Environment Canada
Health Canada

Canada

Approach for identification of chemicals and polymers as risk assessment priorities under Part 5 of the *CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999* (CEPA 1999)

2014

Contents

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999), which is aimed at preventing pollution and protecting the environment and human health, is jointly administered by Environment Canada and Health Canada, and includes specific requirements for the assessment and management of substances. The Act contains mandatory and enabling provisions that require, or permit, the assessment of the risks to human health and the environment that may result from exposure to substances.

Canada is a world leader in the regulation of environmental and health risks from chemicals and polymers, and has been assessing and managing these substances for decades through the Priority Substances Assessment Program (Priority Substances Lists 1 and 2) and the New Substances Program, and more recently through Canada's Chemicals Management Plan (CMP).

Under Part 5 of CEPA 1999, Environment Canada and Health Canada were required to complete the "Categorization" of approximately 23,000 existing substances on Canada's *Domestic Substances List* (DSL) by September 2006. This Categorization process was completed within the legislated timeframe, and approximately 4,300 substances were subsequently identified as requiring further evaluation (risk assessments) under CEPA 1999.

Since 2006, assessment and management activities have been conducted under the CMP, which is a highly integrated program that addresses environmental and health risks under various laws, including the *Canadian Environmental Protection Act, 1999*, the *Pest Control Products Act*, the *Canada Consumer Product Safety Act*, and the *Food and Drugs Act*. Under the CMP, Environment Canada and Health Canada have made significant progress in evaluating the substances identified as priorities following the Categorization process, and have implemented appropriate risk management measures where necessary.

The Categorization process was based on information available at the time, and is one of seven key mechanisms which help to identify candidates for risk assessment. These seven mechanisms are:

- Results of Categorization of the DSL
- Industry information
- Information exchange and review of decisions of other jurisdictions
- Nominations to the Priority Substances List
- New substances notifications
- Emerging science and monitoring
- International assessment or data collection

Scientific information and regulatory actions on chemicals continue to evolve, as does the use of chemicals. Environment Canada and Health Canada are highly engaged with other federal regulators and international programs, and participate in a variety of fora related to the assessment and management of chemical risks. Both departments actively collect information on substances; monitor for emerging risks; and integrate newly acquired information into decisions about the assessment and management of chemicals and polymers, including the prioritization of substances for future risk assessments, or reassessments.

The CMP is enhancing the ways in which it incorporates new scientific knowledge and is seeking to increase collaboration with other regulatory and international agencies. This approach represents a more formal process for integrating information collected by the program and provided by stakeholders. This approach will aid in priority setting for the CMP and allow for judicious addition of emerging priorities for risk assessment, enabling the program to keep current. It also helps to increase transparency in the process of identifying new priorities.

Purpose of this document

This document provides an updated description of the approach taken by Environment Canada and Health Canada to keep current with new information, and the considerations applied when identifying priorities for risk assessment.

Priority setting activities relating to risk assessment work under CEPA 1999 are complemented by priority setting done in other programs, including risk management, monitoring and surveillance, and research programs.

Core priorities

Most of the substances that have been assessed under CEPA 1999 since 2006 have been identified through two key mechanisms:

1. Categorization of the *Domestic Substances List*
2. Notification of new substances and significant new activities

Section 74 of CEPA 1999 requires that a screening assessment be conducted on the priorities identified from the Categorization process. Sections 80 to 89 of CEPA 1999 (and the associated regulations) define the process for notification and evaluation of substances and activities that are new to Canada. These notifications are received on a continuing basis, and constitute a steady stream of substances requiring risk assessment under CEPA 1999.

The combination of approximately 4,300 substances requiring a screening assessment identified following Categorization, and the annual receipt of 400 to 500 New Substance Notifications comprise the core of the risk assessment work currently being conducted under the CMP.

However, additional mechanisms exist for the identification of priorities for risk assessment. Examples of substances identified through these additional mechanisms include polychlorinated naphthalenes, which were assessed and subsequently managed following their nomination to Annex I of the *Protocol on Persistent Organic Pollutants* under the United Nations Economic Commission for Europe (UNECE) Convention on Long Range Transboundary Air Pollution (LRTAP). Recently, a state of the science assessment on lead was developed in response to a request from the Federal-Provincial-Territorial Committee on Health and the Environment. Further examples can be drawn from the 118 assessment priorities that were identified in an update of the Categorization results, performed in 2009, which included substances which were added to the DSL after 2006 that met the ecological criteria for Categorization, and several substances which were identified as being highly hazardous to human health in the period after 2006.

