

INSPECTION

Inspection and enforcement of the Regulations

Under the Canadian Environmental Protection Act, 1999, Environment Canada enforcement officers may carry out inspections to ensure persons subject to the Act are in compliance with all regulatory and legislative provisions.

In verifying compliance with these Regulations, Enforcement Officers will abide by the **Enforcement and Compliance Policy** of CEPA, 1999, which was established to ensure that the Act is applied throughout Canada in a manner that is fair, predictable and consistent.

Where there is sufficient evidence of a violation, Enforcement Officers will take the necessary and appropriate measures in accordance with the criteria set out in the Policy. The possible responses for dealing with violations range from warnings to prosecution. Other available measures are discussed in further detail in the Enforcement and Compliance Policy, which can be found at :

<http://www.ec.gc.ca/enforce/homepage/cepa/english/99policy.pdf>

With respect to the NSNR, anyone convicted of an indictment under CEPA, 1999 is liable to a fine not exceeding one million dollars and/or imprisonment for a term not exceeding three years. Upon summary conviction, anyone who commits an offense is liable to pay a fine of up to \$200,000 and/or serve up to six months in prison.



NSNR

For more information about the NSNR



For further information or documentation regarding the NSNR, please:

- visit the Environment Canada Web site at www.ec.gc.ca/substances/
- visit the Health Canada New Chemical Substances & Biotechnology Products Website at http://www.hc-sc.gc.ca/ehp/ehd/bch/new_chemicals/newchem.htm
- visit the Environmental Registry on-line at www.ec.gc.ca/CEPARRegistry
- obtain your copy of the **Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers and Guidelines for the Notification and Testing of New Substances: Organisms** from our Web site or by using the enclosed order form, or
- contact us directly at Environment Canada Headquarters or your nearest regional office.

Environment Canada Headquarters

New Substances Division,
Commercial Chemicals Evaluation Branch
Environment Canada

Tel: (800) 567-1999
(toll free within Canada)
(819) 953-7156 (outside Canada)
Fax: (819) 953-7155

