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Compliance under *CEPA*

What you need to know

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Meeting Objectives

Facilitate understanding of pharmaceutical industry responsibilities related to:

- ***Canadian Environmental Protection Act (CEPA)* compliance for new and existing substances in products regulated under the *Food and Drugs Act (F&DA)***

Learning Outcomes

Describe *CEPA* and the *NSNR*, their relevance and respective requirements for the pharmaceutical sector.

Define the language of *CEPA* and describe how those acronyms are relevant to managing environmental compliance under the Act.

Explain how *CEPA* compliance impacts a company's chemical inventory management with respect to **new** and **existing** substances.

What are these *F&DA* Substances?

Substances contained in products regulated in *F&DA* commodities:

- pharmaceuticals
- radiopharmaceuticals
- veterinary drugs
- biologics
- cosmetics
- food additives
- medical devices
- natural health products
- novel foods

Chemicals Management Plan Fall 2015 Report

- Chemicals Management Plan (CMP) Status
- Risk Assessment and Risk Management Highlights
- Stakeholder Engagement
- *Food and Drugs Act* Substances and Products: Consultation Planned on Non-regulatory Initiatives
- Human Health a Focus of Conference on Nanomaterials
- Information-Gathering Notices Published in Canada Gazette
- National Pollutant Release Inventory: Facility-Reported Data for 2014 to be Released
- Webinar showcased Canadian participation at Stockholm, Basel and Rotterdam Convention meetings
- Strategic Approach to International Chemicals Management
- United Nations 2030 Agenda for Sustainable Development
- Progress in Canada-U.S. Regulatory Cooperation Council Activities
- Microbeads: Measures Announced
- Assessment of Phthalates Proceeding
- Product Testing Supports the CMP
- In-Commerce List: Progress on Prioritization
- Snapshot: The Canadian House Dust Study
- Exposure of Pregnant Women and Children to Chemicals: Study Results
- Risk Management Instruments
- Coming Publications

Coming stakeholder engagement activities		
Coming events	**Tentative date**	**Description**
Stakeholder consultation on non-regulatory initiatives to mitigate potential environmental and indirect human health impacts of substances/products regulated under the *Food and Drugs Act*	Early 2016	For information, contact the Environmental Impact Initiative Division at <nri_consultations@hc-sc.gc.ca>
Nanotechnology stakeholder workshop	Spring 2016	For information, contact the Nanotechnology Section at <brad.fisher@canada.ca>.

FOOD AND DRUGS ACT SUBSTANCES AND PRODUCTS: CONSULTATION PLANNED ON NON-REGULATORY INITIATIVES

Health Canada is encouraging stakeholders to take part in a month-long online consultation, starting in January, on non-regulatory initiatives aimed at reducing the release into the environment of substances and products regulated by the *Food and Drugs Act*.

The goal of the consultation is to support a dialogue about new or improved non-regulatory initiatives. These include such things as voluntary policies, guidelines, standards of practices, procedures, environmental stewardship programs, extended producer responsibility and good manufacturing processes.

Health Canada is hoping for participation from a wide range of stakeholders across the *Food and Drugs Act* commodity groups. These include pharmaceuticals, cosmetics, veterinary drugs, natural health products, biologics, radiopharmaceuticals, novel foods, food additives and medical devices.

The outcome of the consultation will help identify a path forward for Health Canada and/or other stakeholder groups for protecting the environment and, indirectly, human health, and may include the development of partnerships or relationships.

Four themes identified as potential areas for improvement will help organize the dialogue:

- Take-back programs for products regulated by the *Food and Drugs Act*;
- Education/guidance on how to properly dispose of products regulated by the *Food and Drugs Act* and on non-regulatory initiatives in general;
- Logos/labelling; and
- Uniform definitions as well as monitoring and tracking of data surrounding initiatives.

Once an analysis of the consultation findings has been completed, a report detailing the outcome and possible next steps will be distributed to participants.

For information, contact <nri_consultations@hc-sc.gc.ca>. ◆

Background: *CEPA*

1985: Task force reviews *Environmental Contaminants Act*

CEPA 1988 proclaimed June 30,1988

- **Cradle to Grave** approach
- Governs pollution prevention in Canada by protection of the environment

Two legislative requirements had to be met:

- The Act requires a Notice to be given prior to manufacture, import or sale of a substance
- The Act must have the authority to establish an assessment framework to determine if the new substance poses a risk to health or the environment

CEPA 1999 brought into force on March 31, 2000

Impact to *F&DA* substances

As of September 14, 2001, all ingredients in products regulated under the *Food and Drugs Act*, including those in pharmaceuticals, became subject to *CEPA*, 1999

Two streams under *CEPA* treated differently has lead to the evolution of **chemicals management**:

- **New** Substances
  - ‘New‘ based on whether the substance is on the national chemical inventory (Domestic Substances List)
  - Must have a CAS RN in order to determine DSL listing
- **Existing** Substances

Environmental Assessment Regulations (EARs)

Notice of Intent published in *Canada Gazette* Part I, September 1, 2001.

Health Canada's Environmental Impact Initiative (EII) to develop

Objective

- Ensure that new substances in products regulated under the *Food and Drugs Act (F&DA)* are evaluated for risks to the Canadian environment and human health through environmental exposure

Environmental Assessment Regulations

Under construction….

