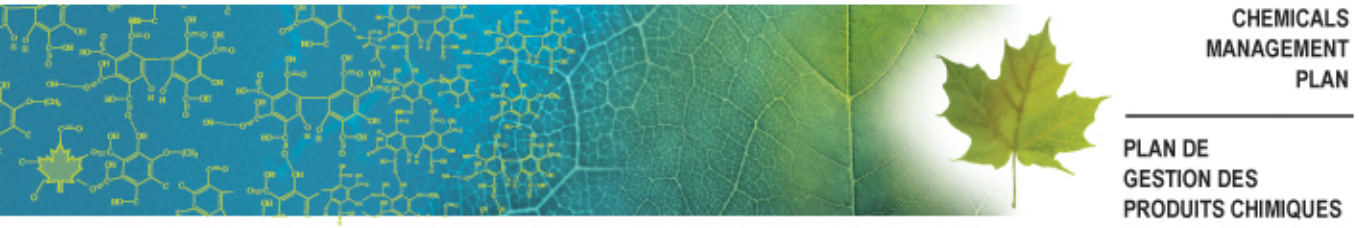
Government of Canada | Gouvernement du Canada

The Canadian New Substances Notification Program

Health Canada – PAHO Workshop

Lima, Peru

November 8-10, 2016



CHEMICALS MANAGEMENT PLAN

PLAN DE GESTION DES PRODUITS CHIMIQUES

Canada

The New Substances Program

- The New Substances program is jointly administered by the Program Development and Engagement Division of Environment and Climate Change Canada (ECCC) and the New Substances Assessment and Control Bureau of Health Canada (HC)

- The NS program is responsible for administering the *New Substances Notification Regulations* (Chemicals and Polymers) and the *New Substances Notification Regulations* (Organisms). Collectively known as the Regulations

Legislative Authority

The *Canadian Environmental Protection Act,1999 (CEPA)*

- 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 the criteria for conclusion of “toxic” - S.64 of the Act
- Outlines the Domestic Substances List and the Non-domestic Substances List
- Outlines New Substances Provisions

The Regulations

- There are two *New Substances Notifications Regulations*:
  - *The New Substances Notification Regulations (Organisms)*
    - *Organisms other than Micro-organisms and Micro-organisms*
  - *The New Substances Notification Regulations (Chemicals and Polymers)*
    - *Chemicals, biochemicals, polymers and biopolymers*
- The Regulations were created to ensure that no new substances (chemicals, polymers, animate products of biotechnology or nanomaterials) 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
- No person can import or manufacture a new substance until:
  - the prescribed information is provided, and
  - the period for assessing the information has expired

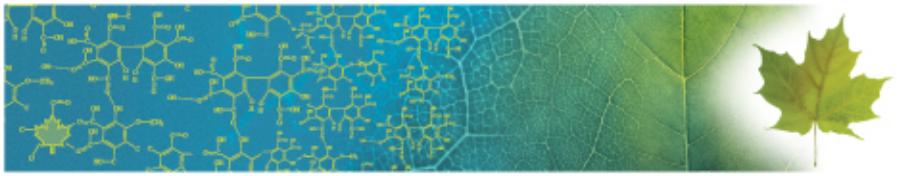
Substance

Defined as:

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

For the purposes of defining new substances, items that are not included are:

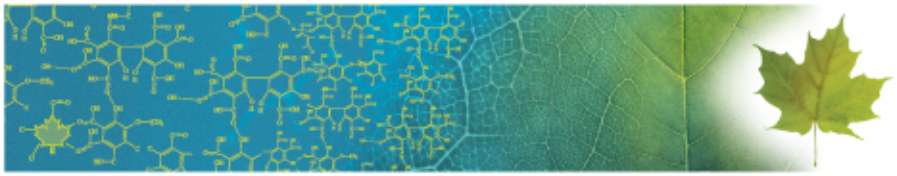
- Mixtures
- Manufactured items
- Wastes



Living Organism

- **A <u>substance</u> that is an animate product of <u>biotechnology</u>**

  - **Biotechnology:**
    - The application of science and engineering to the organism (ex. Genetic Modification)
    - The application of science and engineering in the use of the organism



Who is Required to Notify?

- Canadian manufacturers and importers

NOTE: If the importer is not a resident, then a Canadian agent is required.