Alberta, Saskatchewan, Manitoba, Northwest Territories and Nunavut

Environmental Protection -
Prairie and Northern Region
Environment Canada

Tel: (780) 951-8766
Fax: (780) 495-2758

Québec

Environmental Protection -
Québec Region
Environment Canada

Tel: (514) 283-7303
Fax: (514) 496-6982

British Columbia and Yukon

Environmental Protection -
Pacific and Yukon Region
Environment Canada

Tel: (604) 666-2739
Fax: (604) 666-6800

Ontario

Environmental Protection -
Ontario Region
Environment Canada

Tel: (416) 739-5892
Fax: (416) 739-4405

New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland and Labrador

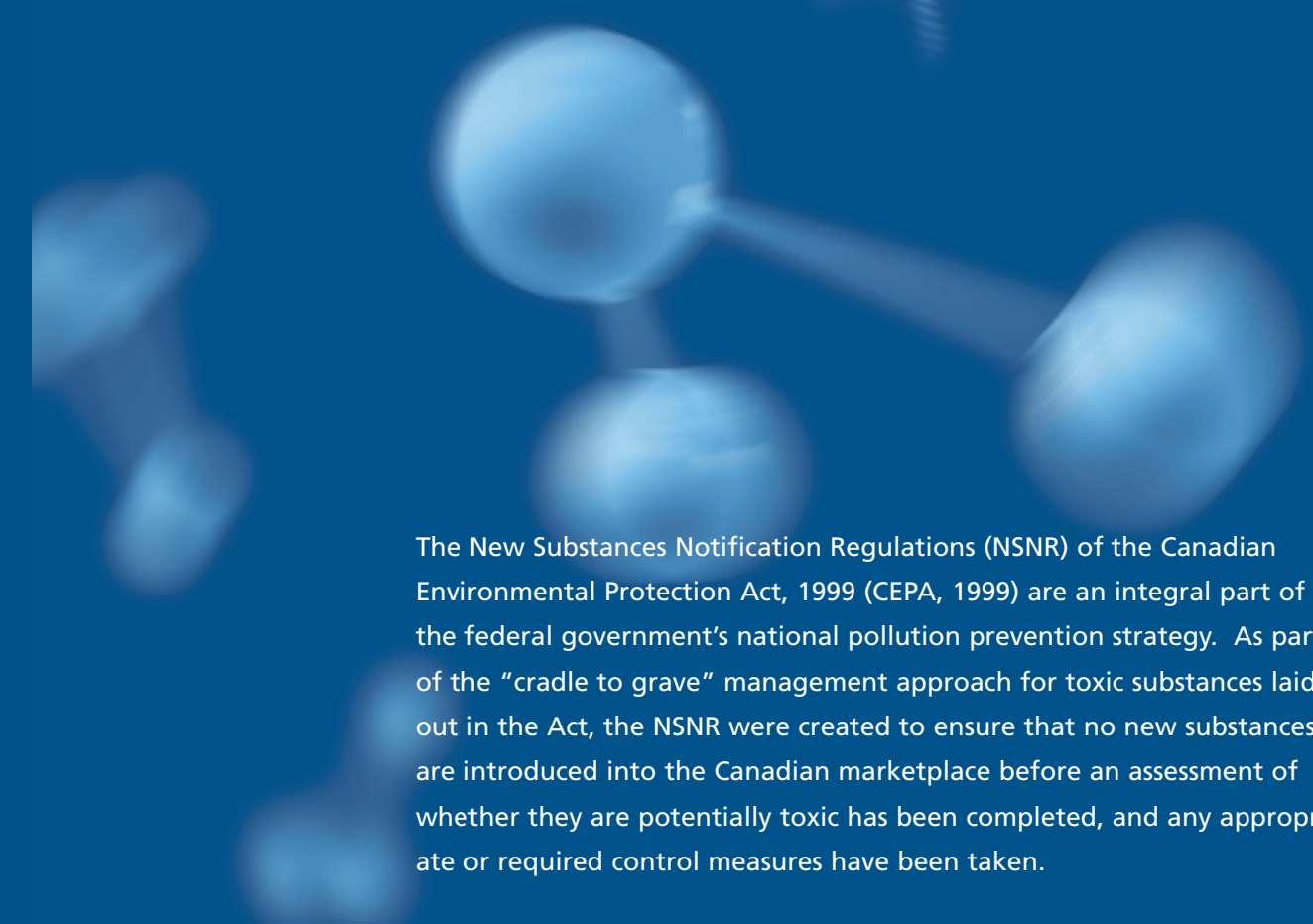
Environmental Protection -
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Managing Risk to Health and the Environment

The New Substances Notification Regulations of The Canadian Environmental Protection Act, 1999



The New Substances Notification Regulations (NSNR) of the Canadian Environmental Protection Act, 1999 (CEPA, 1999) are an integral part of the federal government's national pollution prevention strategy. As part of the "cradle to grave" management approach for toxic substances laid out in the Act, the NSNR were created to ensure that no new substances are introduced into the Canadian marketplace before an assessment of whether they are potentially toxic has been completed, and any appropriate or required control measures have been taken.

New substances and the Government of Canada's pollution prevention strategy

The CEPA, 1999 approach to the control of new substances is both proactive and preventative, employing a pre-import or pre-manufacture notification and assessment process. When this process identifies a new substance that may pose a risk to health or the environment, the Act empowers Environment Canada to intervene prior to or during the earliest stages of its introduction into Canada. This ability to act early makes the new substances program a unique and essential component of the federal management of toxic substances.

CEPA, 1999 and the scope of the NSNR

CEPA, 1999 features a number of provisions, including criteria for identifying substances new to Canada, notification obligations for importers and manufacturers, a detailed assessment mechanism and key enabling powers for the implementation of specific controls.

The NSNR specify the information that must be provided to meet notification obligations applying to a wide range of substances, including both chemicals and polymers (in effect since July 1, 1994) and products of biotechnology (in effect since September 1, 1997).

A rapidly growing segment of the Canadian economy, products of biotechnology refer to animate products like micro-organisms and other organisms, as well as to the inanimate products that are produced by microorganisms, like biochemicals and biopolymers. Products of biotechnology covered by the NSNR include but are not limited to those used in such activities as:



- bioremediation,
- biosensing,
- biofiltration,
- mineral leaching,
- fossil fuel desulfuration,
- enhanced oil recovery,
- biological waste treatment,
- biomass conversion,
- enzyme production,
- fuel production,
- microbial drain cleaning and degreasing, and
- wax separation.

New Substances Notification Regulations and the DSL and NDSL

The **Domestic Substance List (DSL)**, a comprehensive compilation of all known substances that have or continue to be in Canadian commerce, is used as the sole basis for determining whether a substance is new for the purposes of CEPA, 1999 and the NSNR.

Section 3 of CEPA, 1999 provides the definition of "substance." Substances listed on the DSL are considered to have existed in Canadian commerce and are subject to scrutiny under CEPA as existing substances (e.g., categorization and screening, Priority Substances List assessment). As such, they do not require notification before being imported or manufactured. Any substance not listed on the DSL is considered to be a "new" substance to Canada and is therefore subject to notification requirements under the NSNR prior to manufacture in, or import into, Canada.