Lists

- **Domestic Substances List (DSL)**
- **Non-Domestic Substances List (NDSL)**

- **Revised In-Commerce List (RICL)**
- ***Food and Drugs Act*-DSL (FDA-DSL)**

Lists

Domestic Substances List (DSL)

- Compilation of substances known to be in Canadian commerce between January 1, 1984, and December 31, 1986 or that were added to the DSL in accordance with CEPA 1999
  - 24,000+ Chemicals and Polymers
  - 71 Organisms

Non-Domestic Substances List (NDSL)

- Inventory of substances assessed by the US Environmental Protection Agency (USEPA) by listing on the Toxic Substances Control Act (TSCA) Chemical Substances Inventory.
- Substances are added to the NDSL one year after being listed on the TSCA Chemical Substances Inventory. The update is done twice a year
- Subject to fewer information requirements for notification under the NSNR.
  - Chemical not on DSL or NDSL notify 5 days before exceed 100 kg/yr
  - Chemical not on DSL but on NDSL notify 30 days before exceed 1000 kg/yr

FDA-DSL

- Substances in products regulated under the *Food and Drugs Act* (*F&DA*) that were in commerce in Canada between January 1, 1984 and December 31, 1986
- For substances not on the DSL (only industrial chemicals or polymers), Health Canada identified substances that were in the Health Canada databases but did not have enough information to add to the DSL. These became the FDA-DSL.

A non-statutory, policy list

In-Commerce List

There are two In-Commerce Lists and both are non-statutory, policy lists:

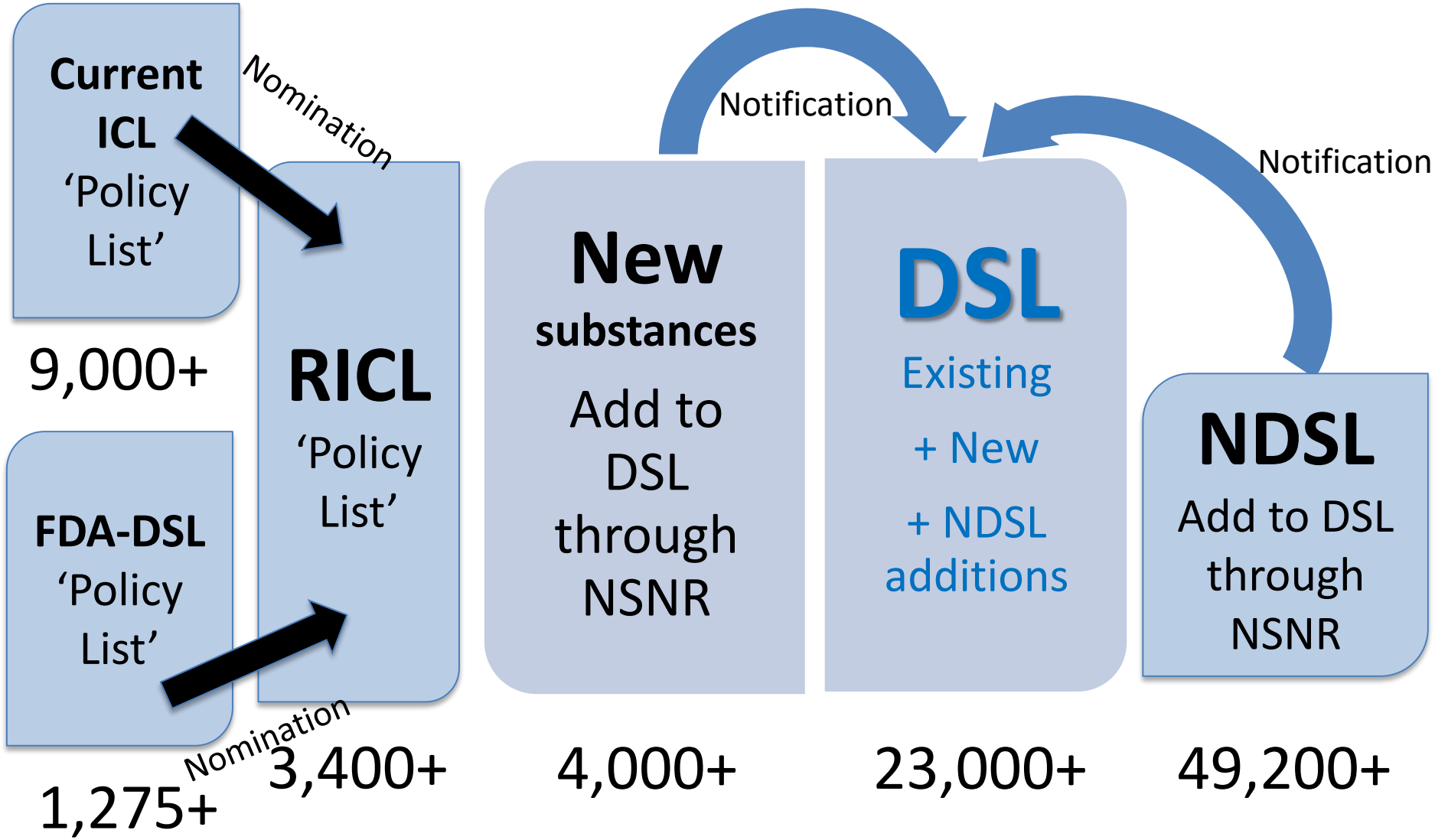
- **Current**
- **Revised**

Current ICL of ~9,000 substances was compiled from Health Canada (HC) records for those that were in commerce between January 1, 1987 – September 13, 2001.

Revised ICL consists of 3,400+ substances

- Substances from the Current ICL whose identity has been verified by Health Canada prior to the nomination process; and
- Substances accepted for addition to the revised ICL during the Phase I and Phase II of the voluntary nomination process for which substance identity and eligibility criteria have been verified.
- Note: Substances that meet the definition of 'Naturally Occurring Substances' or 'Originating in Nature' do not need to be nominated to the list

DSL and RICL



Evolution of the Lists:
Chemicals Management Plan

These are not static lists:

- DSL
- NDSL
- Revised ICL

- Substances can be added to each list through notification or nomination processes
- Substances on each list are being continuously reviewed for accuracy and potential for risk to human health and the environment.

