Minister of Health the authority to make regulations to help recover the costs of providing services. The *New Substances Fees Regulations* were created as a cost recovery scheme for processing new substance notifications. The amount of fees required is dependent on the notifier's annual sales in Canada, the specific category of notification being submitted, and other services requested, such as confidential searches.

4. Other aspects/considerations

Planning and reporting

Critical to transparency and government accountability are mechanisms to track and report on progress made under the CMP. The GC publishes the Chemicals Management Plan Progress Report to report on advances in major initiatives and highlight key activities relating to its implementation.

The GC also publishes Departmental Plans (DPs), which describe departmental priorities, programs, expected results, and associated resource requirements. It also publishes Departmental Results Reports (DRRs) to report on the results achieved against expected results in the DPs with respect to its core responsibilities. In addition, the Chemicals Management Plan Horizontal Initiative reports on the financial and non-financial information related to planned activities and shared outcomes under the CMP. Finally, annual reports on the administration and enforcement of CEPA are prepared and tabled in Parliament.

Intergovernmental coordination mechanisms

CEPA provides the GC with a clear mandate to ensure that human health and the environment are protected from exposure to harmful chemicals. Interested parties, including industry, non-governmental organizations, academia, Indigenous partners, and the public also play key roles throughout the assessment and management cycles by informing processes and technical approaches used within the program.

Environmental protection is a shared jurisdiction in Canada, and CEPA recognizes the importance of collaboration among all levels of government. Section 6 of CEPA calls for a National Advisory Committee (NAC) to act as an intergovernmental forum. Consisting of representatives from provincial, territorial, and Indigenous governments, the NAC advises the GC on chemicals management activities and on other environmental matters of mutual interest. This ensures a coordinated, national approach to regulation and avoids the duplication of regulatory activities among governments.

A joint CMP governance structure addresses shared responsibilities and ensures a coordinated delivery of CMP activities across both departments. Within this joint structure, HC and ECCC leverage existing CMP horizontal governance mechanisms at three distinct levels of senior management to support integration, coordination, joint decision-making, and accountability, with participation adjusted periodically based on priority activities:

- The **CMP Horizontal Initiative Oversight Committee** is an Assistant Deputy Minister (ADM) level committee that is co-chaired by the ADM of HC's Healthy Environments and Consumer Safety Branch and the ADM of either ECCC's Environmental Protection Branch or Science and Technology Branch. This Committee provides strategic direction and management oversight for the integrated delivery and management of the CMP. The Committee reports to the Deputy Ministers of HC and ECCC and is responsible for the overall management of the CMP. It meets approximately four times per year.
- The **CMP Steering Committee** is a Director General (DG) level committee that includes all implicated DGs within HC and ECCC. It also meets four times per year, with some DG sub-groups meeting monthly. The CMP Steering Committee provides strategic direction, oversight, and a challenge function for the CMP's overall implementation, including integrated program delivery and management accountability.
- The **CMP Working Group** is a Director-level committee that meets every two weeks. It provides oversight of CMP's implementation and coordination and seeks to resolve issues that may arise by developing options, providing advice, and making recommendations to Directors General as needed.

Key terms and principles

Section 3 of CEPA defines terms that have a particular meaning in the Act. In particular, the definitions of “environment” and “substance” are key to the operation of the Act. Both definitions are broad in scope to avoid limiting the government’s authority to prevent pollution from substances that could harm any aspect of the environment or human health. The GC maintains a complete online glossary of terms related to its work on substances.

In addition, CEPA sets out guiding principles in its preamble and embodies them in the administrative duties of the government.

Information / Data

A key technical element of the IOMC Toolbox is the Information/Data element, which describes information management activities that support risk assessments and risk management actions. It contains three sub-elements:

1. Data collection
2. Data storage
3. Data dissemination

For more information, refer to the Information / data page on the IOMC website.

In the context of Canada's Chemicals Management Plan (CMP), information gathering activities are used to inform prioritization, risk assessments, and risk management decisions for both existing and new substances. These processes rely on internal, centralized tools for data storage and information management. The GC employs different mechanisms to communicate program information, updates, and decisions to stakeholders and the public.

1. Data collection

Technical and scientific information is collected from multiple sources, including stakeholder submissions of information through voluntary or mandatory information gathering initiatives, or information requirements for new substances notifications.

Approach to management of Confidential Business Information

Any person or company submitting information under the *Canadian Environmental Protection Act, 1999* (CEPA) can request that the information provided be treated as Confidential Business Information (CBI) pursuant to section 313 of CEPA. To strike an appropriate balance between transparency and industry's right to protect CBI, the GC implements an *Approach to disclose confidential information and promote transparency in chemicals management*. Amendments to CEPA in 2023 codified the Approach in law, requiring a person or company claiming confidentiality under section 313 to provide reasons to support their request that take into account criteria set out in the *Access to Information Act* (e.g., the information is a trade secret, disclosure could reasonably compromise the competitive position of the submitter resulting in financial or commercial loss, etc.).

Information gathering for existing substances

Mandatory mechanisms

CEPA grants the Minister of Environment and Climate Change the authority to require industry to provide information needed to inform prioritization, risk assessment, and risk management activities. These provisions are outlined under sections 46 and 71 of CEPA and may be used to request scientific and commercial information on a given substance.

Provisions in section 46 allow the GC to demand reporting of information on pollutants being released or disposed into air, water, or land. The National Pollutant Release Inventory (NPRI) was developed as Canada's Pollutant Release and Transfer Register (PRTR), to collect and track the discharge of over 300 pollutants, including CEPA toxic substances, from industrial facilities. If facilities exceed thresholds for specific substances or conduct certain specified activities, operators are required to report information such as specific quantities, types of uses, and destinations, among other information. The NPRI is a key resource for identifying and monitoring sources of pollution in Canada.

Provisions in section 71 allow the GC to gather information required for various initiatives. These include providing information on whether a substance should be prioritized for assessment or assessing whether reportable substances are toxic or capable of becoming toxic. This information is also used to assess whether to control, or prescribe the manner in which to control, reportable substances, the products that contain the substances, or the products that may release substances into the environment. These notices may request samples of a substance and require the generation of data (e.g., toxicological) and other tests. Under these provisions, an official notice is published in the Canada Gazette detailing the substances to which the notice applies, the type of persons or entity it applies to, and the information being requested.

Under section 70 of CEPA, persons that possess information supporting that a substance is toxic or is capable of becoming toxic are obliged to provide this information to the government without delay, unless the person has actual knowledge that the government already has the information.

Voluntary mechanisms

The CMP relies on some voluntary information gathering mechanisms (e.g., questionnaires and specific data requests) to collect useful information and data from importers, users, or manufacturers. Voluntary information gathering processes tend to be more flexible with the information that is requested, the interested parties that are targeted, and the amount of time it can take. Voluntary mechanisms may be used for the same reasons as mandatory approaches, but they may also be used to build on the government's knowledge for future mandatory information gathering initiatives. Voluntary information gathering approaches are typically considered before mandatory information gathering activities are undertaken or as an alternative to mandatory approaches.

The effectiveness of voluntary information gathering processes is largely dependent on having collaborative stakeholder relationships, understanding the data stakeholders have in their possession or are capable of producing, and the quality of information provided.

Information gathering for new substances

Mandatory mechanisms

Mandatory information gathering approaches under the New Substances Program require any person who intends to import or manufacture a new substance into Canada to submit a New Substances Notification, which contains information and data necessary to conduct a risk assessment and determine if a new substance poses a risk to the environment or human health. The specific data requirements can be found in the *New Substances Notification Regulations (Chemicals and Polymers)* [NSNR (Chemicals and Polymers)] and the New Substances Notification Regulations (Organisms) [NSNR (Organisms)].

