

# Types of Chemicals Management Plan risk assessment documents

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

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## Understanding and reducing risks posed by substances

Part 5 of and Part 6 of [CEPA 1999](#) are 2 of the primary legislative tools used to prevent and reduce the release of substances that may be harmful to Canadians and their environment. It provides the mandate for the Minister of Environment and Climate Change and for the Minister of Health (the Ministers) to conduct risk assessments to support the protection of the environment and health of Canadians from exposure to toxic substances. Under section 64 of CEPA 1999, a substance is defined as toxic if it is:

- entering or may enter the environment in in a quantity or concentration or under conditions that have or may have an

immediate or long-term harmful effect on the environment or its biological diversity

- constitute or may constitute a danger to the environment on which life depends, or
- constitute or may constitute a danger in Canada to human life or health.

## CEPA 1999 and risk assessments

The various sections of Part 5 of CEPA 1999 under which the assessment of substances can or must be undertaken include:

- **Assessment of substances and activities new to Canada: Section 83 and section 108** of CEPA 1999 requires 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.
- **Screening assessments: Section 74 of CEPA 1999** requires the Ministers to conduct screening assessments of substances that have been identified as meeting [categorization](#) criteria, in order to determine whether the substances are toxic or capable of becoming toxic.
- **Reviews of decisions of other jurisdictions: Section 75 of CEPA 1999** 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.

- **Priority Substances List Assessments: Section 76 of CEPA 1999** requires the Ministers to establish a Priority Substances List (PSL) that identifies substances to be assessed on a priority basis to determine whether they are toxic or capable of becoming toxic.
- **Other assessments: Section 68 of CEPA 1999** provides further general provisions for assessment of whether substances are toxic or capable of becoming toxic, or whether to control or the manner in which to control substances. Screening assessments of substances that did not meet categorization criteria, state of the science reports, and science approach documents may all be published under authority of section 68.

## Risk assessment documents

All risk assessments are based on sound-science, consider multiple lines of evidence and uncertainties, and apply precaution. Furthermore, they are all conducted to evaluate the potential of a substance or a group of substances to cause harm to Canadians and/or the Canadian environment.

The different sections of Part 5 determine the context for the type of assessment produced. The different assessment documents are further described below.

## Risk assessment summaries

Risk assessment summaries are prepared pursuant to section 83 or section 108 as a result of the notification of the manufacture or import of a substance that is new to Canada. A brief risk assessment summary is prepared for publication to indicate

whether the substance is toxic or capable of becoming toxic. When that assessment indicates a need for risk management, the risk assessment summary also presents the control measure required.

## **Screening assessments**

A screening assessment is conducted to determine if a substance is toxic or capable of becoming toxic, and may be conducted under section 68 or section 74 of CEPA 1999. It is not intended to represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies and lines of evidence pertinent to the conclusion. A screening assessment is fit-for-purpose, in that it may address one to hundreds of substances and will follow an approach that is most appropriate for the substance(s). Screening assessments can range from simple to very complex technical analyses. The different types of approaches are described in the [Risk Assessment Toolbox](#). Screening assessments 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 risk of substances. SciADs also include the results of the application of the scientific approach to substances that were identified as priorities for assessment because they met the categorization criteria under section 73 of CEPA 1999 or were identified through other feeders as assessment priorities. The SciAD is published under section 68 and does not include regulatory conclusions. A period of consultation on the SciADs is

provided to the public as an opportunity to comment and provide additional information. The approach and results for substances identified as low concern in the SciADs will form the basis, in conjunction with any other relevant information that becomes available after the publication of the SciAD, for the conclusion in the screening assessment that will be published at a later time. This staggered approach, with publication of the scientific approaches and results in SciADs and subsequent publication of formal screening assessments, will assist the government in addressing substances that may be of low concern to either human health or the environment in a more effective manner.

## **State of the science reports**

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

## **Priority Substances List assessment reports**

Priority Substances List (PSL) reports are risk assessment reports that are conducted on substances that have been added to the PSL. The Ministers may place a substance on the PSL following a screening assessment, a review of another government's assessment decision or at the request of any person (under certain conditions) or under other circumstances.

## **Publication of risk assessments**

A summary of the scientific considerations and proposed measures from the assessments or reviews conducted under

section 74, section 75 and section 76 must be published in the *Canada Gazette* for a 60-day public comment period. For these publications, the Ministers must also propose 1 of the following 3 measures:

- taking no further action in respect of the substance
- adding the substance to the PSL, or
- recommending the addition of the substance to the List of Toxic Substances (Schedule 1 of CEPA 1999) with the development of risk management instruments and, where applicable, implementation of virtual elimination

Following the public comment period, the final decision 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. While not required, the same process is applied to screening assessments and other documents published under section 68 that include a conclusion as to whether a substance is toxic or capable of becoming toxic.

In order to provide the public with an opportunity to more fully review, comment and/or share additional information for consideration, draft assessments are made available through this website. Following consideration of public comments received, the final assessments, as well as a table summarizing the public comments received and the government's response to them, are made available through this website.

Risk assessment summaries may be made available through this website for substances assessed pursuant to notification as new substances.