DSL Inventory Update Process

DSL IU2

- December 1, 2012, *Gazette* Publication for response by September 4, 2013
- Mandatory survey under Section 71 of *CEPA* seeking to collect updated use volume information pertaining to the remaining existing substances priorities identified under the Canadian Chemicals Management Plan (CMP).
- Approximately 2,100 chemicals and roughly 600 polymers.
- Purpose was to confirm the current commercial status of these substances in Canada to inform corresponding prioritization efforts and support future risk assessment and management activities under the CMP.
- Outcomes: Deletions from DSL for those not in commerce and other risk management measures.

DSL IU3 Implementation and Manageability

- Build on experience of prior DSL IUs
- DSL IU3 substances list projected to be published in Spring, 2016 for data from calendar year 2015: ~1,500 substances this time

NDSL Cleanup

- NDSL list is being cleaned up to address:
  - Substances on DSL and NDSL
  - Substances on NDSL erroneously with risk management flags
  - This will result in substances being deleted from the NDSL

- This will become an ongoing process with publications of the revised NDSL list expected to be published twice a year

CEPA: Areas of Responsibility

- New Substances Notification
- Existing Substances Management
- Pollution Prevention and Disposal and Emissions Controls
- Hazardous Waste Management
- Environmental Emergency Planning
- Environmental Protection on Federal and Aboriginal Lands

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NEW SUBSTANCES NOTIFICATION REGULATIONS

- **Chemicals and Polymers**
- **Organisms**

New Substances Notification Regulations (NSNR)

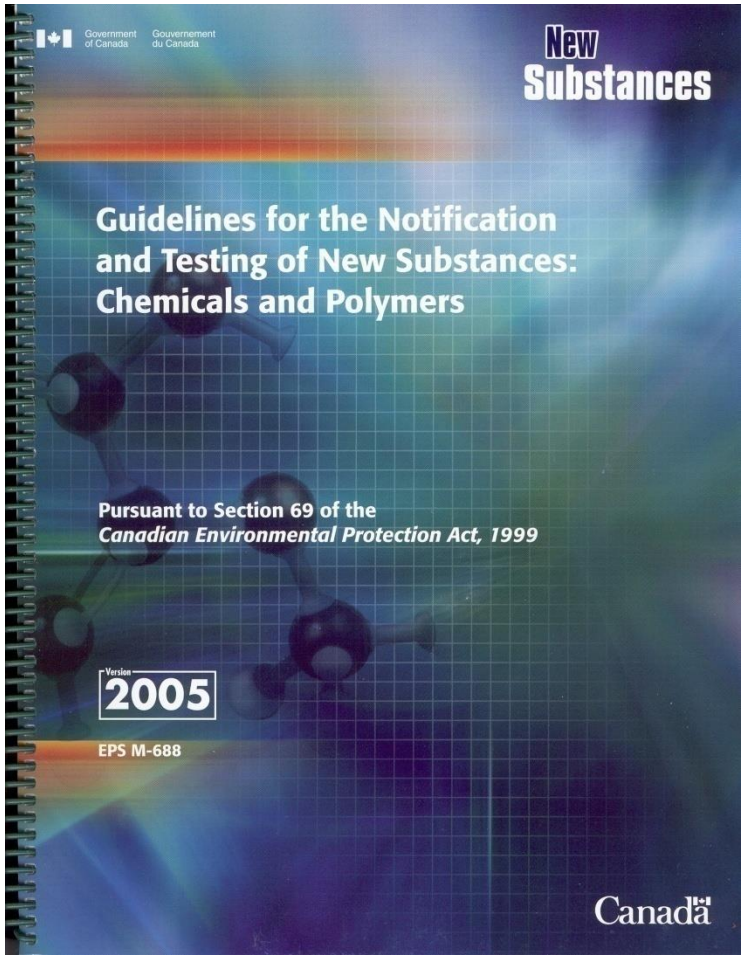
The *NSNR and NSNR(O)*

Applicable to 'new' substances

Chemicals, polymers, biochemicals, biopolymers, products of biotechnology, as well as organisms