Information gathering for new and existing substances online

Environment and Climate Change Canada's Single Window is an online data reporting system that enables reporting of data for various environmental programs, including the CMP and NPRI. It can be used to provide both mandatory and voluntary data. The CMP's online form allows users to add notes and upload documents, such as program reporting forms in Excel and PDF, as well as supporting documents.

Information collected through both mandatory and voluntary information gathering initiatives is reviewed by program officials and is assessed for quality, completeness, and relevance within the Canadian chemicals management context.

Other information gathering

Program staff review publicly available information (e.g., studies published in peer-reviewed scientific journals) and draw on information from other programs within the GC (e.g., ECCC and HC research, monitoring, and surveillance activities) as well as from provincial/territorial governments. The government also relies on information collected under other Acts, such as the *Food and Drugs Act* and through a variety of other means.

Chemicals agencies in other jurisdictions, notably the United States Environmental Protection Agency (U.S. EPA), the European Chemicals Agency, and the Australian Industrial Chemicals Introduction Scheme, are also valuable sources of information. Information may also be gathered by working in collaboration with interested parties during various stages of risk assessment and risk management activities.

2. Data storage

Collected information is stored using centralized information management and information technology solutions that provide program-wide access. These tools are critical to offering a repository for documents and communications, tracking key information and decisions, and querying to summarize or report on program information. Program staff can access the

information to inform risk assessment and risk management work and support program decisions. These tools consist of commercial off-the-shelf software for case management, document management, substance data management, and business intelligence purposes (e.g., queries or reporting). They are used to collaborate and efficiently manage the integrity of core program information on new and existing substances, ensure business continuity and transparency, and support business needs in a cost-effective manner.

Storing confidential business information

Data collected by program staff or submitted to the CMP is shared program-wide. Since program staff have access to information that may include CBI to perform their duties, the secure, internal-only system they use protects any submitted CBI. As per GC directives, every employee is responsible for maintaining proper marking, storage, transmission, and disclosure of any protected information that comes into their possession, and are required to access or consult information following the need-to-know principle.

Case/document management

The case and document management software used by the CMP is customized to the program and is integral to the centralized tracking of information. The case management software tracks and links different pieces of work related to a substance, along with information about that work, enabling full tracking of risk assessment and risk management processes. Work tracked in the case management software includes links to substance data used in certain risk assessment and risk management documents.

Substance data management

Program staff use a variety of substance databases or information repositories, including the International Uniform ChemicaL Information Database (IUCLID). IUCLID is used to store substance identity/property information and key endpoint data.

In addition, Canada participates through the OECD Chemicals and Biotechnology Committee Working Parties on activities related to data generation and management. In particular, Canada contributes to and benefits from the OECD QSAR Toolbox and eChemPortal.

Business intelligence

The centralized tracking of core CMP information allows data to be extracted and analyzed through business intelligence software. These capabilities facilitate the creation of reports for program use and dissemination, used for purposes such as the program website and the online Substances Search tool. CMP data stored in other repositories can also be used to report and share information.

3. Data dissemination

In line with the Government of Canada's commitment to making government more accessible, compilations of non-confidential information collected through mandatory information gathering notices (section 46 and section 71 notices) are published through the Open Data portal. In addition, the government keeps stakeholders appraised of its plans through the Information Gathering Plan, which provides an overview of current and potential upcoming information gathering initiatives. The plan is updated to reflect priorities, as necessary.

Communicating on risk assessment and risk management

Risk assessments for existing substances are published on the CMP Program website, along with substance information sheets or fact sheets that may be updated from time to time to include key information about the technical and regulatory stages of the risk assessment and risk management processes.

The GC publishes risk assessment summaries for New Substances Notifications (NSNs) for selected substances received under both the NSNR (Chemicals and Polymers) and the NSNR (Organisms) on an ongoing basis. In addition, the New Substances program publishes summaries of NSNs submitted for higher organisms and invites stakeholders to share relevant scientific information and data to inform the risk assessment process. This consultation process is mandatory for vertebrates and prescribed organisms, and the New Substances program encourages notifiers for other higher organisms to participate voluntarily. For more information, refer to Consultations on certain living organisms new to Canada.

In addition, the program has a Substances Management Information Line, dedicated to responding to inquiries related to information gathering activities, which supplement the public communications interface.

Communication tools related to risk management are described under the Risk Management element, engagement and communication component, of this case study.

Official publication of the Government of Canada

The *Canada Gazette* is an online official publication that is used to communicate and consult on assessment outcomes (notices) for existing substances and risk management (notices, orders, and regulations) for new and existing substances. The CMP uses the Canada Gazette to give notice of the publication of content such as complete assessment reports, summaries, risk management scopes, policy documents, guidance documents and operational guidance, among other documents. For other communication platforms used by the GC see the Awareness Raising element of this case study.

Protecting CBI

As described in the Approach to management of Confidential Business Information section of this document, protecting CBI is an important consideration for the GC when sharing information. For example, CEPA and its regulations allow for the publication of masked names on the Domestic Substances List when the substance identity is considered to be confidential. Confidential substances on the DSL are identified by their masked name and their confidential substance identity number, also referred to as a confidential accession number (CAN), assigned by ECCC. For more information, see the *Masked Name Regulations*.

National Industrial Chemicals Register

The National Industrial Chemicals Registers element of the IOMC Toolbox contains five sub-elements:

1. Aim of register
2. Information
3. Timeline
4. Reporting and maintenance
5. Access to data

For more information, refer to the IOMC toolbox generic description of National Industrial Chemicals Registers.

Canada's National Industrial Chemicals Register is the Domestic Substances List (DSL), a list of substances manufactured in, or imported into Canada on a commercial scale. Since its creation, the DSL has become an integral part of decision-making under Canada's Chemicals Management Plan (CMP).

1. Aim of the DSL

The original DSL was published in the Canada Gazette in January 1991. Following consultation and amendments, it was later repealed and replaced with an updated list. The amended DSL, published in 1994, included approximately 23,000 substances deemed to have been in Canadian commerce between January 1984 and December 1986. This exercise served to outline the primary aim of the DSL in the Canadian context, which is to provide the GC with information on the substances and their quantities that were in commerce within Canada's jurisdiction during this period.

The second aim of the DSL is to provide a basis for the GC to distinguish between "existing" and "new" substances for the purposes of assessments. Substances on the DSL are not subject to notification under the NSNR (Organisms) or the NSNR (Chemicals and Polymers), but they may be subject to other requirements under CEPA. The DSL is regularly amended to include substances that entered Canadian commerce following assessment under the New Substances program.

The DSL is a post-market register for substances in commerce, including those in the Canadian marketplace between 1984 and 1986, as well as those assessed under the NSNR (Chemicals and Polymers) and the NSNR (Organisms).

The Non-Domestic Substances List

To reduce regulatory burden, the GC maintains a Non-domestic Substances List (NDSL) containing substances listed on the U.S. EPA's *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory for a minimum of one year. Certain substances on the TSCA inventory are not added to the NDSL. This includes substances that are subject to risk management controls in Canada or the U.S. and substances subject to the Stockholm Convention on Persistent Organic Pollutants or the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. Substances on the NDSL are subject to reduced information requirements under Canada's New Substances program.

2. Information

The DSL is divided into eight parts, each one containing substances that have been segregated based on substance type, confidentiality claims, and whether the Significant New Activity provisions of CEPA have been applied to the substance.

Substances listed on the DSL may be accompanied by one or more of five available flags, which provide more information on the regulatory status of the substance or identify substances added to the DSL under specific scenarios.

The following types of information are found on DSL publications:

- Substance identifier (e.g., Chemical Abstracts Service Registration Number (CAS RN), American Type Culture Collection Number, etc.).
- ECCC Confidential Accession Number.
- Specific substance name or masked name.