The Lists

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

Domestic Substances List

- List of substances existing in Canadian commerce
  - Substances that were manufactured or imported into Canada between January 1, 1984 to December 31, 1986
  - Substances added through the New Substances provisions
- Substances can be listed with a flag
  - S flag indicates a Significant New Activity provision
  - P flag indicates Reduced Regulatory Requirements version of polymer is on DSL
- Currently over 26,000 substances listed

Non-domestic Substances List

- List of substances existing in international commerce (based on US EPA -Toxic Substances Control Act - inventory)

- Currently over 48 000 substances on the Non-domestic Substances List (NDSL)

Substances excluded from Notification

For the purposes of the portion of CEPA dealing with Substances and Activities New to Canada (sections 80 to 89), substances described by the following circumstances are not subject to the Regulations and are therefore excluded from notification.

- ***Mixtures***: Prepared formulations or reaction mixtures that are fully characterized in terms of constituent. (Note that if any of the constituents of the mixture are new substances, that constituent is subject to the Regulations).
- ***Manufactured Item***: Item formed into a specific physical shape or design with a function or functions dependent in whole or in part on its shape or design
- ***Wastes***: Material contained in effluents, emissions and wastes

Substances Not subject to Notification

Unlike exclusions, which define substance not subject to notification because they do not meet the statutory definition of “substance”, exempted substances are not subject to the Regulations

- ***Substances listed on the DSL***: Substances on the DSL do not require notification unless they are subject to a SNAc (“S” or “ S’”) or no longer qualify as an RRR polymer (“P”)
- ***Substances Carried through Canada:*** A substance loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there is a change of carrier during transit.
- ***2% polymer rule:*** A polymer listed on the DSL that is modified by adding reactants, none of which constitutes more than 2% by weight of the polymer
- ***Other acts of parliament***: A substance used and regulated under any other Act of Parliament or regulation listed in Schedule 2 to CEPA:
    - *Pest Control Products Act & Pest Control Products Regulations*
    - *Feeds Act & Feeds Regulations*
    - *Fertilizers Act & Fertilizers Regulations*

  Organisms, as above and:
    - *Seeds Act & Seeds Regulations; and*
    - *Health of Animals Act & Health of Animals Regulations (veterinary biologics).*

Substances Not subject to Notification

- ***Transient reaction intermediates:*** Substances that are not isolated and are not likely to be released or produced within a sequence of chemical reactions between the starting materials and the end product
- ***Impurities and contaminants:*** Substances that are normally found in minimal concentration in the starting materials or are the result of secondary reactions that occur during the manufacturing process
- ***Incidental Reaction Products:*** Substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors
- ***Low Volume:*** The Regulations do not apply to substances manufactured or imported in a quantity less than the lowest amount that first triggers a requirement to provide information under the Regulations
- ***Substances occurring in nature:*** defined as naturally occurring, and either unprocessed or processed only by manual, mechanical or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water; or extracted from air by any means.

Food & Drugs Act

- *Food & Drugs Act* (F&DA) is not listed in Schedule 2 of CEPA
- New substances in F&DA products are subject to the Regulations
- Notification not currently being requested for substances that:
  - Are on the Revised In Commerce List (ICL), **AND**
  - Are imported/manufactured solely for F&DA use
  - The Revised ICL is a list of F&DA substances known to have been in Canadian commerce between Jan 1, 1987 and Sept 13, 2001
  - http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/list/revised-icl_lsc-revisee-eng.php
- The Government of Canada has completed the prioritization of substances on the Revised In Commerce List (R-ICL) and results will be published on the Chemicals Management Plan website.
  - Substances identified for further consideration will undergo a more detailed evaluation which could include information gathering through an Inventory Update (IU).

S.64 of CEPA

Toxic is defined as:

- 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 life or health

Risk based assessments consider both hazard and exposure

Consultation Processes

- ***Pre-notification Consultation (PNC)***
  - Notifiers can consult the New Substances program during the planning or preparation of their notification package
- ***North American Notification Consultation (NAN-C)***
  - Joint consultation process with the US to enable companies that intend to notify a new substance to Canada and the U.S. in the near future to discuss data requirements with New Substances programs from both countries at the same time
- ***OECD Parallel Process***
  - Multilateral notification arrangement which enables governments to work cooperatively and involves acceptance of hazard assessments by participating jurisdictions