Import and Manufacture activities

NSNR Chemicals and Polymers*



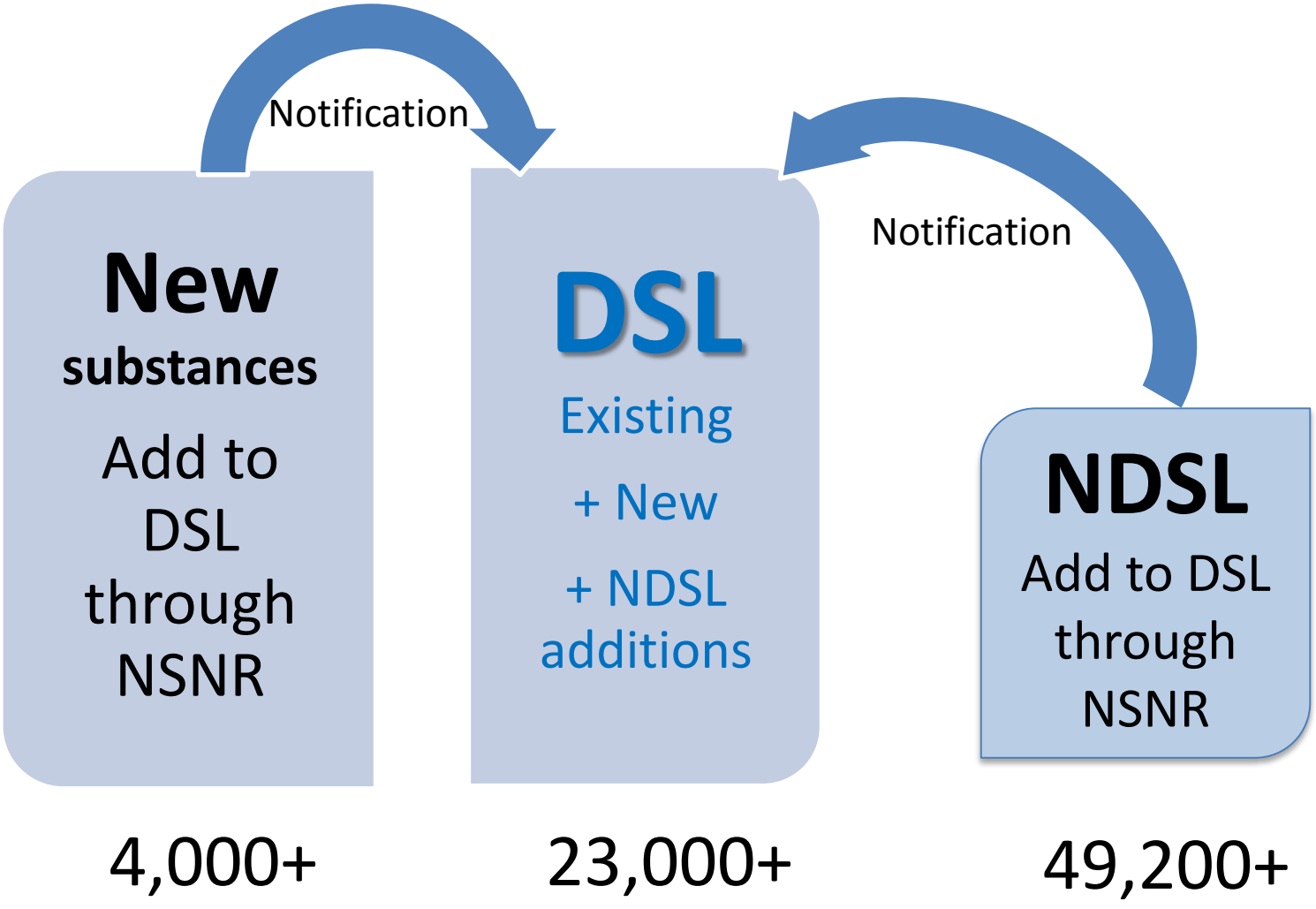
Graduated pre-market assessment process

- Based on increasing volumes of substance introduced into the market

Sets out 'clear' guidance as to when and how a substance should be notified to the government.

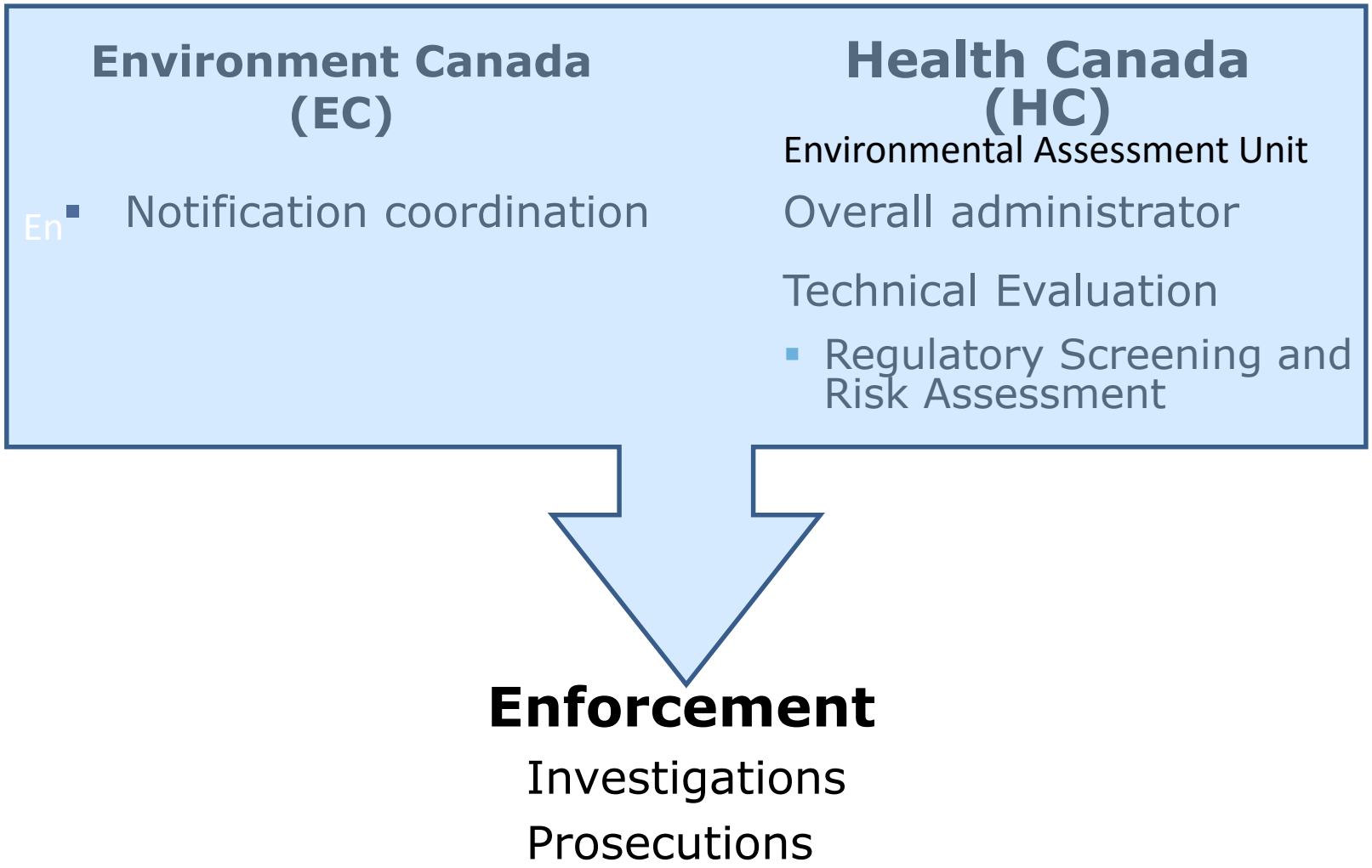
* Different process for organisms under the *Guidelines for the Notification and Testing of New Substances: Organisms* (August 2010)