3. Timeline

To establish the DSL, the GC invited manufacturers and importers to nominate substances in commerce over the quantity of 100 kg during any one calendar year between January 1984 and December 1986. Along with the nomination forms, manufacturers and importers were required to submit complementary information, such as use, sites of manufacture, and quantities. All complete nominations were accepted and added to the DSL.

The development of the DSL required the commitment of considerable GC resources to develop policies, draft preliminary lists, consult with interested parties, and publish. The creation and publication of the DSL spanned a three-year period.

4. Reporting and maintenance

DSL updates

The Minister of Environment and Climate Change must add a substance to the DSL within 120 days of an assessment of the new substance under the NSNR (Organisms) or NSNR (Chemicals and Polymers), provided that certain listing criteria are met. For additional information on the criteria that could trigger addition of a substance onto the DSL, refer to section 87 and section 112 of CEPA. On average, the DSL is amended 14 times per year to add, update, or correct substances.

In 2023, amendments to CEPA broadened the Minister's powers to add and remove certain substances on the DSL. For example, the Minister may remove a substance from the DSL if it is no longer being manufactured in Canada, imported into Canada, in Canadian commerce, or used for commercial manufacturing purposes in Canada.

Cost recovery

As described in the Cost Recovery Mechanisms section this case study, the *New Substances Fees Regulations* provide the GC with a cost recovery scheme for New Substance Notifications, including risk assessment, risk management when required, and addition of a new substance on the DSL.

5. Access to data

Transparency

In the interest of promoting transparency, there are certain types of information that are not expected to be confidential and are considered eligible to be disclosed by the Government of Canada, as described in the Data Collection element of this case study.

In June 2023, amendments to CEPA authorized the Minister of Environment and Climate Change to disclose explicit substance names after 10 years have passed from the date the name was masked, following the publication of a notice of intent. The GC is conducting a review of substances listed confidentially on the DSL since 2013 or earlier, beginning with the oldest substances.

Substances Search tool

The Substances Search tool can be used to look up substance names and substance identifiers that are referenced in legislative, regulatory, and non-regulatory instruments or GC websites, including the DSL. Search results for substances link to the authoritative source for regulatory or legislative decisions. Results for lists can also be downloaded into Excel. This tool, however, should not be relied upon as the only source for regulatory decisions in Canada, as it is not an exhaustive compilation of regulatory lists.

Scientific Evaluation

The IOMC Toolbox outlines the process of scientific evaluation to determine the risk posed by chemicals to human health and the environment throughout three separate technical elements: Hazard assessment, Exposure assessment and Risk characterization.

In the Canadian context, scientific evaluations of substances are referred to as risk assessments or screening assessments. They are conducted as a single activity under the CMP, encompassing all three technical elements described in the IOMC Toolbox. Risk assessments are conducted under the *Canadian Environmental Protection Act, 1999* (CEPA) to determine if a given substance poses a risk to the environment, human health, or both. Substances manufactured at the nanoscale are also assessed under CEPA. Scientific evaluations assess whether a substance meets the criteria to be considered "toxic" (or capable of becoming toxic) under section 64 of CEPA. The risk posed by a substance is a function of both its hazardous properties and the nature of the exposure that takes place.

Risk assessments involve both an Ecological Assessment and Human Health Assessment to evaluate the inherent hazard, exposure, use, source, and fate of a substance. They are conducted by government scientists from ECCC and HC, with ECCC experts responsible for conducting the ecological assessment aspect, and HC experts assuming responsibility for undertaking the human health assessment.

The lines of evidence considered in risk assessments for existing and new substances are fundamentally similar. A combination of qualitative and quantitative approaches may be used to characterize the overall risk of a substance, resulting in a variety of types of risk assessment documents produced under CEPA.

In 2023, amendments to CEPA added provisions aimed at replacing, reducing, or refining the use of vertebrate animals in toxicity testing, which included requiring that the Minister of Environment and Climate Change and the Minister of Health, to the extent practicable, use scientifically justified alternatives when generating data and conducting investigations under paragraph 68(a) for the purpose of assessing whether a substance is toxic or is capable of becoming toxic.

Existing substances

Existing substances are those that are on Canada's Domestic Substances List. Different risk assessment tools and approaches for existing substances are available to ensure that efforts focus on substances of highest concern and to engage stakeholders on substances as efficiently as possible.

A small number of remaining priorities identified through the DSL categorization (prioritization) process continue to be addressed under the CMP. In addition, ECCC and HC conduct a regular review of available information, known as the Identification of Risk Assessment Priorities (IRAP), to identify and prioritize additional substances that require attention under CEPA.

In 2023, amendments to CEPA modernized many of its provisions with respect to chemicals management and introduced a requirement that the GC publish a Plan of Chemicals Management Priorities by June 2025. This new requirement replaces the completed DSL categorization exercise.

New substances

Before any company or individual can import or manufacture a new substance (i.e., a substance not on the DSL) or a flagged substance in Canada, they must submit a New Substances Notification (NSN) to the New Substances program. This is done to ensure that the substance does not pose ecological or human health risks. The onus is on the importer or manufacturer of the new substance to ensure that all information provided in the NSN is accurate and meets the requirements of the *New Substances Notification Regulations (Chemicals & Polymers)* or *New Substances Notification Regulations (Organisms)*.

CEPA prohibits new substances from being manufactured or imported in Canada unless the company or individual that intends to do so has provided the prescribed information within the prescribed time, and the period for assessing the information has expired or has been terminated early by the Minister of Environment and Climate Change. If government officials determine that information is missing or incomplete, they will contact the notifier to obtain clarification or additional information before and/or during the assessment period.

When reviewing an NSN, government officials consider methodology, reproducibility, and experimental/modelling conditions of the data submitted. In addition, the Ministers must consult any "interested persons" when assessing whether certain new living organisms, including those that are vertebrate animals, are toxic or capable of becoming toxic. Government officials also search public literature for information relevant to their assessment.

If additional time is required to complete an assessment, the Minister of Environment and Climate Change may extend the assessment period only once, for a length of time not exceeding the time prescribed for the initial assessment period. When an assessment decision is made, it is communicated to notifiers at or before the end of the assessment period. The decision indicates whether the substance is suspected of being toxic or capable of becoming toxic when used for any activities described in the NSN (or any other activities), as per any of the criteria set out in section 64 of CEPA. If a substance is suspected of being toxic or capable of becoming toxic, the notifier is informed, and risk management measures may be imposed.

A New Substances Notification can be provided by postal mail or email to ECCC or online via ECCC's Single Window (see the Information gathering for new and existing substances online section of this case study). The New Substances program has developed guidance documents to help notifiers fill out and submit notifications. For more information, consult the following guidance documents: Chemicals and Polymers, Organisms, and Single Window Information Manager.

Hazard assessment (effects assessment)

A hazard assessment (referred to as an "effects assessment" in the Canadian context) evaluates the type (**hazard identification**) and magnitude (**hazard characterization**) of adverse effects that could occur to human health and the environment following exposure to a substance. A hazard assessment begins with information gathering (see the Data collection section of this case study).

Ecological

Hazard identification in an ecological assessment considers the effects a substance may have on both the biotic and abiotic components of the environment. For hazard characterization, government scientists typically determine a threshold concentration at which the assessed substance begins to cause adverse impacts in the receiving environment. For more information on how hazard identification is undertaken in an ecological assessment of chemicals, refer to section 5.1 and 5.2 in CEPA's overview of ecological assessment of substances.

