

# Canada's New Substances Notification Regulations

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## Introduction

- Under the New Substances (NS) Program, Health Canada (HC) and Environment and Climate Change Canada (ECCC) administer the New Substances Notification Regulations (Chemicals and Polymers) [NSNR (Chemicals and Polymers)] and New Substances Notification Regulations (Organisms) [NSNR (Organisms)] of the Canadian Environmental Protection Act, 1999 (CEPA 1999) to examine the potential risks to Canadians and their environment before the substances enter the Canadian marketplace. These regulations are an integral part of the Canadian government's national pollution prevention strategy. Under this joint endeavour between HC and ECCC, the New Substances program has completed over 20,000 New Substances Notification assessments. The following poster presentation outlines the NSNR and the substances subject to them.
- An overview of the regulations is provided including the definition of a new substance, the notification process, risk assessment and potential assessment outcomes, and how to find additional information and resources.

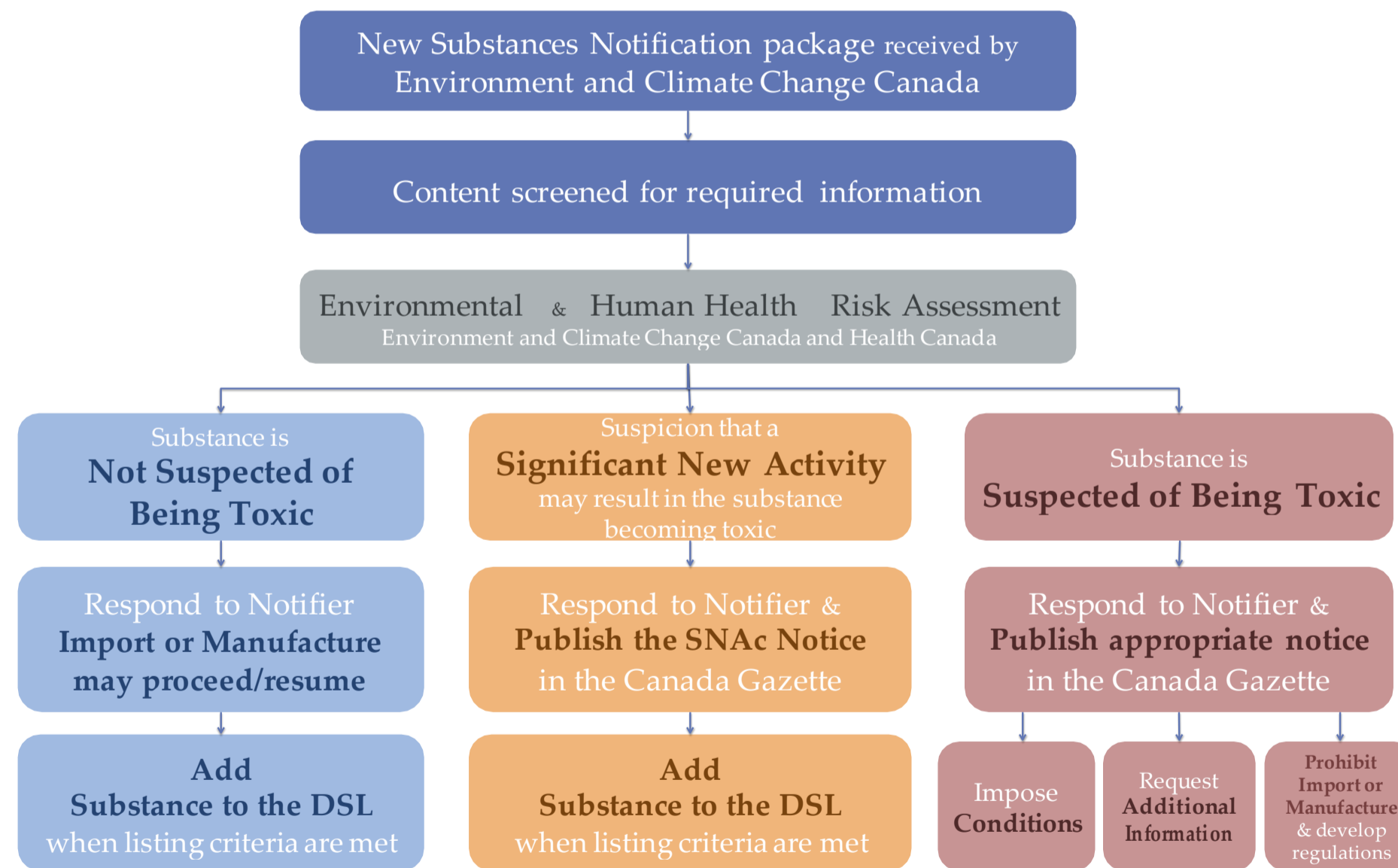
## What is a New Substance?