NSNR and the Lists



Administration of the *NSNR*

for Substances in *F&DA* Products



Regulatory Compliance

To be compliant with *NSNR* and *CEPA*, all chemical, polymer, organism, food, cosmetic, natural health product and pharmaceutical substances should be:

- Inventoried on the DSL (Revised ICL option for food, cosmetic, natural health products or drugs);

OR

- Eligible for exclusion from the provisions of the *NSNR*;

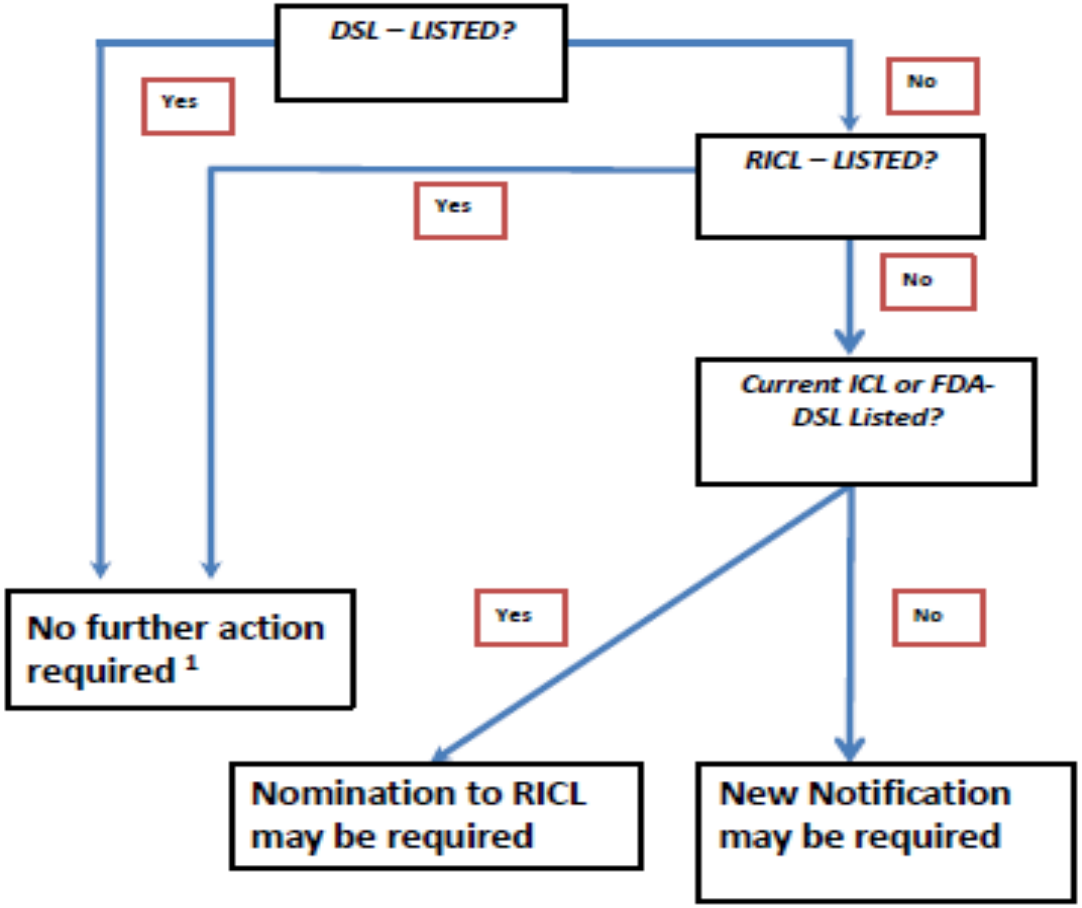
OR

- Under the minimum volume threshold requiring notification
  - Chemicals 100 kg/yr
  - Polymers 1,000 kg/yr
  - Organisms 0 kg/yr

OR

- Notified, through the submission of a regulatory dossier

Substances in *F&DA* Products
Compliance Algorithm



[1] If on DSL and no risk management measures imposed i.e., SNAc then free to import/manufacture for any use.

New Substances Notification (NSN)

10 steps to NSN Compliance

R&D/Product Development

1. Characterize substance
2. Assess whether substance can be
   - Exempted
   - Nominated
3. Determine volumes
4. Identify notification schedule
5. Gather existing information
6. Acquire outstanding information/data
7. Complete regulatory dossier