Human health

Hazard identification in a human health assessment considers the type of impacts that exposure to a substance may cause in a person. For hazard characterization, government scientists classify these effects into broad categories that indicate what bodily systems are expected to be adversely affected by exposure to the substance and at which concentrations a substance adversely interacts with these bodily systems. For more information on how effect characterization is conducted in a human health assessment, refer to CEPA's risk assessment process.

Exposure assessment (entry, fate and exposure)

An exposure assessment evaluates a variety of information to determine the concentration of particular substances to which humans and the environment are exposed.

While doing exposure assessments, government scientists may use calculated or measured numerical values to estimate exposures provided by industry, found in scientific literature, or generated internally using databases and models. These estimates may be based on predictive computer models or the result of monitoring activities.

Ecological exposure assessment

For ecological exposure assessments, government scientists gather and evaluate information on the amount of a particular substance that may enter the environment. This evaluation provides information about how the substance may be distributed in the environment, how long it will remain in the environment, and whether there is exposure to the environment. There are different approaches for characterizing exposure, which can be selected depending on the information available regarding sources, uses, handling, and disposal of the substance.

Information on how a substance enters the environment is integrated with information on its fate in the environment to establish the degree of contact that may occur between an ecological receptor and the substance. Chemical structures provide substance identity information and help inform their physical-chemical properties and environmental fate, such as solubility, volatility or potential for degradation and bioaccumulation. For more information on how exposure characterization is undertaken in an ecological assessment, refer to sections 4.1 and 4.2 of the Characterization of entry, fate, and exposure section of the CEPA overview of the ecological assessment of substances.

In an ecological assessment, models are commonly used to estimate levels of a substance in the environment, with environmental monitoring and measured data being used to estimate the quantity of a substance present in the environment media (air, water, soil, etc.) when available. Both environmental monitoring data and the use of models often provide complementary information for an assessment. For more information on how exposure assessments are conducted in an ecological assessment of chemicals, refer to section 4.3 of the Characterization of entry, fate, and exposure section of the CEPA overview of the ecological assessment of substances.

Human health exposure assessment

For human health assessments, certain parameters used in estimating exposure are standardized to ensure consistency of approach (exposure factors). Among the various sources and uses of substances that may result in exposures, everyday products and food-related uses are often considered in risk assessments for human health and the environment. For more information on how exposure characterization is conducted in a human health assessment, refer to section 2.1 in the CEPA Human Health Risk Assessment for Priority Substances document.

In addition, direct and indirect exposures are assessed to estimate the quantity of a substance in a living organism. Human biomonitoring data may be used to estimate how much of a substance, its precursors, or metabolites are present in a person. For more information on how exposure assessment is conducted in a human health assessment, refer to section 3.1 in the CEPA Human Health Risk Assessment for Priority Substances document. Additional information on human biomonitoring in risk assessments is also available.

Risk characterization

Risk characterization is the resulting product of a scientific evaluation and integration of all of the information gathered from literature review and industry submissions, as well as calculated during the scientific evaluation process, whether quantitative or qualitative.

In 2023, amendments to CEPA clarified that, when conducting and interpreting the results of an assessment, available information regarding vulnerable populations, vulnerable environments, and cumulative effects must be considered.

Ecological risk characterization

In an ecological assessment, risk characterization is the combination of methods used to evaluate the potential for harmful effects of a substance in the environment. One of the various approaches for evaluating this potential is the risk quotient method, which compares quantitative estimates of hazard and exposure concentrations to derive a risk conclusion.

Various lines of evidence are considered in a weight-of-evidence approach to evaluate the potential for harmful effects of a substance in the Canadian environment. Additional information is available on the considerations that determine the outcome of risk characterization in an ecological assessment.

Human health risk characterization

To estimate the likelihood of effects or potential for risk in a human health assessment, levels of human exposure are compared to levels that are known to cause adverse effects. Referred to as margins of exposure (MOEs), these are used in risk assessments of substances, and are consistent with approaches used to carry out risk assessments in other regulatory jurisdictions.

Drafting and concluding a risk assessment

During the development of a draft risk assessment, structures and processes are in place to allow the risk assessor to engage the broader risk assessment community, including risk managers, to access expertise and support consistency in risk assessment approaches and decision-making. In some cases, government officials may use risk assessments on substances conducted by other regulatory jurisdictions to inform their CEPA risk assessments. Decision-making is informed by internal and external peer review, including legal review. Draft risk assessments are approved through the hierarchy of senior management all the way to both the Minister of Environment Climate Change and the Minister of Health.

The conclusion of a risk assessment summarizes the key information described above and provides an official conclusion of whether the substance being assessed poses a risk to the environment or human health by meeting the criteria to be considered as toxic (or capable of becoming toxic) as defined under section 64 of CEPA.

Risk Management

The risk management element of the IOMC Toolbox describes the process for selecting and developing appropriate regulatory actions to control and prevent risks to human health and the environment posed by a substance. It contains three sub-elements: (1) Risk evaluation (consideration); (2) Exposure control; and (3) Risk monitoring. For more information, refer to the IOMC toolbox.

In the Canadian context, risk management occurs after a determination has been made that a substance poses or may pose a risk to human health, the environment, or both. The goal of risk management is to reduce or eliminate the risks associated with a given substance by reducing exposure from its use, release, or manufacture. The development and implementation of risk management instruments allows the GC to take a flexible, adaptive, and phased approach to address the risks posed by harmful substances in Canada under the CMP.

1. Risk evaluation (consideration)

Once a risk assessment determines that a substance meets the criteria to be considered toxic under the *Canadian Environmental Protection Act, 1999* (CEPA), the substance is usually added to Schedule 1 of the Act, in either Part 1 or Part 2. As a result, the GC has a legal obligation to manage and prevent risks to human health and the environment associated with the use of that particular substance. This legal obligation is fulfilled through the toxic substances management process, which outlines a science-based framework for preventing and controlling risks from a substance through risk management actions. If a new substance not on the DSL is suspected of being toxic or capable of becoming toxic, risk management measures may be imposed to mitigate any risks to human health, the environment, or both. These risk management measures are explained in the Guidance document for the *New Substances Notification Regulations (Chemicals and Polymers)* and in the Guidelines for the Notification and Testing of New Substances: Organisms.

Generally speaking, the approach under CEPA to dealing with substances that pose, or may pose, risks to the environment and human health is consistent with the Government of Canada's Toxic Substances Management Policy. However, in 2023, amendments to CEPA updated the way in which risks are managed such that the particular risk management approach used will differ depending on whether the toxic substance is added to Part 1 or Part 2 of Schedule 1:

- Toxic substances that are either: (i) persistent and bioaccumulative and inherently toxic (PBiT), (ii) carcinogenic, mutagenic, or toxic for reproduction, or (iii) otherwise found to pose the highest risk will be added to Part 1 of Schedule 1.
    - Initially, toxic substances on Part 1 will be those that have been found to meet the criteria in the existing *Persistence and Bioaccumulation Regulations*.
    - Going forward, those regulations will be amended or new regulations made to prescribe additional thresholds for carcinogenicity, mutagenicity, and reproductive toxicity (CMR), and any other relevant circumstances or conditions.
    - The GC will engage interested persons in developing new regulatory criteria to define toxic substances that pose the highest risk.
- Other substances are added to Part 2 of Schedule 1.
    - Priority will be given to preventing pollution from all substances added to Schedule 1, either Part 1 or Part 2.
    - For those added to Part 1, priority will be given to full, partial, or conditional prohibition. In short, CEPA requires a stricter risk management approach for toxic substances that are added to Part 1 of Schedule 1.

Instrument selection and socio-economic analysis

Risk managers develop and implement risk management tools that are most likely to achieve the intended environmental and/or human health objectives. These objectives are quantitative and qualitative statements that describe what needs to be done to address the risks posed by a substance. Risk Management Objectives (RMO) are then established to achieve the environmental and/or human health objectives and they inform the development of risk management instruments or tools.