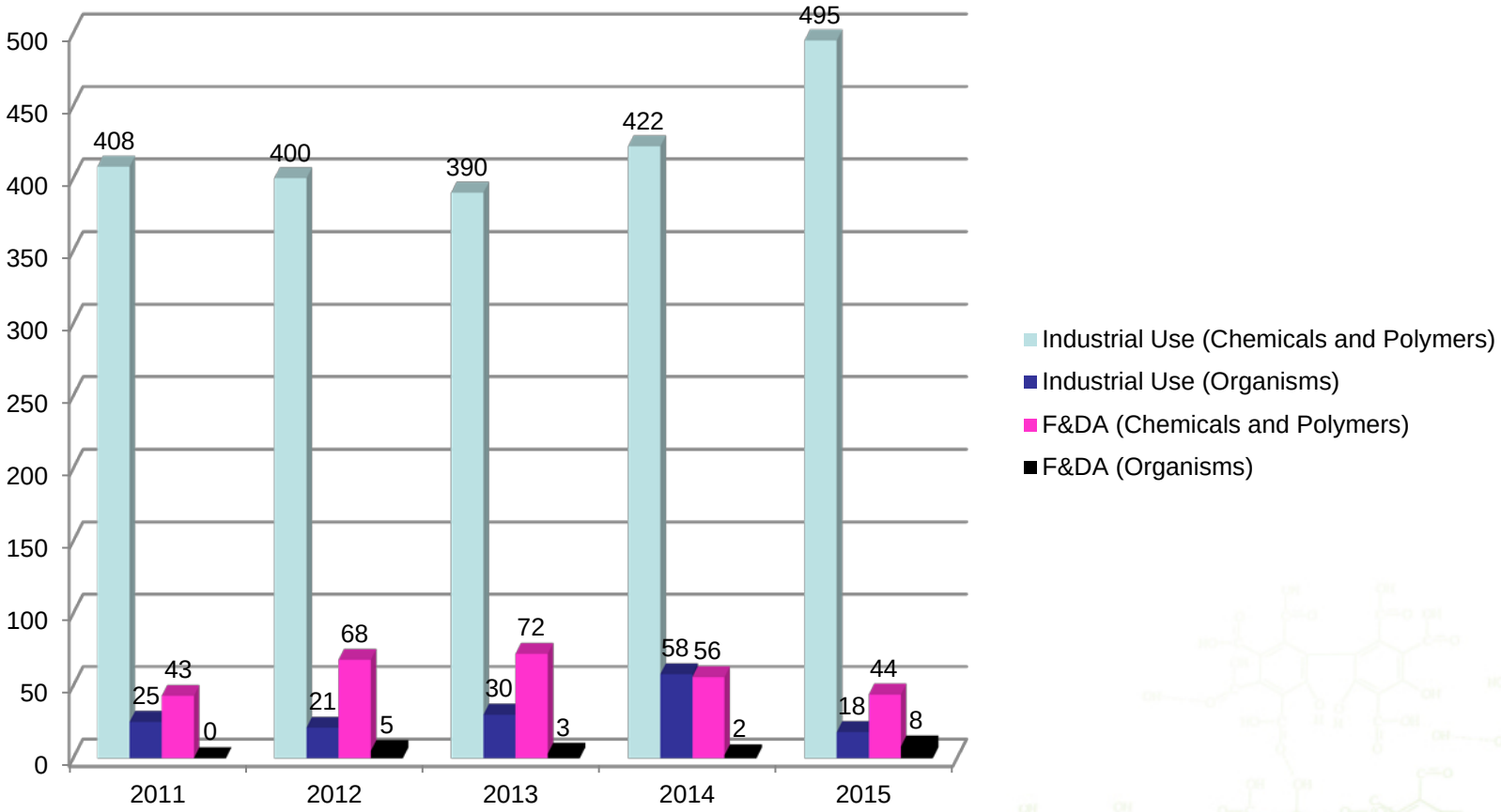
Overview Numbers

- Number of notifications has stabilized, over the last 5 years, to approximately 500 notifications per year

