

***The Canadian Environmental Protection Act, 1999* and the Assessment of New Substances**

What is a new substance?

According to the *Canadian Environmental Protection Act, 1999* (CEPA 1999), a "new substance" is one that is not on the Domestic Substances List (DSL). The DSL was originally an inventory of approximately 23 000 substances manufactured in, imported to or used in Canada on a commercial scale. It is based on substances that were present in Canada, under certain conditions, between January 1, 1984 and December 31, 1986. New substances that are deemed eligible after assessment are added to the DSL, thus becoming "existing substances".

What are risk assessments?

Risk assessments conducted under CEPA 1999 consider the impacts of substances on human and non-human organisms and the physical environment. These assessments consider the hazard posed not only by the inherent toxicity of a substance but also by its exposure, which is the likelihood that a person, organism, or the environment will come in contact with it. Exposure or potential for exposure depends, among other things, on the quantity of a substance that might be released throughout its life cycle.

What main programs are responsible for assessing new substances?

The New Substances Program (NSP) is responsible for administering the *New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)* (NSNR) of CEPA 1999. The NSNR are an integral part of both the federal government's national pollution-prevention strategy and the "cradle-to-grave" management approach for harmful substances set out in Part 5 of the Act. These Regulations were created to ensure that no new substance (chemical, polymer or product of biotechnology) is introduced to the Canadian marketplace before a risk assessment is completed and the appropriate control measures taken.

How does the assessment process work?

When Environment Canada receives a notification from a company or individual proposing to import or manufacture a new substance, the Department carries out a joint assessment with Health Canada to determine whether the substance has the potential to cause adverse effects on the environment and human health. This assessment requires that

new substance notifications provide specific administrative and technical data to Environment Canada by a prescribed date in advance of manufacture or import.

What type of information is required?

A company or individual planning to import or manufacture a new substance subject to notification under the NSNR must, before carrying out such activities, provide Environment Canada with a notification package containing all of the information prescribed in the NSNR. The type of information required and timing of the notification depend on such factors as the type of substance, the quantity to be imported or manufactured, its intended uses, and the circumstances associated with its introduction.

What happens after a new substance is assessed?

The assessment process results in one of the following outcomes:

- a determination that the substance is not suspected to meet or be capable of meeting the criteria of "toxicity" as defined under section 64 of CEPA 1999;
- a suspicion that the substance meets or is capable of meeting the criteria of "toxicity" as defined under section 64 of CEPA 1999; or
- a suspicion that a significant new activity (SNAc) may result in the substance's meeting the criteria of "toxicity" as defined under section 64 of CEPA 1999

The typical time-limit for an assessment is 45 days; however, it can vary from 5 to 90 days, depending on the type of substance and the quantities intended for import or manufacture.

When the assessment process identifies a new substance that may pose a risk to human health or the environment, CEPA 1999 empowers Environment Canada to intervene prior to or during the earliest stages of its introduction into Canada. This ability to act early makes the NSP a unique and essential component of the federal management of toxic substances. Substances suspected of meeting the criteria of section 64 of CEPA 1999 may be controlled by one of the measures set out in CEPA 1999, including:

- conditions on the import, manufacture, use, or disposal of the substance;
- prohibition of import and manufacture; or
- prohibition pending the submission and assessment of additional information determined to be required by the departments of Environment and of Health.

If there is no suspicion of toxicity, but there is a suspicion that a significant new activity (SNAc) in relation to the substance may result in the substance becoming "toxic", the substance can be subject to a SNAc notice. A SNAc notice communicates the criteria under which a new notification will be required for the same substance. The new notification allows Environment Canada and Health Canada to assess the potential impacts of the substance as it relates to the new activities being proposed.

New substances for which control measures are taken or SNAc notices are issued are published in the *Canada Gazette* and are available on both the New Substances Web site www.ec.gc.ca/substances/nsb/eng/home_e.shtml and the Environmental Registry Web site (<http://www.ec.gc.ca/ceparegistry>).

The NSP undertakes activities to support effective and efficient decision-making about human health and the environment by seeking common ground in international efforts. Such initiatives strengthen CEPA 1999's principles of pollution prevention and sustainable development.

Further information

Internet:

www.ec.gc.ca/substances/nsb/eng/home_e.shtml.

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