



The New Substances Program

- The New Substances Program is jointly administered by Environment and Climate Change Canada (ECCC) and Health Canada (HC)



The Law

The Canadian Environmental Protection Act, 1999

- It is an important part of Canada's federal environmental legislation aimed at preventing pollution and protecting the environment and human health
- Defines Substance
- Defines when a substance is considered Toxic
- Outlines the Domestic Substances List and the Non-domestic Substances List
- Outlines New Substances Provisions



The Regulations

- There are two *New Substances Notifications Regulations*:
 - Organisms
 - Chemicals and Polymers
- Industry responsibility to submit prescribed information and all information in their possession or which they should have access prior to manufacture or import
- Government responsibility to assess information and take action where warranted within prescribed timeframes



Substance

Defined as:

- Any distinguishable kind of organic or inorganic matter whether animate or inanimate

Items that are not included:

- Mixtures (hydrates, homogeneous and heterogeneous alloys)
- Manufactured items
- Wastes



The Lists

- Domestic Substances List (DSL)
- Non-domestic Substances List (NDSL)
- All additions or deletions are published in the Canada Gazette
 - Listed by Chemical Abstracts Service (CAS) number on the public portion of the inventory
 - Listed by Confidential Accession Number and Masked Name on the confidential portion of the inventory



New Substances Provisions

- Ensures that no new substance is introduced into the Canadian marketplace before an assessment of its potential risks has been completed
- No person can import or manufacture a new substance until:
 - the prescribed information is provided; and
 - the period for assessing the information has expired; or
 - The restriction or prohibition is rescinded
- Required information and assessment periods are outlined in the *New Substances Notification Regulations (Chemicals and Polymers)* [the Regulations]



Who is Required to Notify?

- Canadian manufacturers and importers
- End-users in cases where the substance is subject to a Significant New Activity as published by the authorities

Note: if the importer is not a resident of Canada
a local agent is required



Risk Quotient

Risk based assessments consider both hazard and exposure

Exposure:

- Characterization of Entry, Fate and Exposure
- Environmental Entry, Fate and Exposure
- Direct human exposure
- Indirect human exposure
- Quantification of exposure

Hazard:

- Human health effects
- Ecological effects
- Abiotic effects



Risk Characterization

- Risk characterization involves using a combination of **qualitative and quantitative approaches** to understand and describe the risk a substance may pose to the environment or human health.
- **Various lines of evidence** are considered in a **weight-of-evidence approach** to evaluate the potential for adverse effects of a substance.
 - Risk Quotients
 - Margin of exposure
 - Significant hazard
 - Persistence and bioaccumulation
 - Evidence of widespread presence and increasing concentration
 - Abiotic effects



Outcome of Assessment and Next Steps

- Ultimately the outcome of an assessment is a recommendation whether the substance meets the definition of “Toxic” as described in Section 64 of the Act:
 - A substance that is entering or may enter the environment in amounts or concentration that may pose a risk to:
 - The environment (such as fish or wildlife);
 - The environment on which life depends (such as water, air & soil); or
 - Human health



Risk Management Measures

- Risk management measures applied to minimize any risk to human health and/or environment:
 - **Ministerial Condition** - restrictions placed on manufacture or import activities
 - **Ministerial Prohibition** - manufacture or import prohibited in any amounts
 - **Ministerial Request for additional information** - prohibition of manufacture or import pending required testing
 - **Significant New Activity** - additional information may be required if the substance is proposed for a significant new activity

*Thank you for
your attention!*

Dan Bastien
Director of Business Development
Industrial Chemicals, North America

+1 819 639-3770
dbastien@knoellUSA.com

