

Types of assessment documents published under the Canadian Environmental Protection Act, 1999

Fact Sheet Series: Topics in risk assessment of substances under the *Canadian Environmental Protection Act, 1999* (CEPA)

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Understanding and reducing risks posed by substances

[CEPA](#) is the primary legislative tool used to prevent and reduce the release of substances that may be harmful to human health and the environment. It provides the mandate for the Minister of the Environment and for the Minister of Health (the Ministers) to conduct assessments to support the protection of the environment and health of people in Canada from exposure to toxic substances. Under section 64 of CEPA, a substance is defined as toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:

- a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity
- b) constitute or may constitute a danger to the environment on which life depends; or
- c) constitute or may constitute a danger in Canada to human life or health

Assessments under CEPA

The various sections of CEPA under which the assessment of substances can or must be undertaken include:

- **Assessment of substances and activities new to Canada: Sections 81 to 83 and sections 106 to 108 of CEPA** require notifiers to submit specified information and the Ministers to assess this information in respect of the substance in order to determine whether the substance is toxic or capable of becoming toxic.
- **Research, investigation, and evaluation of substances or products: Section 68 of CEPA** provides provisions for the Ministers to assess a substance in order to determine whether the substance is toxic or capable of becoming toxic, or to determine whether to control or the manner in which to control a substance, a product that contains a substance or a product that may release a substance into the environment. This may include assessment of substances identified as priorities through the [Plan of priorities](#).
- **Review of decisions of other jurisdictions: Section 75 of CEPA** requires the Ministers to review decisions of other jurisdictions that have been found to specifically prohibit or substantially restrict substances, in order to determine whether the substances are toxic or capable of becoming toxic in Canada.

Other types of assessments have been completed under previous versions of CEPA. These were similar in intent to assessments that are now being completed under section 68 (noted above) and included:

- **Screening assessments:** before amendments made in June 2023, CEPA required the Ministers to conduct screening assessments of substances that had been identified as meeting [categorization](#) criteria in 2006, in order to determine whether the substances are toxic or capable of becoming toxic.
- **Priority Substances List assessments:** before amendments made in June 2023, CEPA required the Ministers to establish a [Priority Substances List \(PSL\)](#) that identified substances to be assessed on a priority basis to determine whether the substances are toxic or capable of becoming toxic.

Assessment document examples

All assessments are conducted to evaluate the potential of a substance or a group of substances to cause harm to human health and the environment, whether they are existing substances that are in commerce in Canada [substances on the [Domestic Substances List](#) (DSL)] or new substances intended to be imported into or manufactured in Canada (not yet on the DSL). In determining this potential risk, both the hazardous properties (harmful effects on human health or the environment) and exposures are considered. Furthermore, assessments are all based on sound-science, consider multiple lines of [evidence and uncertainties, and apply precaution](#).

The different sections of CEPA determine the context for the type of assessment document produced. Examples of different types of assessment documents are further described below. Other types of documents not listed below may also be used, as appropriate.

New substances

Risk assessment summaries for new substances

When industry members notify the Government that a new substance will be manufactured in or imported into Canada, the Government prepares risk assessment reports under section 83 or section 108 of CEPA to determine whether the substance is or may become harmful to human health or the environment as set out in section 64 of CEPA. A summary of the report is prepared for publication to provide an overview of information examined during the assessment period, as well as the conclusions. When that assessment indicates a need for risk management, the risk assessment summary also presents the control measure required. Risk assessment summaries for new substances may be made available through the New substances: Risk assessment summaries web page.

Existing substances

Assessments of existing substances

An assessment of an [existing substance](#) is conducted under CEPA to determine if it is toxic or capable of becoming toxic, as defined under [section 64 of the Act](#), or to determine whether to control or the manner in which to control the substance. When conducting an assessment, all available data are critically reviewed; however, only the most critical studies and lines of evidence pertinent to the conclusion are presented in the assessment. In some cases, assessments present a critical review of all data because data are so limited. An assessment is fit-for-purpose, in that it may address 1 to hundreds of substances and will follow an approach that is most appropriate for the substance(s). Assessments can range from simple to very complex technical analyses. Examples of different types of approaches for assessments are described in the [Risk Assessment Toolbox](#). Assessments under CEPA typically include a regulatory conclusion on the substance(s).

Science approach documents

A [science approach document](#) (SciAD) provides a description of a scientific approach to evaluate environmental or human health risks posed by substances. SciADs may also include the results of the application of the scientific approach to substances that were identified as priorities for assessment. Typically, a SciAD does not include regulatory conclusions. A period of consultation on the SciADs is generally provided to the public

as an opportunity to comment and provide additional information. The approach and results for substances identified in the SciADs may form the basis, in conjunction with any other relevant information that becomes available after the publication of the SciAD, for conclusions in assessments that are published separately.

Risk characterization documents

A risk characterization document (RCD) is used to communicate significant new information identified or generated after publication of an assessment. Publication of an RCD provides the opportunity for the public to comment on the new information received after publication of a draft assessment prior to it being considered in the final assessment. RCDs may also be published when further risk characterization (due to new hazard or exposure data) is conducted on a substance that has already been concluded toxic, to inform the need for risk management of additional sources of release or exposure.

State of the science reports

A state of the science (SoS) report consolidates the latest ecological or human health science on a particular substance. A SoS report may or may not include a regulatory conclusion on the substance(s).

Publication of assessments

A summary of the scientific considerations and proposed measures from the assessments or reviews conducted under section 68 or section 75 must be published in the [Canada Gazette](#) for a 60-day public comment period.

Following an assessment of an existing substance to determine if it is toxic or capable of becoming toxic, the Ministers must propose 1 of the following 4 measures under section 77:

- a) taking no further action in respect of the substance
- b) adding the substance to a list of substances of potential concern (referred to as the Watch List) if it has been determined, or there is reason to suspect, that the substance is capable of becoming toxic
- c) recommending the addition of the substance to Part 1 of [Schedule 1](#) to CEPA if the substance is toxic and meets criteria for substances that pose the highest risk; or
- d) recommending the addition of the substance to Part 2 of Schedule 1 to CEPA if the substance is toxic

Following the public comment period, the final assessment decision about whether a substance meets the criteria under section 64 of CEPA must be published in the *Canada Gazette*, including a summary of the assessment, the proposed measure

and, in the case of a substance recommended for addition to Schedule 1, a statement indicating the manner in which a proposed regulation or instrument will be developed.

If a draft assessment conclusion has not been finalized within 2 years, the Ministers must publish a statement in the [Environmental Registry](#) indicating the reasons for the delay and an estimated time frame for finalizing the assessment.

In order to provide the public with an opportunity to more fully review, comment or share additional information with the Government for consideration, draft assessments are made available through the [Chemical substances web page](#), as announced in the [Latest News \(subscription service available\)](#). Following consideration of public comments received, the final assessments as well as a table summarizing the public comments received, if any, and the government's response to them, are also made available.