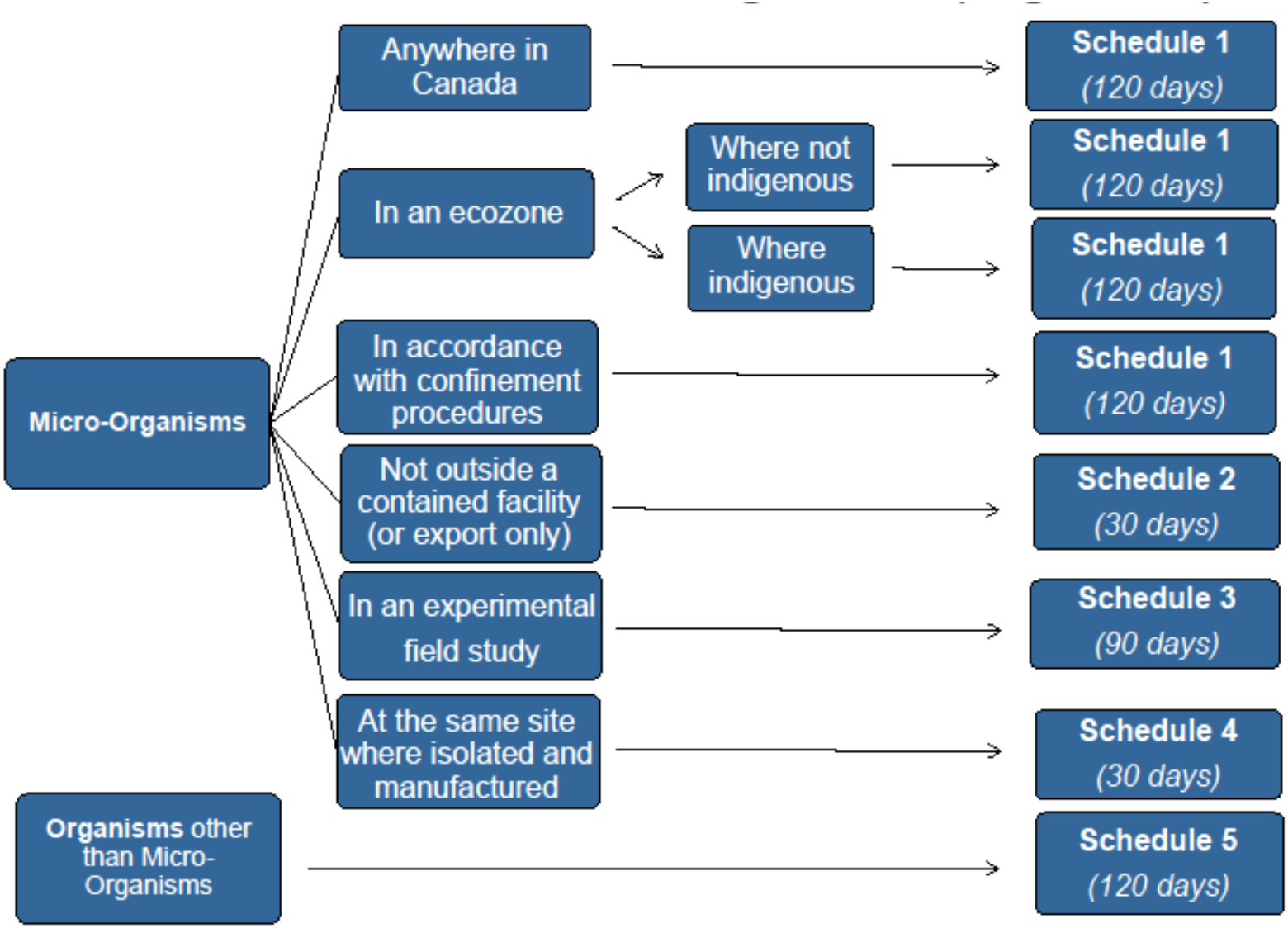
Market Access

8. Post-Notification Responsibilities

Inventory Management

9. Existing substance management
10. Ongoing inventory management
    - Volumes
    - Modifications to substances

Schedules for Organisms



Current Activities

What's New on the New Substances Website:

- Order 2015-66-13-01 Amending the Domestic Substances List
  2016-01-13 - *Canada Gazette* - Part II, Vol. 150 No. 1
- Order 2015-87-13-01 Amending the Domestic Substances List
  2016-01-13 - *Canada Gazette* - Part II, Vol. 150 No. 1
- Waiver of information requirements for living organisms (subsection 106(9) of the *Canadian Environmental Protection Act, 1999)*)
  2015-12-26 - *Canada Gazette*, Part I, Vol. 149 No. 52
- Waiver of information requirements for substances (subsection 81(9) of the *Canadian Environmental Protection Act, 1999)*)
  2015-12-26 - *Canada Gazette*, Part I, Vol. 149 No. 52
- New Substances Notification Advisory Note 2015-05 - Documentation to support the addition of a substance to the *Domestic Substances List* (Updated December 10, 2015)
- New Substances Advisory Note 2015-04 - Clarification in relation to certain micro-organisms listed by Chemical Abstract Services (CAS) Registry Number on the *Domestic Substances List* (Updated December 10, 2015)

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Existing Substances Management

Substances Management

Our Regulatory Landscape

Is Changing

Impetus for Change

CEPA 1999

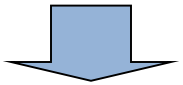
Chemicals Management Plan

- PM Announcement (Friday, Dec 8, 2006)
  Conservatives cracking down on toxic chemicals

Existing Substances Management

Chemicals Management Plan (CMP)

Categorization of Domestic Substances List



Chemicals Management Plan (CMP) for the screening of all substances categorized based on impact these substances may have on human or environmental health

Timeline: to be completed by 2020

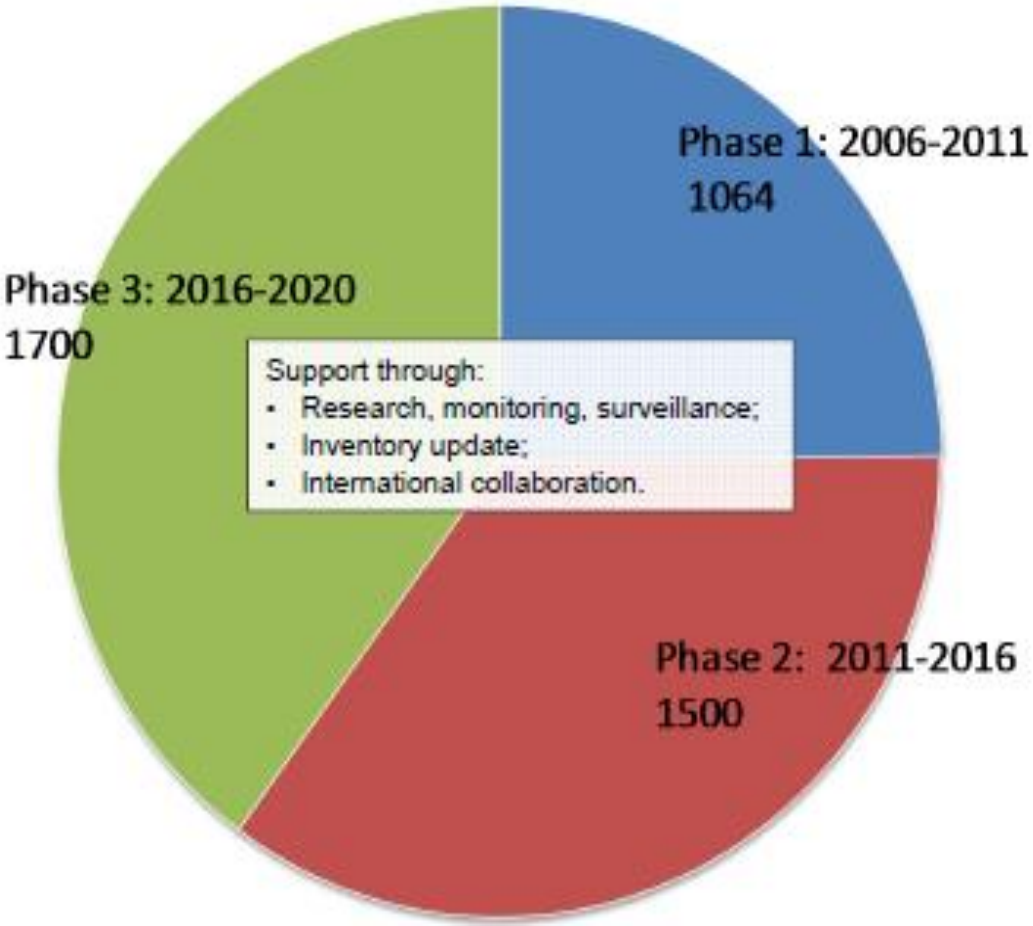
Initial focus on High priorities and Low priorities

