Environment Canada Environnement Canada

New Substances

The *Canadian Environmental Protection Act, 1999* and the *New Substances Notification Regulations*

An Overview

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Canada

OVERVIEW

- The *Canadian Environmental Protection Act, 1999*
- The *New Substances Notification Regulations*
- Assessment Conclusions and Risk Management Decisions
- Link to the *Food & Drugs Act*

CEPA 1999 - Background

- *Canadian Environmental Protection Act, 1999*
- Gives the Canadian government the authority to address pollution issues
- Part 5 = bio/chemicals & bio/polymers
- Part 6 = animate products of biotechnology
- Section 64 establishes criteria for “toxic”

  A substance that is entering or may enter the environment in amounts that may pose a risk to:
  - (a) the environment (such as fish or wildlife);
  - (b) the environment on which life depends (such as water, air & soil); or
  - (c) human health

CEPA 1999 – Background cont…

Regulatory powers for all phases of the life cycle of a substance or product containing a substance (eg. Manufacture, import, release, use, etc. (s.93(1)) that meets section 64 criteria.

Contains provisions for:

- Information gathering
- Risk assessment
- Risk management
- Remedial measures
- Enforcement

CEPA 1999 – Background cont…

- Avoids duplication: Substances subject to Acts or regulations listed in Schedules 2 and 4 of CEPA (covered under another federal law in a manner that provides sufficient protection to the environment and human health) are not subject to CEPA
- CEPA gives the Minister authority to maintain a Domestic Substances List (DSL)
- CEPA 1999 currently being reviewed

Domestic Substances List (DSL)

- Substances on the DSL are considered to be “existing” and are not subject to the NSNR
- Contains substances that were manufactured in or imported into Canada between 1984 and 1986
- Contains substances that have been notified, assessed under the NSNR and not suspected to meet CEPA section 64 criteria

Domestic Substances List (DSL)

DSL eligible substances must meet the following criteria:

- Prescribed info has been provided
- Assessment timeframe has expired
- Justification for confidentiality requests has been provided
- A Notice of Manufacture or Import provided
- A Notice of Excess Quantity provided

The NSN Regulations

- Shared responsibility between Environment Canada and Health Canada – “New Substances Program”
- Implemented in 1994 for chemicals/polymers
- Amended in 1997 to include organisms
- Revised in 2005 based on recommendations developed by industry, government and public advocacy groups
- Divided into 2 parts: NSNR (Chemicals & Polymers) and NSNR (Organisms)
- NSNR (Organisms) currently under review