To minimize the adverse effects of harmful substances on the environment and human health, instruments must be developed and published within strict timelines and requirements under relevant Acts. Although CEPA is the main federal legislation for managing chemicals in Canada and under which regulations and other risk management instruments are developed and enforced, actions can be taken to develop instruments under other key federal laws (see the list of other key federal laws earlier in this case study).

A variety of voluntary and mandatory instruments are used to manage risks posed by chemical substances. This range of options allows risk managers to use flexible, adaptable, and phased approaches when dealing with harmful chemical substances in an integrated global market. Under CEPA, instruments are chosen based on several environmental, health, economic, and social considerations, while risk managers also consider existing federal laws and programs, laws in provinces and territories, and sometimes those made in other countries.

Some examples of risk management instruments are:

- Regulations, which are enforceable instruments that can restrict or prohibit the use or release of a chemical substance, set limits on the concentrations allowed under various conditions, or prevent the use of chemical substances in certain products.
- Pollution prevention planning notices that require companies to prepare and implement a pollution prevention plan in order to minimize or avoid the creation of pollution or waste.
- Release guidelines or codes of practice that recommend limits and best practices to manage the use, release, or disposal of a chemical substance.
- Significant New Activity provisions that require any major changes in the way a substance is used be reported so that the government can decide whether to control the new use.
- Ministerial conditions for new substances that restrict the manner in which a new substance may be imported or manufactured.

The selection of instruments and tools under the CMP is guided by the Instrument Choice Framework (ICF) for Risk Management. The ICF is a systematic process that identifies the most appropriate risk management instrument or mix of instruments to address environmental and human health risks on a sustained basis and at an acceptable cost.

The ICF consists of four major steps:

1. Gathering background information (e.g., technical information, stakeholder profile, activities/area of concern, policy objective, management measures already in place).
2. Pre-screening the most appropriate instruments.
3. Assessing the pre-screened instruments against specific criteria to make a final selection.
4. Documenting and approving the recommendations.

The process applies four specific assessment criteria, as well as other considerations, to investigate and evaluate the various management approaches available:

- **Environmental and/or health effectiveness:** Ability of a risk management instrument to achieve and sustain the risk management objective, the time required to do so, and its flexibility to adapt to changing conditions.
- **Economic considerations:** Expected impacts of an instrument on the administrative burden for stakeholders and the Canadian government (based on qualitative assessment).
- **Acceptability and compatibility:** Acceptability of an instruments by the department, interested parties, other levels of government, non-governmental organizations, Indigenous people, and the Canadian public. Compatibility of an instrument with proposed or existing measures at the federal level and in other Canadian jurisdictions.
- **International considerations:** Impact of an instrument on environmental, trade, and investment agreements (bilateral and international) to which Canada is a party or a signatory.

Other considerations include distributional impacts, the act best placed to manage the risks (see Other key federal laws, earlier in this case study), and administrative aspects.

Engagement and communication

Under CEPA, the GC has a duty to engage and consult with interested parties to provide feedback and information that may inform the path forward on developing and implementing risk management instruments for substances on the DSL. This responsibility is carried out through publication of documents and public comment periods, including the risk management scope (normally published at the draft screening assessment stage), the risk management approach (normally published at the final screening assessment stage), and proposed regulation or instrument.

Risk managers develop instruments based on the risk management approach, incorporating relevant input received during its public comment period. Proposed draft instruments are published in the Canada Gazette to offer interested parties the opportunity to provide feedback and information to inform the path forward (these consultations may continue throughout the development of a risk management instrument). Stakeholders are encouraged to provide input on information gaps, technical considerations, and socio-economic impacts. The input received is considered by risk managers when developing the final regulation or instrument. More information can be found in the “Engaging in Risk Management” and “Making Information Available” sections of the Risk management of chemical substances website.

To provide interested parties with information on planned publications and consultations related to risk management, the CMP produces quarterly mail-outs to stakeholders and partners listing risk management publications for the coming year.

2. Exposure control (implementation)

Once risk managers are satisfied that a risk management instrument has been thoroughly developed and that it is capable of reducing or preventing the risks posed by a particular substance, the final instrument is published in the Canada Gazette. Regulations must receive Governor in Council approval, while other instruments require Ministerial or departmental approvals. Once put in place, mandatory instruments, such as regulations, become enforceable. A final regulation (or other instrument) may contain a delayed coming into force clause, which allows the government to prepare for its implementation and allows stakeholders to adapt to the requirements set forth by the regulation. Additional can be found on the environmental risk management instruments website.

Instruments being developed or amended are accompanied by an implementation strategy to ensure implementation activities are supported, delivered, and tracked. Information contained in the implementation strategy includes compliance promotion messages and timing, enforcement needs, and the development of a logic model with measurable outcomes and indicators for each instrument.

3. Risk monitoring (performance measurement)

Risk Management is a cyclical process that does not end with the implementation of a risk management action. The GC measures the performance of chosen risk management instruments, as well as risk management approaches and strategies. This helps to ensure that the strategies and instruments put in place by the government are fulfilling their intended purposes. The Government of Canada's performance measurement evaluation strategy outlines the decision-making process for evaluating the management of toxic substances and sets out the approach to measuring progress. Performance measurement evaluations help determine the progress achieved through implementation of risk management strategies in meeting environmental, human health, or risk management objectives. If these objectives have not been met, recommendations may be made to adjust the implementation of a risk management action or to develop additional actions to ensure that risks relating to a particular substance are being reduced or prevented. Additional information on performance measurement of risk management actions under the CMP can be found on the performance measurement for toxic substances website.

Awareness Raising

This element of the IOMC Toolbox describes the mechanisms for gaining public, political, and industry interest and support for implementing a chemicals management system. It contains two sub-elements:

1. Public awareness raising; and
2. Raising awareness among decision makers (including the regulated industry).
   For more information, refer to the IOMC Toolbox.

Raising awareness and engaging interested parties and the public on the management of chemicals is a core component of Canada's Chemicals Management Plan. The GC works with industry, academics, civil society, Indigenous organizations, and other interested parties to share information, fill data gaps, and mobilize knowledge about the harmful effects of certain substances. This engagement contributes to promoting transparency in government actions, establishing government accountability, and strengthening industry's understanding of its obligations under CEPA. The GC also collaborates with other governments and international organizations to avoid duplication of scientific research, share data and best practices in the management of chemicals, and contribute to the global sound management of chemicals by providing technical assistance.

1. Public awareness raising

Information and communication

Publications

To strengthen public participation and ensure that stakeholders and partners are informed about proposed actions regarding harmful substances, the GC publishes a variety of documents for public consultation and disclosure. The public, stakeholders, and partners are invited to provide comments or express concerns directly to the government regarding proposed actions and to provide supplementary information to be considered before a final assessment or management action is issued. Notices of publications must be published through the Canada Gazette, and the GC also publishes these notices along with other documents on the Chemical substances website.

In addition, the Minister of Environment and Climate Change is required to create and maintain the *Canadian Environmental Protection Act* (CEPA) Registry for the purpose of facilitating access to documents relating to matters under the Act. The CMP program uses this tool as an information

hub regarding the administration of CEPA and the availability of documents, such as notices of consultations, environmental quality guidelines, and objectives, and voluntary and regulatory risk management instruments.

Public outreach

HC's platform for disseminating CMP-related information to the public is the Government of Canada's Healthy Home campaign. Healthy Home provides science-based information to people in Canada to motivate them to take action to reduce risks from certain chemicals and pollutants found in and around the home. Public outreach under the campaign employs a variety of communication and marketing tactics, such as social media, web content, print publications, and videos.