Currently government is making decision on how to manage Medium priorities

Chemicals Management Plan

(Courtesy EC)

Priorities under CMP



4,300 substances to be assessed by 2020

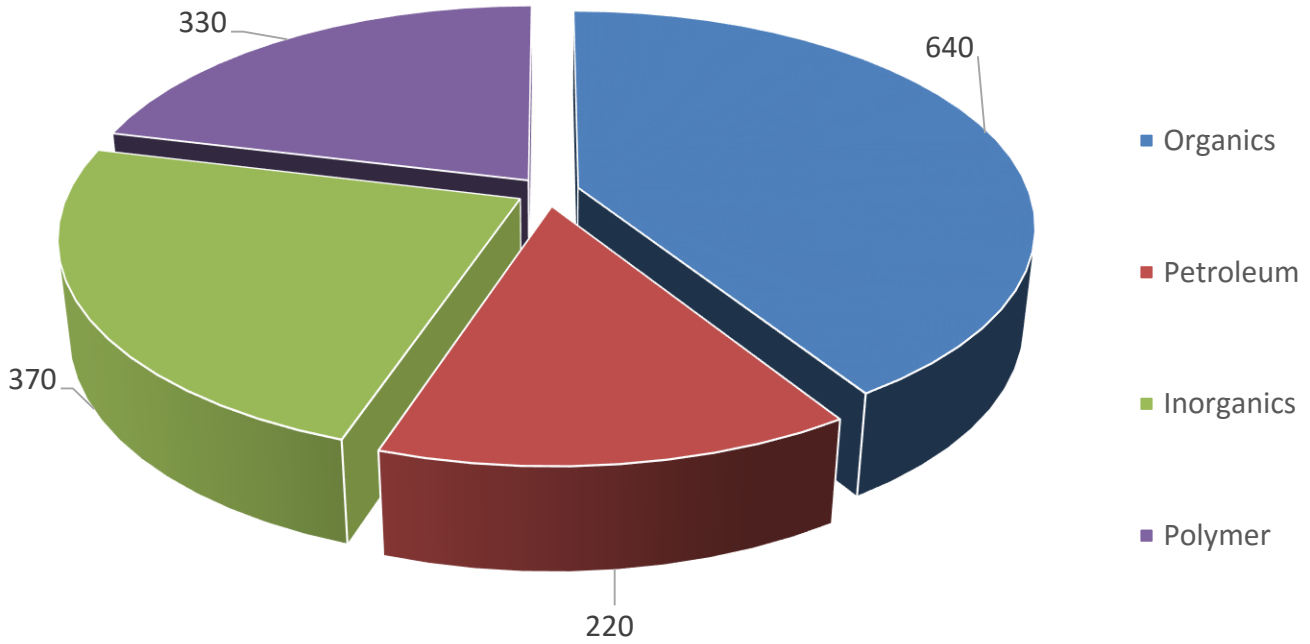
~19,000 substances were identified as "not requiring further action at this time"

(Courtesy EC)

CMP3

Approximately 1,550 substances to be addressed in CMP3

Breakdown of CMP3 Substances



(Courtesy EC)

Emerging Themes for CMP3

- Delivering on Strategic Approach to International Chemicals Management (SAICM) commitment
  - sound management of chemicals achieved by 2020
- Consumer Products
  - CMP3 has predominantly substances with consumer product uses (more than 50%)
- "Chemicals in Canadians"
  - more substances with biomonitoring data than in previous 2 phases (~20%)
- Staying Relevant
  - new priorities identified for risk assessment, beyond those identified from categorization (e.g. parabens)

(Courtesy EC)

Existing Substances Management

Existing Substances Review

- Categorization and Screening of the DSL
- Chemicals Management Plan (CMP)
  - Challenge to Industry
- Substance Groupings Initiative (CMP2)
- CMP3
- DSL IU

Section 71 Notices

Mandatory surveys issued under section 71 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) gather information needed to support risk assessment and, if necessary, risk management activities.