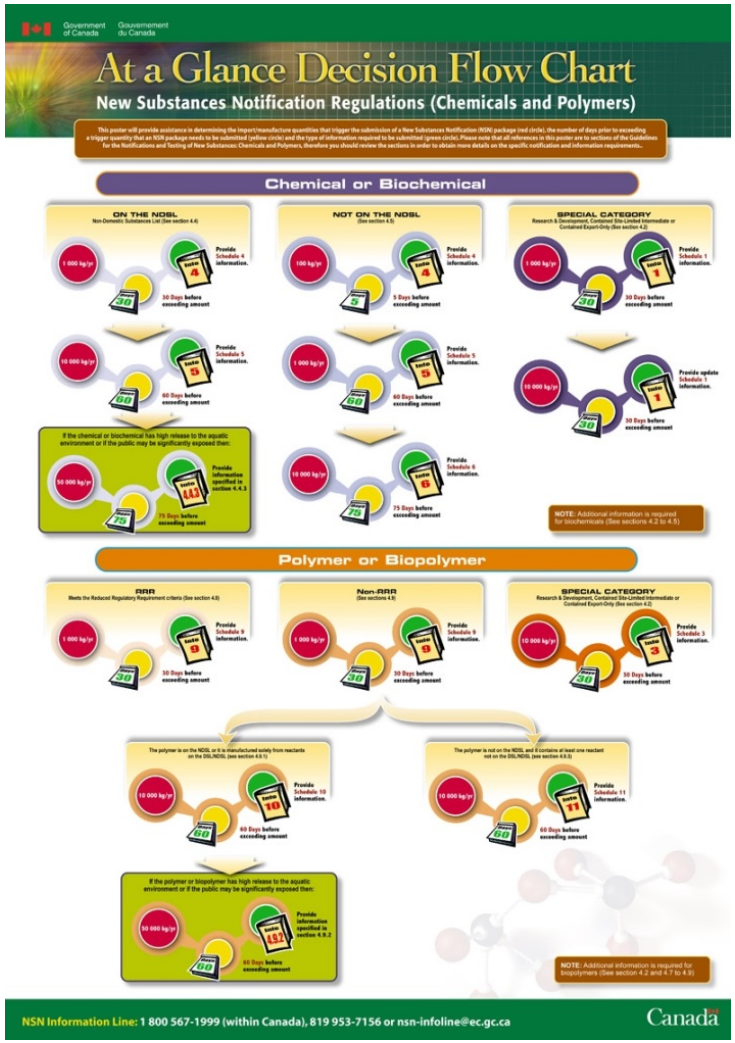
- Over the last 5 years (January 1, 2011 to December 31, 2015):

NSNs received	SNAcs	Conditions	Prohibitions	Request for Testing	Substances to the DSL
2,644 (1,073 chemicals, 1,401 polymers, and 170 organisms)	**60** (2.3%)	**34** (1.9%)	**0** (0%)	**0** (0%)	**1078** (40.8%)