Under the CMP, new information will continue to be sought and developments relevant to the prioritization of substances for risk assessment will continue to be tracked. The approach taken under the CMP to acquire, evaluate and act on new information is described in the following section.

Process for identifying new priorities for assessment

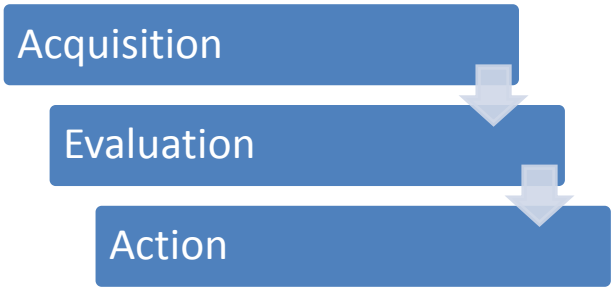
As described in the *Final Integrated Framework for the Health-related Components of Categorization of the Domestic Substances List under CEPA 1999* and the series of guidance manuals and approach documents used by Environment Canada, a set of well-defined information inputs and criteria were used during Categorization, which permitted the Ministers to identify those that were:

- Inherently toxic to humans or to the environment and that might be:
  - Persistent, and/or
  - Bioaccumulative
- Substances to which people might have the greatest potential for exposure.

The objective of the ongoing prioritization activity is different. Rather than examining each chemical on the DSL, the aim is to selectively identify the substances for which there are indications suggesting that the substance should be considered as a new priority for assessment or further work.

Unlike prescribed criteria like those used during Categorization, the ongoing prioritization activity described here is based on a set of guiding principles and a series of considerations. These guiding principles and considerations support the selection of additional priorities for assessment.

The process used to identify these additional priorities can be broken down into three steps: Acquisition, Evaluation, and Action.



Each of these steps are briefly described here, and expanded upon in the following sections.

- **Acquisition** refers to the active and passive collection of information relevant to the potential health and ecological risks of substances.
- **Evaluation** refers to the triage of substances for which new information has been received. This evaluation requires expert judgment, and consideration of the different types of information that may be available for any given substance.
- **Action** refers to the type of activity that will be undertaken on the substances identified as candidates for further work. These actions could include assessment, risk management, data collection, method development, generation of new data, etc.

Acquisition

The information relevant to the prioritization of chemicals for risk assessment can come from a variety of sources. Environment Canada and Health Canada compile information from these sources in order to obtain an integrated view, which supports the selection of substances and prioritization of future work.

Provincial/territorial and international organizations

Relevant information may be acquired through Canada's many interactions with domestic and international partners. Through participation in a variety of international activities and relationships with other national regulators, representatives of Environment Canada and Health Canada obtain and share information on issues, concerns and regulatory initiatives relating to specific substances. Partnerships with the Organisation for Economic Co-operation and Development (OECD) also facilitate co-operation in the area of information and data sharing with other member countries. Similarly, Environment Canada and Health Canada work closely with provincial and territorial authorities, which are also a source of information relevant to the identification and prioritization of substances for risk assessment.

Environment Canada and Health Canada also monitor publicly available information sources that relate to data collection, risk assessment and risk management initiatives undertaken on substances by other agencies.

Research, monitoring, and surveillance

Another key source of information is the work done by scientists in Environment Canada and Health Canada to generate new data on the potential exposures and hazards of chemical substances through research, monitoring and surveillance activities. The generation of exposure and toxicity data on substances through these national research programs is a vital source of information that informs the effectiveness of risk management interventions and helps to identify emerging priorities for assessment.

External parties

New information may also be provided to the program by external parties, including industry, health and environmental organizations, and the public. This information may be acquired from annual reports to the National Pollutant Release Inventory (required under section 46 of CEPA 1999), from mandatory information gathering initiatives under CEPA 1999, including section 71 (or similar voluntary initiatives), from submissions received under section 70, from public nominations to the *Priority Substances List* under section 76, or from other voluntary or obligatory submissions received from stakeholders.

Environment Canada and Health Canada also have opportunities to collect information from external parties that is potentially relevant to the identification of candidate substances for assessment of emerging environmental and health concerns. This information can come from industry, the public, academia, from scientific conferences, and from research or review activities conducted in the course of their work.