Nanomaterials

CEPA 1999 section 71 Notice with respect to certain nanomaterials in Canadian commerce:

Canada Gazette, Part I: Vol.149, No. 30 - July 25, 2015

Deadline to report: February 23, 2016, 5 p.m. EST

Hydrofluorocarbons (HFCs)

CEPA 1999 section 71 Notice with respect to Hydrofluorocarbons in bulk:

Canada Gazette, Part I: Vol. 150, No. 1 - January 2, 2016

Deadline to report: March 2, 2016, 5 p.m. EST

Microbeads

CEPA 1999 section 71 Notice with respect to microbeads in certain personal care applications:

Canada Gazette, Part I: Vol.149, No. 31 - August 1, 2015

Deadline to report: October 15, 2015, 5 p.m. EDT

Existing Substances Management

Examples of Risk Management

- Significant New Activities Notices (SNAcs)
- Schedule 1 – List of Toxic Substances
  - CEPA Toxic s.64 of the Act
  - *Substances that enter or may enter the environment at levels or under conditions that:*
    - *Have or may have a harmful effect on the environment;*
    - *Are or could be dangerous to the environment that life depends on;*
    - *Are or could be dangerous to human life or health.*
- Regulations
- Pollution Prevention Plans
- Virtual Elimination
- Prohibition

Examples of Management Activities

- A Notice of intent to amend the Domestic Substances List to apply the Significant New Activity provisions of the Canadian Environmental Protection Act, 1999 to one substance in Batch 5 of the Challenge has been published. The Risk Management Action Milestones table for Batch 5 substances has also been published. http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-5/index-eng.php
- A Notice of intent to amend the Domestic Substances List to apply the Significant New Activity provisions of the Canadian Environmental Protection Act, 1999 to two substances in Batch 4 of the Challenge has been published. The Risk Management Action Milestones table for Batch 4 substances has also been published. http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-4/index-eng.php
- A proposed Order to add chlorinated naphthalenes to Schedule 1 to the Canadian Environmental Protection Act, 1999 was published. http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/naphthalenes-eng.php

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F&DA Substances Considerations

Existing Substances Management

Substances in *F&DA* Products - Special Situations

- Revised In-Commerce List
  - Categorization of the Revised In-Commerce List
- FDA-DSL
- *Environmental Assessment Regulations*

RICL Categorization Approach

1. Substances Previously Reviewed

- Identify substances on revised ICL and DSL

2. Substances with Certain High Health or Environmental Hazard Considerations

- Classifications by national or international agencies/information:
  - in PM that identify substances that are carcinogenic, genotoxic, or toxic to reproduction
  - Endocrine disrupters
  - Persistent Organic Pollutants (POP)

3. Substances from Natural Sources

- Qualitative review of substances from natural sources.
- Not considered further in the revised ICL prioritization process.

RICL Categorization Approach

4. Potential Exposure and Use Patterns

- Exposure is a key factor
  - Substances in commerce at high quantities, or whose use pattern likely to result in significant releases to the environment will generally require further consideration.

5. Substance Groupings

- Substances grouped based on similar chemical structure, or in the case of micro-organisms, their taxonomical classification, and/or use pattern.
  - quaternary ammonium compounds, alcohol ethoxylates, and substances with certain metal moieties.
  - Use patterns: pharmaceuticals with similar mechanism of action, or substances used as fragrances.

6. Remaining Substances

- Substance-specific information regarding the properties, toxicity, ecotoxicity, use pattern, quantities, and releases will be gathered, and/or modelled and used to inform a prioritization decision

CEPA Compliance Options Recap

For Substances in *F&DA* Products

Compliance status for substances in *F&DA* products depends upon when they were marketed:

1984-1986:

- Nominated to DSL
- Subject to environmental assessment through the review of existing substances on DSL (CMP)

1987-2001

- Nominated to ICL
- To be assessed under the EAR once published

2001 – EAR publication (201x??)

- Must be notified under the *NSNR* (as well as meet *F&DA* safety requirements)
- Re-assessment under *EAR* will be considered in the development of the *EAR*

EAR publication (20XX)

- Substances will be notified under *EAR*, not *NSNR* any longer

Out of Compliance Strategies

Out of Compliance

Environment/Health Canada work very closely with Enforcement

- They are required to inform Enforcement of any companies which are believed to be out of compliance (by phone or by submission)

ONE (and only one) strategy for compliance

STOP IMPORTATION OR MANUFACTURING IMMEDIATELY

- File notification ASAP
  - Seek legal or regulatory opinion prior to discussion with government
  - Have legal or regulatory expert accompany you in discussions
  - Take all measures to demonstrate due diligence and willingness to comply
- Await the assessment period prior to re-initializing market access

Chemicals Management

The New Reality

Today…

Regulatory Decision Making

Nanotechnology Provisions (NSNR)

Industry Challenge (High Priorities, Batches 1-12)

Rapid Screening (low priorities)

IUR considerations (medium priorities)

SARs and RM considerations (all priorities)

CMP2 Substance Groupings Initiative (Cobalt, Boron, Phthalate, Selenium, etc.)

YES

CMP

Ministerial Conditions

Revised ICL 'Categorization and Screening'

REACH

?

has become

DSL deletions

?

CEPA 1999

Significantly More Complex

The New Reality

Re-Examine New Product Procedures

- F&DA activity (RICL, FDA-DSL, *EAR*)
- Scheduled NDSL deletions
- Section 71 Nanomaterials
- CMP3… upcoming
- DSL IU3

Track and Monitor

CEPA Compliance

- Much more than just DSL listing
- Should have a dynamic and comprehensive ingredient inventory
  - A 'Chemicals Management Plan'
    - —Premarket review of ingredients before launching products
    - —Process Owner
- Understand CEPA compliance and requirements under existing substances management (CMP2, CMP3, DSL IU3 and beyond)

- **Be Engaged**
- **Be Involved**
- **Stay Connected**
- **Be Prepared**

Questions?

Acknowledgements

- ✓ Responsible Distribution Canada [RDC]
- ✓ Canadian Cosmetic, Toiletry and Fragrance Association [CCTFA]
- ✓ CEPA Industry Coordinating Group [CEPA ICG]
- ✓ Environment Canada
- ✓ Health Canada

Thank You !

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