Purpose of New Substances Notification Regulations

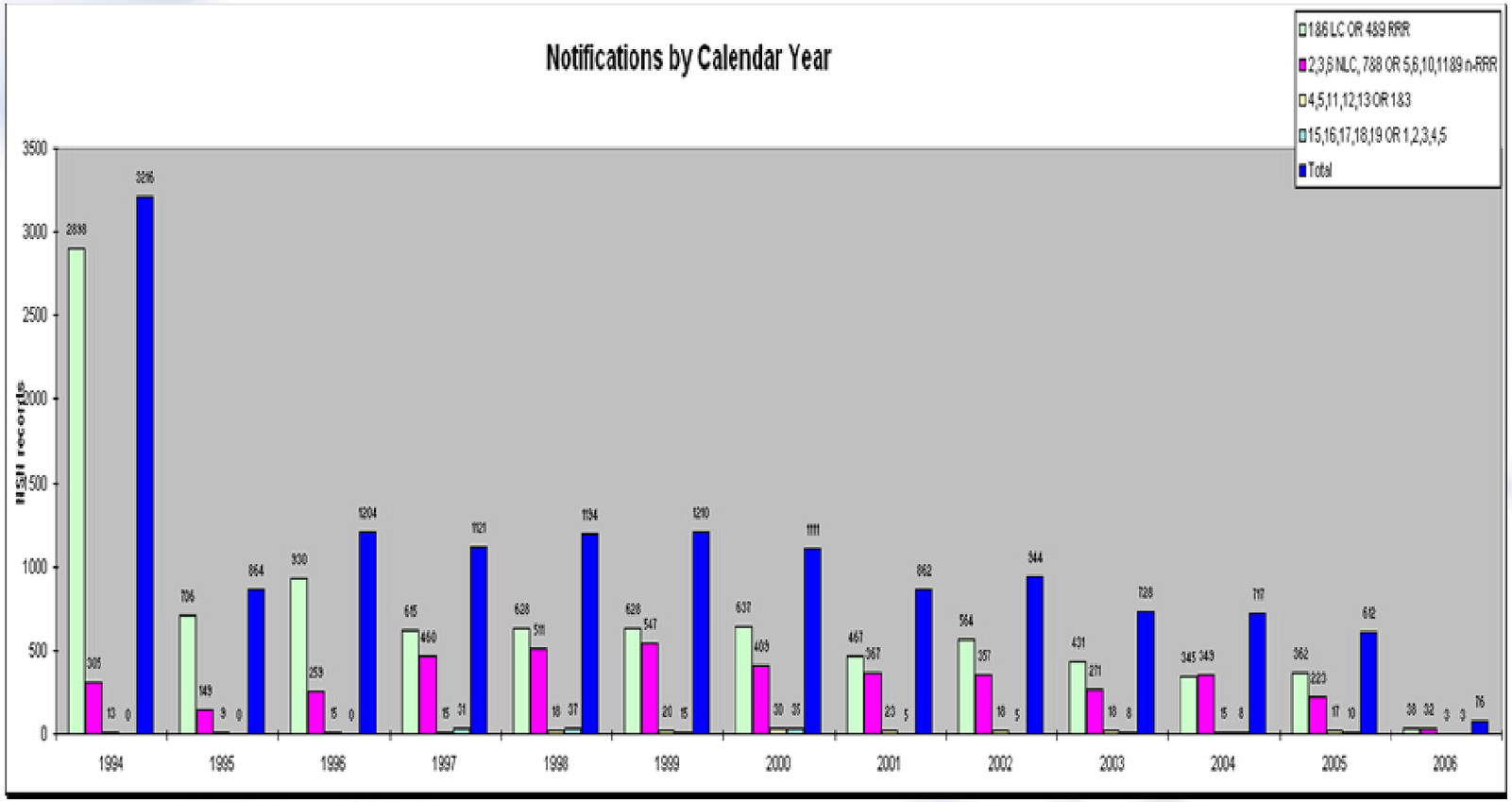
- Ensures that no new substance is introduced into the Canadian marketplace before an assessment of its impacts on human health and the environment is made
- Covers new chemicals, polymers and animate products of biotechnology
- Legal basis: In Sections 80 to 89 (Part 5) and 104 to 114 (Part 6) of CEPA 99 - Define powers and obligations
- Not intended to deal with substances on the DSL or substances covered by other Federal Acts; however, currently apply to substances in products regulated under the *Food & Drugs Act* (F&DA)