A key CMP-specific product published as part of Healthy Home is plain language summaries of CMP-assessed substances. These webpages provide an overview of CMP screening assessments and risk management scopes/approaches for specific substances of concern to the general public, and, in some cases, when there is a need to provide clarification about publicly perceived risks. Additional Healthy Home outreach resources are also available.

Consultation and engagement

From time to time, the GC conducts public consultations on topics related to the CMP. For example, in 2019, the government undertook broad consultations on the future of chemicals management in Canada, for which it published consultation documents and engaged with a broad range of partners and interested parties, including industry, environmental non-governmental organizations, Indigenous groups, scientists, and youth. These consultations were used to inform Canada's approach on issues such as defining populations that are disproportionally impacted, informed substitution and occupational exposure. Engagement for this purpose occurred through online surveys, face-to-face discussions, and focus groups.

The GC is implementing an enhanced approach to stakeholder and Indigenous partner engagement under the CMP, informed by lessons learned and feedback received to support better decision-making in an increasingly complex chemicals management landscape. A central focus of this approach is greater representation of the views of those disproportionately affected by the harmful effects of chemicals. To back this goal, the CMP Engagement and Outreach Contribution Program was launched in 2022 to make dedicated funding available to support the engagement of Civil Society Organizations and Indigenous people (Engagement and Outreach Contribution Program: Public participation stream and Engagement and Outreach Contribution Program: Indigenous participation stream).

Another aspect of the new approach is a shift from a patchwork of engagement spaces to a more integrated approach that will include:

- Regular and formal bilateral meetings with Industry, civil society, and Indigenous partners; and
- Ad hoc multi-stakeholder and science workshops to bring together interested parties and Indigenous partners to advance program implementation and identify program science/ innovation needs.

Dialogue with industry stakeholders is regular and well established through formal engagement forums, notably the CEPA Industry Coordinating Group (ICG). The ICG allows for regulatory and technical discussion between various industry associations and the government on matters related to CEPA's regulatory regime.

2. Raising awareness raising among decision makers (including the regulated industry)

Compliance promotion

The GC conducts promotion activities with the aim of ensuring that regulated stakeholders (regulatees) are aware of risk management instruments and their requirements, understand how to comply with them, and understand the penalties in the event of non-compliance. Promoting compliance is an effective tool in securing conformity with the law and reducing the need for costly enforcement measures.

For each CMP instrument, the GC uses a four-step approach to promote compliance:

1. Characterize the regulated audience: knowing which communities of regulatees are affected by a given risk management instrument helps in tailoring the compliance promotion approach to each specific audience, understanding how best they can be reached (directly or through influencers), and identifying potential hurdles to compliance.
2. Develop compliance promotion tools: the government develops key messages and compliance promotion materials specific to each target audience. Tools are developed to overcome barriers to compliance, using behavioural insight techniques.
3. Interact with stakeholders (delivery activities): the government selects activities tailored to the target audience to deliver key messages. These activities may include in-person interactions (e.g., presentations at conferences or booths at trade shows), sending promotion materials through mailing lists and emails, digital advertising, and articles in specialized newsletters or journals.
4. Measure awareness of requirements and impact of activities: the government measures the performance of compliance promotion efforts through activities like before-and-after surveys. Compliance promotion activities are assessed based on these measures, and approaches are adapted, when needed.

International engagement and collaboration

The GC also engages and collaborates internationally to complement domestic efforts to protect human health and the environment from the risks associated with harmful substances. This includes formal and informal mechanisms for bilateral cooperation with key partners, such as the United States, the European Union, China, and Australia. Multilaterally, this includes membership in multilateral environmental conventions and international organizations and agreements. By working with other jurisdictions and organizations, Canada can access and advance science, fill data gaps, and develop internationally recognized tools and methodologies for the risk assessment and management of chemicals. Through international engagement and collaboration, Canada strengthens protections domestically, while also advancing the sound management of chemicals and waste around the world.

Multilateral engagement

Canada is an active participant in, and contributor to, the OECD Chemicals and Biotechnology Committee and its technical sub-groups. Canada's involvement is premised on strengthening knowledge networks; improving efficiency by avoiding duplicative work; and cost savings through leveraging policy, as well as the scientific and technical expertise, of other developed nations in areas of mutual interest. This collaboration is instrumental in advancing the domestic management of chemicals through the CMP. Additional information is available on Canada's involvement in the OECD Chemicals Programme.

Canada actively contributes to shaping and implementing the work of the United Nations Environment Programme (UNEP) related to chemicals and waste through work undertaken domestically under the CMP, and by engaging internationally. Canada plays a leadership role in shaping and implementing the following multilateral environmental agreements: Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; Stockholm Convention on Persistent Organic Pollutants; Minamata Convention on Mercury; and the Montreal Protocol on Substances that Deplete the Ozone Layer. Canada is also involved in and provides support to the UNEP Global Mercury Partnership, which aims to minimize and, where feasible, eliminate global anthropogenic mercury releases to air, water, and land. Moreover, Canada is actively engaged in discussions to establish a new science policy panel to contribute further to the sound management of chemicals and waste and to prevent pollution (as mandated by UN Environment Assembly Resolution 5/8 adopted in 2022); and in the Intergovernmental Negotiations Committee process under UNEP to develop an ambitious international, legally binding treaty on plastic pollution. Finally, Canada sits on the steering committee of the UNEP International Resource Panel. Additional information is available on Canada's involvement in UNEP.

In support of advancing the sound management of chemicals internationally, Canada contributes to the multi-sectoral, multi-stakeholder efforts of the Strategic Approach to International Chemicals Management (SAICM), the Global Framework on Chemicals (SAICM's replacement, adopted in

September 2023), and its governing body (the International Conference on Chemicals Management). As a world leader on chemicals and waste management, Canada has held important roles in the SAICM forum, notably as one of the only countries represented by its national health ministry, as well as being the regional focal point of the Western European and Others Group from 2015–2023 and as co-chair of the Intersessional Process to negotiate a renewed international framework from 2017–2021. Canada has furthered the implementation of SAICM by providing in-kind expertise on emerging issues, providing funding support for certain activities, advancing the engagement of the health sector in the global sound management of chemicals, and sharing lessons learned from the CMP. Additional information on Canada's involvement in SAICM is available.

Canada also contributes to the work of the World Health Organization (WHO) Health and Environment Programme and related initiatives and strategies to support Health in All Policies (HiAP) approaches to strengthen international and intersectoral collaboration on environmental health (including chemicals) and promote international cooperation. The WHO is an important partner in Canada's work on chemicals management and HC's Safe Environments Directorate was formally designated as a WHO Collaborating Centre on Environmental Health in 2021. Under this designation, Canada assists the WHO in developing guidance and tools to assess, prioritize, manage, and mitigate health effects associated with environmental risk factors, including hazardous chemicals, air pollution, water quality, and climate change. Canada also assists in translating evidence on environmental health to support disease prevention and health promotion by preparing and delivering training materials and supporting education and training efforts more broadly. Canada also provides technical input to the WHO to advance its activities related to the WHO Global Chemicals and Health Network and the WHO Chemicals Risk Assessment Network.

Canada participates in discussions, projects, and activities at several other international forums related to chemicals management. These include the Accelerating the Pace of Chemical Risk Assessment initiative, the Asia-Pacific Economic Cooperation Chemical Dialogue, the North American Commission for Environmental Cooperation, the Convention on Biological Diversity, and groups dedicated to Pollutant Release and Transfer Registers (PRTR). While not a party to the Aarhus Convention or the Kyiv Protocol on Pollutant Release and Transfer Registers, Canada participated in the negotiations as an observer to encourage international consistency with Canada's PRTR and continues to monitor developments to encourage international harmonization and collaboration among member countries.