Notifications Received



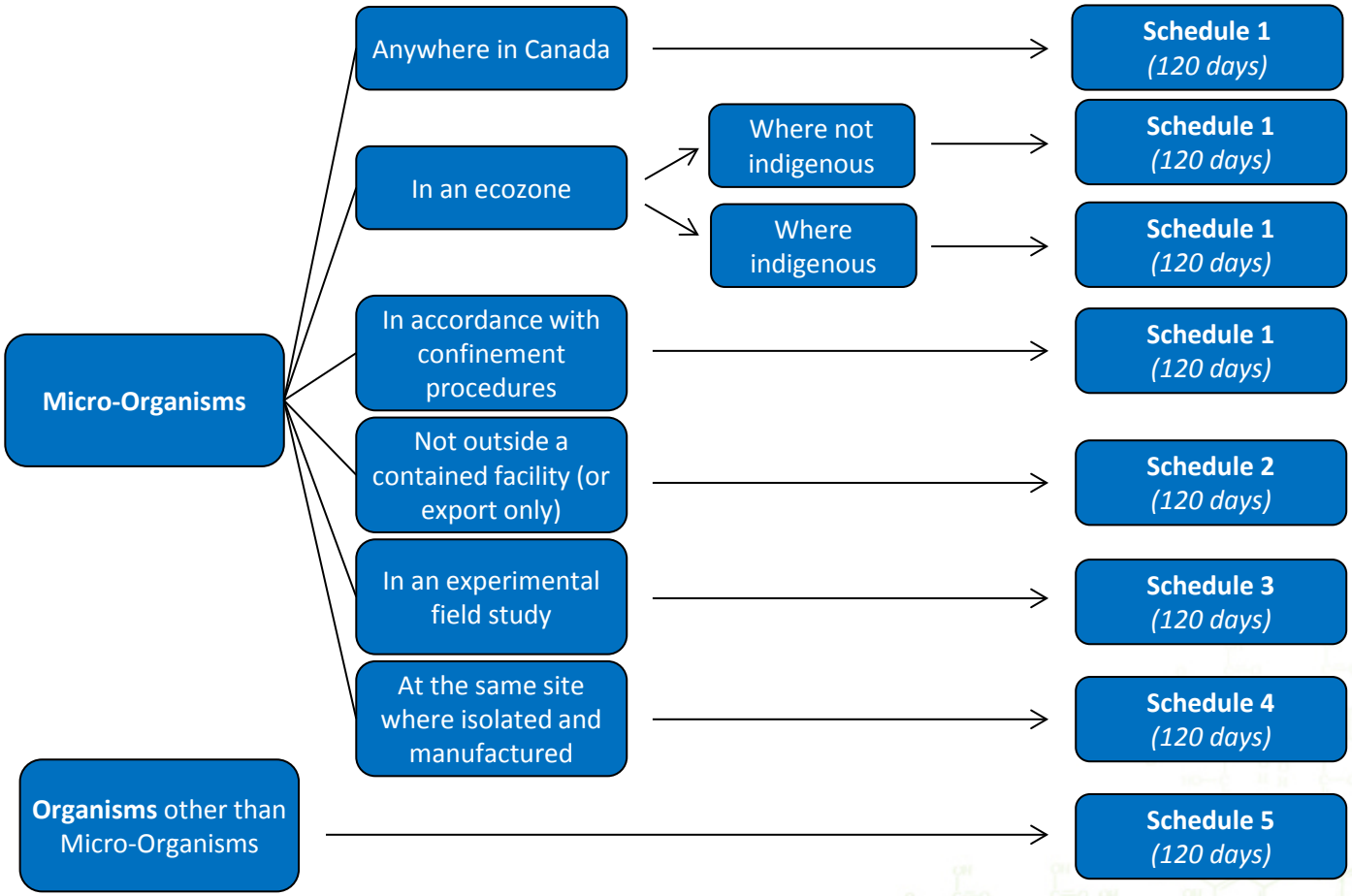
At a Glance Decision Flow Chart



The Decision Flow Chart was created as an aid in determining one's obligation when notification is required. It shows:

- The types of substances;
- The Schedule of information;
- The regulatory triggers; and
- The timeline to supply the information

New Substances Notification Regulations (Organisms)



The New Substances Process: Receipt of Notification Package

- All New Substances Notification (NSN) packages are submitted to Environment and Climate Change Canada:
  - Industrial use
  - Solely for a *Food and Drugs Act* use
  - Dual use (industrial and *Food and Drugs Act* uses)

- NSN package should include:
  - Completed NSN Reporting Form (including appendices)
  - Attachments (if any)