- A new substance is any substance that does not appear on the Domestic Substances List of CEPA 1999.
- Substance**: Any distinguishable kind of organic or inorganic matter, whether animate or inanimate. Inanimate matter is addressed under the NSNR (Chemicals and Polymers) and animate matter is addressed under NSNR (Organisms). This includes:
  - organic and inorganic chemicals,
  - biochemicals,
  - polymers,
  - biopolymers, and
  - living organisms
- Domestic Substances List (DSL)**: A compilation of all known substances (approximately 23 000) that were in Canadian commerce between 1984 and 1986 or that were added to the DSL in accordance with CEPA 1999. In certain circumstances, the Minister of Environment may amend the DSL by adding or deleting substances according to CEPA 1999.
  - The DSL can be searched on the New Substances Program's website:  
<https://pollution-waste.canada.ca/substances-search/Substance>
- Other lists**:
  - Non-Domestic Substances List (NDSL)**: An inventory of substances that are not on the Domestic Substances List, but are in commercial use internationally. Substances listed on the NDSL are subject to lesser information requirements.
  - Revised In Commerce List (R-ICL)**: A list of substances that are known to have been in Canadian commerce between Jan 1, 1987 and Sept 13, 2001. Notifications for substances on this list that are intended solely for uses regulated under the *Food & Drugs Act* may not be requested at this time (although they may be requested in the future).

## I want to manufacture or import a new substance. What should I do?

- If you manufacture or import a new substance for use in any of the following applications, whether for commercial purposes or for research and development, you may be subject to the NSNR of CEPA 1999. Please note that this list is not exhaustive: Pharmaceutical active ingredients & excipients, Natural Health Products, Novel Foods, Cosmetics, Biologics, Food Additives, Personal Care Products, Veterinary Drug active ingredients and excipients, Medical Devices, Food Packaging, Enzymes, Foamers, Drilling Fluids, Oil Field Solvents, Degreasers, Cleaners, Deodorizers, Ingredients in Laundry Products, Septic Tank Treatments, Bioremediation, Microbial Enhanced Oil Recovery, etc.
- The prescribed information in the NSNR and the prescribed fee (if applicable) must be provided prior to import or manufacture of the substance in Canada.
- Prescribed technical information must be addressed by submitting test data, alternative data or waiver requests.
- Examples of test methods recommended by the New Substances Program for the generation of physical-chemical, toxicity and ecotoxicity data are provided in Guidance documents.

## Overview of the New Substances Notification Process



## Determination of Toxicity

- When the New Substances Program receives a New Substances Notification package from a company or individual proposing to import or manufacture a new substance, a joint assessment process is carried out (Health Canada and Environment and Climate Change Canada) to determine whether there is a potential for adverse effects of the substance on the environment or human health.
- When this process identifies a new substance that may pose a risk to human health or the environment, CEPA 1999 empowers Environment and Climate Change 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.

## Risk Assessment

- The determination of whether a substance is, or is suspected of being, toxic or capable of becoming toxic involves an assessment of the potential for exposure of humans and components of the environment and of the adverse effects of the substance on humans or the environment (including other living organisms, interacting natural systems and the abiotic components of the environment).
- The potential for exposure to a substance depends on the quantity, rate, frequency and conditions of release of the substance into the environment at all points in its life cycle, as well as the mobility, environmental compartmentalization and persistence of the substance.
- The exposure assessment considers the use of the substance identified by the notifier, as well as other possible ways in which the substance might be used if it were listed on the DSL without restrictions.
- The NS Program evaluates the potential human health and ecological risks based on the hazard of the substance and the level of exposure to the notified substance by the general population (whether the exposure is direct or indirect) as well as potential releases to the environment that could affect the living organisms and the environment on which they depend (including persistence and bioaccumulation potential).
- The assessment of adverse effects on humans and other living organisms may consider endpoints such as lethality, mutagenicity, reproductive effects and organ toxicity.
- When a risk assessment has led to a "suspicion of toxicity", CEPA 1999 permits the Minister of the Environment to undertake one of several risk management measures (Significant New Activity Notices, Conditions, Prohibitions or Ministerial Request for Additional Information).

## Timelines

- The New Substances Notification package must contain all required administrative and technical data required by the NSNR, and must be provided to the New Substances Program prior to the manufacture or import of the substance in Canada.
- The assessment period ranges from 5 and 120 days; the assessment period begins once a complete notification package is received.
- Timelines vary depending on the type of substance (chemical, polymer, living organism) and on the amount of substance being manufactured or imported in Canada.

## Where can I get more information?

- Consult with the New Substances Program before initiating the manufacture or import process of a new substance.
- More information on the New Substances Notification Regulations can be found on Environment and Climate Change Canada's New Substances Program's website, or by contacting:
  - The **Substances Management Information Line** at
    - [eccc.substances.eccc@canada.ca](mailto:eccc.substances.eccc@canada.ca) (email),
    - 1-800-567-1999 (toll free in Canada), or
    - 819-938-3232 (outside of Canada).
- Additional guidance documents on preparing a New Substances Notification can be found on the New Substances Program's website.  
<https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html>