Evaluation

On a continual basis, staff at Environment Canada and Health Canada review the new information obtained on substances for indications of imminent and/or widespread potential for harm. Generally, the development of scientific knowledge is incremental and iterative, so it is unlikely that a single new piece of information collected in this process would prompt immediate intervention; however if this type of information were acquired, mitigating action would be pursued in a timely manner.

The more typical evaluation process is the result of a periodic analysis of the information that has been acquired. There are a series of factors that are considered and weighed, and judgments made on the relative importance of different indicators. Evaluation can be complex, as substances will have entirely different types of information available and prior activities on a substance are taken into account. Prioritization decisions are guided by the following principles and considerations.

Guiding principles

- Information is relevant and scientifically reliable.
- Prioritization is risk-based – greater priority is assigned to substances for which there is new information suggesting a potential concern for **both** exposure and hazard.
- Higher weight may be given when new information comes from multiple sources.
- Information is reviewed in the context of other domestic and international assessment or information-gathering activities that could provide an opportunity for efficiencies, collaboration and/or alignment.
- Information is reviewed in the context of the assessment and management activities of other federal, provincial and territorial programs to determine the most appropriate course of action under CEPA 1999.
- Information is reviewed in the context of past assessment conclusions.
- Information is reviewed in the context of existing risk management, as well as risk management actions that are under development.
- Information is reviewed in the context of existing Chemicals Management Plan commitments; allocation of resources toward additional priorities is done in consideration of existing commitments and other program priorities.

Considerations

- Are there critical data gaps? Does the program have the right tools and information to conduct an assessment, or is other activity required first?
- Under what acts or regulations could the issue be addressed?
- How do the potential risks compare with the risks associated with substances for which there are existing commitments?
- Does the substance fit within the scope of a current risk assessment group?
- Does the recently acquired information refute a key assumption in a past decision or recommendation?
- Does the acquired information result in a markedly different interpretation of the health hazard potential (for example, classification by a competent authority for a previously unrecognized hazard, data indicating a greater toxicological potency)?
- Does the new information suggest a greater ecological hazard (in other words, higher inherent toxicity, persistence and/or bioaccumulation potential)?
- Does the new information suggest a new source of exposure, or an increasing trend in exposure to humans or to the environment in Canada?
- How widespread is the exposure likely to be? (For example, is the substance produced/imported in high volumes domestically or abroad, are there known uses suggestive of direct exposure to the general population or high releases to the environment?)
- Does the new information suggest that a relevant regulatory limit (or an interpretative guideline) is being exceeded – either for environmental monitoring or biomonitoring results?

This list is not comprehensive, but illustrates the types of considerations that factor into the decision to select a substance as an additional priority for assessment or as a candidate for reassessment. During the evaluation of acquired information, consideration is given to the reliability of the information, the potential uncertainties, and the applicability to the Canadian context.

Action

The ongoing acquisition of new information allows the Government to keep current with developments in global chemical regulation and advances in the understanding of exposures in Canada and the potential hazards of substances. If a substance is identified as a candidate for further work, different actions may include:

1. Immediate intervention to prevent or reduce harm would be pursued in the instance that the new information provides compelling evidence of imminent and widespread harm.

2. The substance is added to the current risk assessment workplan (for example, similarity to substances in a group already scheduled, opportunity to collaborate with others, urgency).

3. The substance is added to a list of substances to be further prioritized or to undergo risk assessment in the future.

4. Alone or in conjunction with the aforementioned actions, where additional information would be beneficial to determining the appropriate next step, the substance is included in future data collection activities.

5. Partners are engaged within or outside the departments to collect or generate additional information (including research, monitoring and/or surveillance), or new assessment approaches and methodologies.

6. The substance is referred to other regulatory programs for consideration and appropriate action.

Conclusion

This approach for identification of new risk assessment priorities is used by Environment Canada and Health Canada to keep current with the evolution of scientific knowledge of chemical risks, and the regulation of chemicals around the globe.

This approach builds on the expertise developed and lessons learned from the Categorization of existing substances on the DSL and the New Substances Program. Through a systematic compilation and review of information from a large number of information sources, this approach enables the Government to identify potentially urgent concerns, and prioritize substances requiring further consideration in the future while respecting existing commitments. The integration of a range of information sources and the application of expert judgment supports the identification of the most appropriate responses to emerging issues in consideration of new information.