The **Non-domestic Substances List (NDSL)**, is a compilation of substances other than animate products of biotechnology that are not on the DSL but are believed to be in international commerce. As a basis for this list, Environment Canada chose the United States' Toxic Substances Control Act (TSCA). Substances that are not on the DSL but are listed on the NDSL are still subject to notification, but the information requirements are reduced because of previous U.S. experience.

The complete DSL, NDSL and their amendments are published in the **Canada Gazette**. You can also determine if a substance is listed on the DSL or NDSL by using the search engine from our Web site at www.ec.gc.ca/substances/

Who is required to notify Environment Canada under the NSNR, and what information must they provide?

Any person who plans to import or manufacture a substance subject to notification under the NSNR must provide Environment Canada with a notification package containing all information prescribed in the NSNR **prior to import or manufacture**. The type of information required and the timing of the notification will depend on such factors as the type of substance, the quantity that will be imported or manufactured, whether or not it is listed on the Non-domestic Substances List (NDSL), the intended use of the substance and the circumstances associated with its introduction.

In cases where the prescribed information is considered confidential by a **third party** such as a foreign supplier, the Canadian importer or manufacturer can initiate the notification while the third party provides the remainder of the information directly to Environment Canada.

Where a **Significant New Activity (SNAc) Notice** has been issued for a particular substance, anyone in Canada planning to manufacture, import or use that substance contrary to the prescribed limitations set out in the Notice must submit all information specified in that Notice (see below).

New substances for which SNAc Notices have been issued are published in the Canada Gazette, on our Web site and on the Environmental Registry Web site.

Exclusions and exemptions

CEPA, 1999 and the NSNR establish firm criteria for new substances that do not require notification. These include:

- Mixtures, manufactured items, wastes, transient reaction intermediates, impurities, substances produced by incidental reactions, substances carried through Canada and substances that are not manufactured or imported in amounts greater than the regulatory trigger quantities.
- **Animate products of biotechnology** used solely in the following activities:
 - For substances manufactured in Canada: in situ stimulation of organism growth through the addition of nutrients or by physical means such as tilling; municipal and industrial wastewater treatments that do not isolate the organism from its natural environment and process the organism; and composting and septic tank operations that do not isolate the organism from its natural environment and process the organism from treated waste.
 - For substances manufactured in, or imported into, Canada: Research & Development that is not intended for introduction outside a contained facility and is not in excess of the maximum prescribed quantities.



- **Substances regulated for uses covered by other Acts of Parliament**, including substances manufactured or imported for a use exclusively regulated under any other Act that provides for an assessment of "toxic" as defined in CEPA, 1999 and for notice to be given prior to manufacture, import or sale. Substances regulated under these Acts, including their constituents such as binding agents, emulsifiers, solvents and fillers, are exempt from reporting under the NSNR as long as their use remains solely within the jurisdiction of those Acts. Schedules are being developed under CEPA 1999 to signify where these exemptions exist.

NOTE: Precursor materials not listed on the DSL and excluded from the scope of these Acts or Regulations, including isolated reaction intermediates, production organisms, feedstocks and other starting materials used in the manufacture of any new substance covered under one of these Acts and Regulations are subject to notification under the NSNR.

Assessment process and possible outcomes

When Environment Canada receives a **new substance notification** from a company or individual proposing to import or manufacture a new substance, a **joint assessment process** is carried out by the Departments of Environment and of Health to determine the potential adverse effects of the substance on the environment and human health. To facilitate this assessment, new substance notifications must contain all required administrative and technical data, and must be provided to Environment Canada by a prescribed date in advance of manufacture or import.

The assessment process, which must be completed within a time limit specified by the NSNR, results in either:

- a determination that the substance is not suspected of being "toxic" or capable of becoming "toxic",
- a suspicion that the substance is "toxic" or capable of becoming "toxic", or
- a suspicion that a significant new activity (SNAc) may result in the substance becoming toxic if there was adequate information available to assess it.

Substances suspected of being toxic may be controlled by one of the measures laid out in CEPA, 1999, including:

- controls on import and manufacture,
- the prohibition of import and manufacture, or
- prohibition pending submission and assessment of additional information determined to be required by the Departments.

When it is suspected that a significant new activity (SNAc) in relation to the substance may result in the substance becoming toxic, a SNAc Notice may be issued for the substance.

New substances for which control measures are taken or SNAc Notices are issued are published in the Canada Gazette, on our Web site, and are also available from the Environmental Registry Web site.