Preliminary Screening

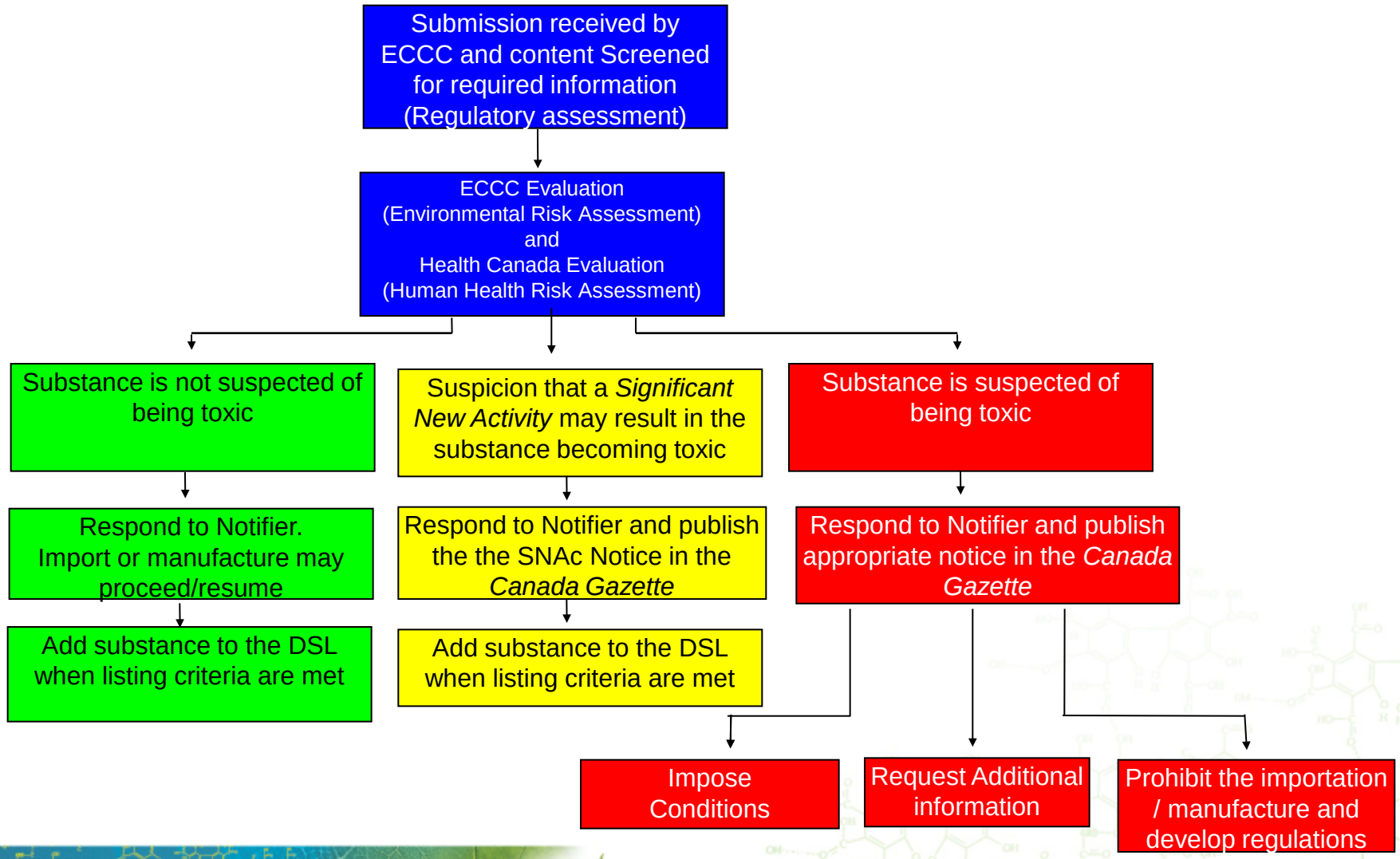
- Notifications and Client Services Section reviews the NSN package to ensure that it meets the regulatory requirements under the Regulations:
  - Complete NSN package
  - Incomplete NSN package
  - Unacceptable NSN package

NOTE: Acceptability of waivers, surrogate data and test data are not reviewed at this stage

Risk Assessment

- Assessment occurs after the NSN package has been acknowledged
- Review and determination of data quality, acceptability of any waiver requests, surrogate data and alternate data proposals
- Assessment of potential risk to human health and the environment
- The Government of Canada must complete its risk assessment and propose any risk management actions within an Assessment Period
  - The Assessment Period ranges from 5 to 120 days from receipt of the notification package, and depends on the type of substance and the volume to be imported or manufactured

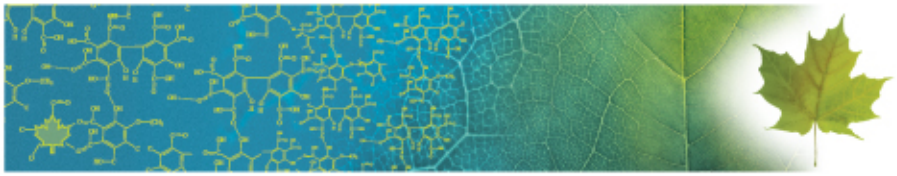
Risk Assessment and Next Steps



Final Assessment Outcome: Substance is not suspected of being Toxic

- If the assessment of a substance has determined that there is no suspicion that it is toxic or capable of becoming toxic, no controls will be imposed on the substance.

- After the end of the assessment period, the notifier may begin manufacturing or importing the substance in amounts exceeding the quantity that triggered the notification.



Final Assessment Outcome: Risk Management Measures

- When a new substance is suspected of being toxic or capable of becoming toxic, the government may take, before the end of the assessment period, one of the following actions:
  - impose conditions on its manufacture or import (Ministerial Condition);
  - prohibit its manufacture or import for a period not exceeding two years (Ministerial Prohibition);
  - request supplementary information or test results, and prohibit its manufacture or import until this information has been submitted and assessed (Ministerial Request for additional information);
  - Request additional information by issuing a Significant New Activity Notice.