Bilateral engagement

Canada engages other countries through bilateral agreements (e.g., memoranda of understanding (MOUs) and cooperative arrangements) and informal mechanisms. For example, Canada and the United States collaborate through the Canada-U.S. Regulatory Cooperation Council on regulatory approaches under its Initiative on Chemicals Management. One of the outputs from this collaboration is an Assessment Collaboration Framework, which seeks to enhance alignment and collabration on chemical risk assessment activities.

Other examples of bilateral agreements include an MOU with the European Chemicals Agency for technical cooperation on issues of mutual interest related to chemicals management, and a cooperative arrangement with Australia's Department of Health related to enhancing technical cooperation and sharing information on industrial chemicals. The Compendium of Canada's Engagement in International Environmental Agreements and Instruments is a non-exhaustive list that compiles many of Canada's bilateral agreements related to chemicals management.

Canada also cooperates with countries (e.g., Israel, Colombia, Brazil, Chile, Costa Rica and Peru) on an ad hoc basis to share knowledge and exchange experiences on respective approaches to chemicals management. In some instances, this engagement occurs in the context of these countries joining the OECD, whereby Canada can offer technical assistance during the development of a chemicals management system.

Evaluation of the Effectiveness of the System

The Evaluation of the Effectiveness of the System element of the IOMC Toolbox describes the processes for ensuring that risk management actions are having the intended effect. It consists of three sub-elements: (1) Health monitoring, (2) Environmental monitoring, and (3) evaluations and audits. For more information on the Evaluation of the Effectiveness of the System element refer to the IOMC toolbox.

The GC monitors exposure to substances to provide essential information about their effects on human health and the environment. Monitoring both human and environmental exposure to substances is the basis on which the Government of Canada's performance measurement evaluation strategy relies on (see the Risk monitoring section of this case study). The GC does so by gathering physical, chemical, and biological data by measuring chemicals in air, water, wildlife, and humans. This information can inform priority setting, risk assessment, and risk management activities, and serve to assess whether risk management instruments are meeting their objective to reduce the overall risk of toxic substances to human health and the environment. The latter is addressed under the Risk Management element, risk monitoring and performance measurement section, of this document.

1. Health monitoring to evaluate the effectiveness of the system

Human exposure to substances is an important area of focus for the CMP. Human biomonitoring measures a chemical, the by-products it makes after it has broken down, or the by-products that might result from interactions in the body. These measurements are usually taken in blood and urine samples and sometimes in other tissues and fluids, such as hair, nails, and breast milk. The measurements indicate how much of a substance may be present in a person or to how much of that substance a person has been exposed. The presence of a substance in the body does not necessarily result in a harmful or adverse effect. Under section 45 of the *Canadian Environmental Protection Act*, *1999* (CEPA) the Minister of Health must conduct research and studies, including biomonitoring surveys, relating to the role of substances in illnesses or in health problems. The research and studies may relate to vulnerable populations. Additional information is available on biomonitoring efforts under the CMP.

2. Environmental monitoring to evaluate the effectiveness of the system

To identify and track exposure to and movement of substances in the environment, the CMP implements an Environmental Monitoring and Surveillance Program that measures specific chemicals in outdoor air, water, sediment, fish, wildlife, and wastewater across Canada. This program allows the GC to monitor the presence of substances known to be in the Canadian marketplace and serves to provide information on emerging chemicals of concern. Environmental monitoring data is used to inform performance measurement evaluations of risk management measures taken for toxic substances.

Depending on the environmental component that is being monitored, procedures for sampling and analyzing samples to generate data may vary. Additional information is available on the various environmental components monitored by CMP and its procedures.

As a complement to its monitoring and surveillance efforts, the GC conducts research on CMP priority substances to better understand exposure and effects on human health and the environment. Research under the CMP is undertaken by government scientists and involves generating and disseminating evidence-based information to support the sound management of chemicals. For example, CMP research outputs can provide information to bridge critical data gaps, develop new methodologies for risk assessments, evaluate fate and impacts of substances, understand exposure pathways, and ultimately determine a substance's toxicity levels.

3. Evaluations and audits

Evaluations

Before each funding renewal, the CMP is subject to mandatory evaluations to assess the relevance and performance (effectiveness, economy, and efficiency) of each phase of the program. Each phase of the CMP has been evaluated by HC's Office of Audit and Evaluation (OAE):

- Chemicals Management Plan – Horizontal Evaluation (October 2011)
- Evaluation of Phase II of the Chemicals Management Plan 2011–2012 to 2015–2016 (June 2015)
- Evaluation of the Chemicals Management Plan 2014–2015 to 2018–2019 (January 2020)

Audits

From time to time, the OAE conducts an audit of the CMP to assess the effectiveness of the management control framework for implementing the program as it relates to governance, risk, and internal controls. For example, in 2013 the OAE conducted and published an audit of the CMP's existing substances activities to ensure proper management of public funds administered by the departments, and to ensure commitments are met within the allotted timeframe.

As part of the audit, recommendations were made to the program's management committees to highlight areas identified as benefiting from review, changes, or both. The program's management committee responded to the recommendations made in the audit through a Management Response and Action Plan document that outlined its planned actions to address the recommendations.

In addition, from time to time, certain aspects of the CMP are subject to independent audits by the Commissioner of the Environment and Sustainable Development to the Parliament of Canada. For example, the Commissioner published their report on Toxic Substances (2018) where they audited whether Environmental and Climate Change Canada adequately met its obligations to enforce regulations under CEPA to control the risk of certain toxic substances. ECCC's official response to the recommendations was included within the Commissioner's report to the Parliament of Canada.

Compliance Monitoring

In the IOMC Toolbox, the Compliance Monitoring element outlines effective strategies for regulatory authorities to verify industry compliance with legislative and regulatory requirements. It contains two sub-elements: (1) Local control and (2) Customs control. The Compliance Monitoring element is closely related to the Enforcement of Obligations element and some of the information may overlap. For more information, refer to the IOMC Toolbox.

Under CEPA, compliance monitoring activities are commonly referred to as compliance verification activities, and are undertaken to verify that legislative and regulatory requirements are being met by regulated stakeholders. The GC leverages effective tools, such as site visits, inspections, investigations, laboratory analysis, and border control to ensure that industry conforms with laws and standards. Refer to the Compliance and Enforcement Policy for more information on how compliance verification is conducted under CEPA.

1. Local control

Inspections

The purpose of inspections under CEPA is to verify compliance with the Act and its regulations. Authorities for inspections are provided under Part 10 of CEPA. For an enforcement officer to enter and conduct a lawful inspection of a premises other than a private dwelling, they must have reasonable grounds to believe that activities, materials, substances, records, books, electronic data, or other documents that are subject to CEPA or relevant to its administration are inside the building. In the case of conducting an inspection on a private dwelling, an enforcement officer must seek consent from the occupant to conduct an inspection or obtain an inspection warrant. Refer to the Inspection section of the Compliance and Enforcement Policy for more details on CEPA inspection protocols.

Investigations

The purpose of investigations under CEPA is to gather evidence and information relevant to a suspected violation from a variety of sources. An enforcement officer must use judgement to determine whether they have reasonable grounds to conduct an investigation. If the enforcement officer determines there are reasonable grounds, they must obtain a warrant, unless certain exigent circumstances are met. During an investigation, an enforcement officer may conduct a search during which they may seize and detain anything they deem was used to commit an offence under the Act, is related to the commission of an offence, or will provide evidence of an offence. For more information on the investigation process under CEPA, refer to the Investigation section of the Compliance and Enforcement Policy.

Laboratory analysis

Enforcement officers, as well as CEPA analysts when accompanied by an enforcement officer, are permitted to take samples to verify compliance with CEPA. Any samples collected are sent to laboratories for testing.