NSN Regulations – Content

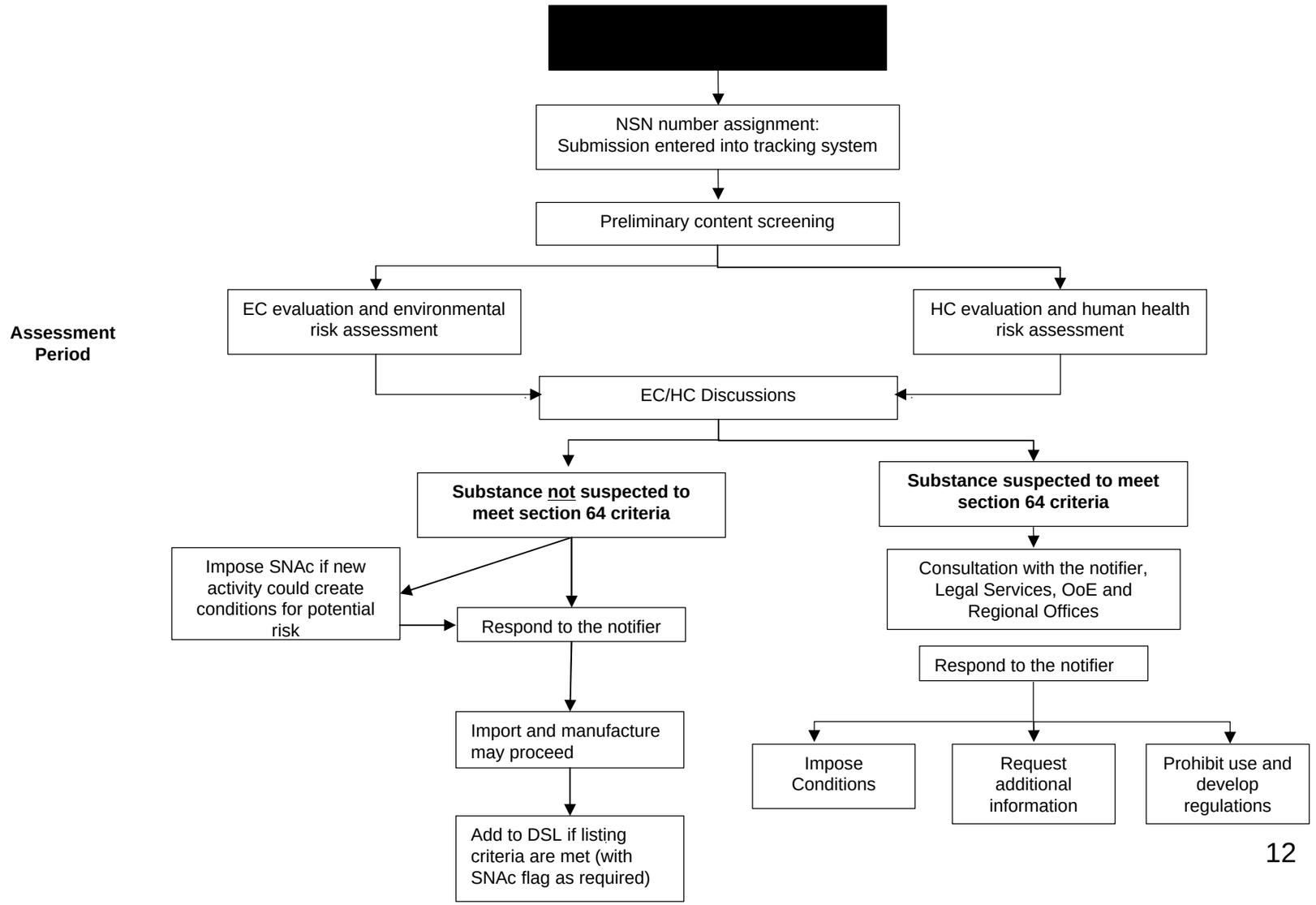
- Prescribe information requirements, assessment period lengths and conditions for adding a substance to the Domestic Substances List
- Uses a tiered approach with Schedules
- Information is required before manufacturing/importing a new substance in certain amounts
- Information used to assess whether a substance is suspected to meet CEPA section 64 criteria
- Onus on Industry to supply test data
- Onus is on government to assess information in a timely manner

Notifications Received Per Year

Up to February 2006



Overview of New Substances Notification
Risk Assessment and Management Process



Assessment Conclusions and Risk Management Decisions

Assessment Conclusions

Three possible outcomes:

- No suspicion of meeting criteria in s.64 of CEPA 1999
- No suspicion of meeting criteria in s.64 of CEPA 1999 but new activity could create conditions for potential risk
  - Risk Management Option: Significant New Activity Notice (SNAc) Triggers re-notification and assessment if proposed activity is different from the one originally notified
- Suspicion of meeting criteria in s.64 of CEPA 1999
  - Risk Management Options:
    - Conditions
    - Prohibitions
    - Prohibition pending testing

Risk Management Measures

- Minister must approve risk management measures
- Management measure must be communicated by end of assessment period
- If deadlines are not respected, substance may be introduced without restriction

Why are we concerned with environmental assessment of new F&DA substances?

- F&DA not scheduled under CEPA 1999
- New substances in products covered by F&DA for safety and efficacy assessment default to CEPA NSNR for environmental risk assessment since Sept. 2001
- MOU between EC and HC signed in April 2002

Legislative Requirements for Scheduling under CEPA

- Two legislative requirements need to be met:
  - The Act required a Notice to be given prior to manufacture, import or sale of a substance
  - The Act has the authority to establish an assessment framework to determine if the new substance is CEPA toxic or capable of becoming CEPA toxic
- Two policy tests also added to ascertain equivalency:
  - Whether the entire lifecycle of the substance is covered in RA/RM
  - Whether there is authority to impose and enforce risk management measures