NOTE: The assessment period can be extended if there is a potential concern and more time is required to develop a risk management measure

Ministerial Condition

- When a substance is suspected to be toxic or capable of becoming toxic, conditions may be imposed to mitigate any risk to human health or the environment. A Ministerial Condition under paragraphs 84(1)(*a)* of CEPA allows the manufacture or importation of a substance with restrictions.

- Where risks are anticipated from reasonably foreseen activities beyond those notified, a Ministerial Condition may be used.

Ministerial Prohibition

- When a substance is suspected to be toxic or capable of becoming toxic, and when a Ministerial Condition will not mitigate the risk, a Prohibition may be imposed to prevent any risk to human health or the environment. Prohibitions imposed under paragraph 84(1)(*b*) of CEPA prohibit the notifier from manufacturing or importing the substance in any amount.

- The Prohibition expires two years after it is imposed unless, before the expiry of the two years, the government publishes *a Notice of proposed regulations* under sections 93 of the Act in respect of the substance.

- The substance may be added to the DSL after regulations have been developed and published in the *Canada Gazette.*

Ministerial Requests for Additional Information

- When additional information is needed to determine whether the substance is toxic or capable of becoming toxic and the current data is not sufficient to determine the level of concern, a ministerial request for additional information with a prohibition of manufacture or import pending the submission of this information may be imposed to mitigate any risk to human health or the environment.
- Ministerial requests for additional information are imposed under paragraph 84(1)(*c)* of the Act, and the associated prohibition of manufacture or import is imposed under subsection 84(2) of CEPA.
- Once the required additional information has been submitted the substance undergoes further assessment and potential risk management consideration.

Significant New Activity

- The SNAc provisions of CEPA are an information gathering tool and are applied where there is a suspicion that a significant new activity may pose a risk to human health or the environment
- SNAcs require notification to the federal government prior to commencement of significant new activities in order to assess and manage potential impacts that may affect the wellbeing of Canadians and their environment
- Note that unlike other risk management tools, the government may publish a SNAc 90 days after the assessment period
- There are SNAcs in place for 422 substances which span the full suite of substances subject to CEPA:
  - chemicals, polymers, nano-scale substances and living organisms
  - new and existing substances
  - toxic or non-toxic, in commerce or not in commerce substances

Post-notification Responsibilities

- Correction of information (subsection 81(11) or 106(11) of the Act)
- Section 70 of CEPA
- Notice of Excess Quantity (NoEQ) or, alternatively Notice of Manufacture / Notice of Import (NoMI)

Inspection & Enforcement

- Environment and Climate Change Canada enforcement officers may carry out inspections under CEPA
- If convicted, possible penalties are:
  - Fine and/or imprisonment
- Discussed in further detail in the Enforcement and Compliance Policy for the *Canadian Environmental Protection Act, 1999*:

http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5082BFBE-1

Continuous Improvement

- Areas of ongoing effort:
  - Work diligently to meet and improve service standards
  - Improve transparency (e.g. increase number of new substances risk assessment summaries published)
  - Responding to stakeholder comments, particularly with regards to control measures
  - The New Substances program publishes advisory notes on an ongoing basis to inform notifiers and clarify reporting requirements

- In an effort to be pro-active, the New Substances program has regular meetings with key stakeholders and industry advocacy groups

Increasing Transparency

- Regular publication of risk assessment summaries has now been implemented for both Chemicals and Polymers (C&P) and for Organisms
- Work is underway to examine transparency initiatives in other pre-market assessment programs to identify potential options to increase transparency of the New Substances program
- The Website is intended to aid those individuals or companies that are required to notify new substances regulated under the *Canadian Environmental Protection Act, 1999* and to provide general information on the New Substances program

http://www.ec.gc.ca/subsnouvelles-newsubs/

Contact Information

If you have any questions, contact the Substances Management Information Line:

E-mail:	eccc.substances.eccc@canada.ca
Telephone:	1-800-567-1999 (toll free in Canada) (819) 938-3232 (outside of Canada)
Facsimile:	(819) 938-3231
Telewriter:	(819) 994-0736 (General Inquiries Line)
Website:	http://www.ec.gc.ca/subsnouvelles-newsubs/

Thank You!