2. Customs control

The GC controls the importation of certain toxic substances through various regulations, such as the *Prohibition of Certain Toxic Substances Regulations, 2012*. These regulations prohibit the import, use, manufacture, sale, and offer for sale of some of the most harmful substances declared toxic under CEPA, and products containing them, with limited exemptions. Compliance with these regulations is the responsibility of regulatees. They may be subject to monitoring through inspections, investigations, and/or laboratory analysis, as deemed necessary by enforcement officers and subject to the policies and procedures outlined in CEPA's Compliance and Enforcement Policy. For additional information, refer to the overview of these regulations.

ECCC monitors compliance with chemicals and waste legislation and regulations at the border through collaboration with the Canadian Border Services Agency (CBSA). ECCC and CBSA collaborate at Canada's ports of entry and exit to enforce CEPA and its regulations, along with ensuring compliance with the various multilateral environmental agreements to which Canada is a party. This collaboration is formalized through the development and publication of memoranda, which outline the legislation, regulations, policies, and procedures that the CBSA applies to administer customs control programs, including those for importing and exporting certain substances, materials, products, and wastes.

For example, CBSA and ECCC have a Memorandum in place that outlines how the agency and the department collaborate to enforce compliance with the *Cross-border Movement of Hazardous Waste and Recyclable Materials Regulations* (XBR), as well as Canada's obligations under the Basel Convention. The rules under this convention require that the exporting country receive the prior informed consent of the importing country before certain waste can be exported. Once this permission is obtained, ECCC issues an import or export permit to the Canadian importer or exporter. The XBR requires anyone proposing to export (or import) a hazardous waste (HW) or hazardous recyclable material (HRM) to submit a notice that serves as an application for a permit from the Minister of Environment and Climate Change. ECCC tracks the movement of shipments until the HW or HRM is disposed of or recycled. The Memorandum between ECCC and CBSA details the requirements (documents and permits) for the importation, exportation, and transit of HW and HRM by importers, exporters, customs brokers, custom service providers, or authorized carriers, as well as customs procedures.

Another example is collaboration between CBSA and ECCC to enforce compliance with the *Ozone-depleting Substances and Halocarbons Alternatives Regulations*, as well as Canada's obligations under the Montreal Protocol. This collaboration is established through the Memorandum on Requirements Concerning the Importation and Exportation of Ozone-depleting Substances and Halocarbon Alternatives and certain Products Containing or Designed to Contain these Substances.

Enforcement of Obligations

The Enforcement of Obligations element of the IOMC Toolbox outlines the process for ensuring consistent enforcement in the event of non-compliance with legislative and regulatory requirements. It includes two sub-elements: (1) Sanctions and (2) Liability. For more information, refer to the IOMC toolbox.

The GC has a duty to ensure compliance with the *Canadian Environmental Protection Act, 1999* (CEPA) and associated regulations. Enforcement officers consider a range of criteria when deciding the type of enforcement action warranted by a particular instance of non-compliance. Additional information is available on the role of enforcement under CEPA.

Effective enforcement of the law is critical to ensuring the highest level of environmental quality. For an overview of enforcement under CEPA, refer to the enforcement fact sheet. Enforcement measures may include warnings, tickets, compliance orders, court injunctions, criminal prosecution, court orders, and civil suits, among others. When applying these measures, enforcement officers follow the guiding principles established in the Compliance and Enforcement Policy to foster effective and consistent application of the law.

1. Sanctions

The goal of all enforcement actions is to secure timely compliance with CEPA and its regulations. Therefore, enforcement officers will give first consideration to enforcement actions that result in compliance with CEPA within the shortest feasible timeframe and serve as an effective deterrent from future instances of non-compliance.

Warnings

Enforcement officers have the ability to issue warnings to persons, companies, and different levels of governments when they believe that a violation of CEPA has occurred or is occurring and the degree of or potential of harm to human health or the environment appears to be minimal. The objective of a warning is to bring the CEPA violation to the attention of the alleged violator to inform them of non-compliance and promote corrective action. Warnings may be provided orally to alleged violators but are always followed by a formal written warning for record keeping purposes. Furthermore, warnings are not considered a finding of guilt, nor of liability, but may be taken into account in future responses to alleged violations.

Tickets

In addition to issuing a warning, an enforcement officer has the ability to issue a ticket to the alleged violator for every day that an offence continues to occur. To effectively bring a violator into compliance, officers will consider whether issuing one or more tickets is appropriate. The *Contraventions Regulations* identify which offences are "ticketable" under CEPA, the associated fines, and the responsible regulatory authority.

Directions in the event of releases

In cases where the release of a substance has occurred in contravention to CEPA, or release is imminent, enforcement officers may give directions to the persons, companies, and governments that caused or contributed to the release to ensure that they take all reasonable emergency measures to prevent further release. Enforcement officers may issue directions that aim to remediate any dangerous conditions or reduce the danger to human health and the environment caused by exposure. Under CEPA, persons, companies, and governments already have the obligation to undertake these measures, but directions are given as a formal record that these obligations are not being met. Failure to comply with a direction will lead to prosecution and to engaging a qualified expert to take the measures prescribed, at the expense of the violator.

Ministerial orders

In response to alleged violations of CEPA, the Minister of Environment and Climate Change can issue orders to prevent the unlawful manufacture, importation or distribution, or use of a substance that causes or may cause harm to human health, the environment, or both. The types of orders that enforcement officers may request the Minister to issue to ensure prompt and immediate action is taken are as follows:

- **Prohibition orders:** The Minister may issue a prohibition order for any activity that involves new substances that contain an expiry date.
- **Recall orders:** The Minister may issue orders to manufacturers, processors, importers, and/or distributors to recall a substance from the marketplace if it is determined to be in violation of CEPA or its regulations. Recall orders can, among other things, require persons to provide public notice of dangers to the environment and human life or health; forward the notice to upstream users of the substance; and substitute the substance for a safe alternative.

Environmental protection compliance orders

Under CEPA, enforcement officers are empowered to issue an environmental protection compliance order (EPCO) to: i) prevent a violation from occurring; ii) stop a violation that is occurring; and iii) ensure that all preventive actions required under CEPA are being conducted to ensure protection of the environment.

2. Liability

Injunctions

The Minister has the authority to seek an injunction to stop or prevent a violation under CEPA. In addition to the injunction, if the Minister has reason to believe that the violation has already occurred, prosecution or civil action for the recovery of costs associated to the action taken to prevent or remediate a violation of CEPA can be pursued.

Prosecution

If, during the course of an investigation, an enforcement officer determines that an offence has been committed under CEPA that warrants the use of legal recourse, they will recommend charges to the Public Prosecution Service of Canada (PPSC) for every alleged violation. The PPSC must agree that a prosecution is likely to succeed and that it is within the public interest before laying charges.

Penalties

If a violator is convicted under CEPA, enforcement officials will, on behalf of the Minister, recommend that the prosecutors request the court to administer penalties proportionate to the offence committed. Penalties for convictions under CEPA include court orders, fines, and/or imprisonment. In addition, CEPA includes mandatory sentencing criteria for consideration of the court, which is guided by the Polluter Pays Principle.

Civil suits by the Crown to recover costs

Through the process of a civil suit, CEPA allows the Crown to recover costs incurred by the Government of Canada. In many cases, enforcement officers will attempt to recover costs through a negotiation process but will initiate or proceed with civil action in the case of a failed out-of-court settlement.

The Crown may seek to recover these costs if enforcement officers or the Minister were required to take action in the following circumstances: a) to carry out clean-up or hire qualified experts to do so; b) to prevent the unauthorized release of a regulated substance; c) where any person fails to comply with an environmental protection compliance order; d) to publish the facts related to an offence; or e) non-compliance of court orders.