

Canada's experience under the *Canadian Environmental Protection Act* and the Chemicals Management Plan

California Green Chemistry Initiative
Cal EPA Headquarters, Sacramento
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Overview

- **Background and Context**
 - The *Canadian Environmental Protection Act* (CEPA)
 - The Domestic Substances List (DSL)
 - Categorization – A priority setting exercise
- **Canada's Chemicals Management Plan (CMP)**
 - Our immediate focus – The Challenge
 - Links to other priorities under the CMP
- **Considerations for Breakout Session**

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

- Covers a range of activities that can affect human health and the environment, and acts to address any pollution issues not covered by other federal laws.
- Managing chemical substances is a fundamental part of CEPA 1999; responsibility shared by Ministers of Environment & Health
- Provides the regulatory framework and process for risk assessment and risk management of chemicals
- Requires every new chemical substance made in Canada or imported from other countries since 1994 be assessed against specific criteria.

Other Government of Canada Legislation

- In addition to CEPA 1999, there are many other Government of Canada programs and agencies involved in assessing and managing the risks from chemical substances.
- At the federal level, our health and environment is protected through numerous laws that govern chemical substances, examples include:
 - *Food and Drugs Act*
 - Act applies to all food, drugs, natural health products, cosmetics and medical devices sold in Canada
 - *Pest Control Products Act*
 - The Pest Management Regulatory Agency (PMRA) is the federal agency responsible for the regulation of pest control products in Canada
 - *Hazardous Products Act*
 - The Government of Canada protects Canadians by researching, assessing and managing the health risks and safety hazards associated with the consumer products we use everyday



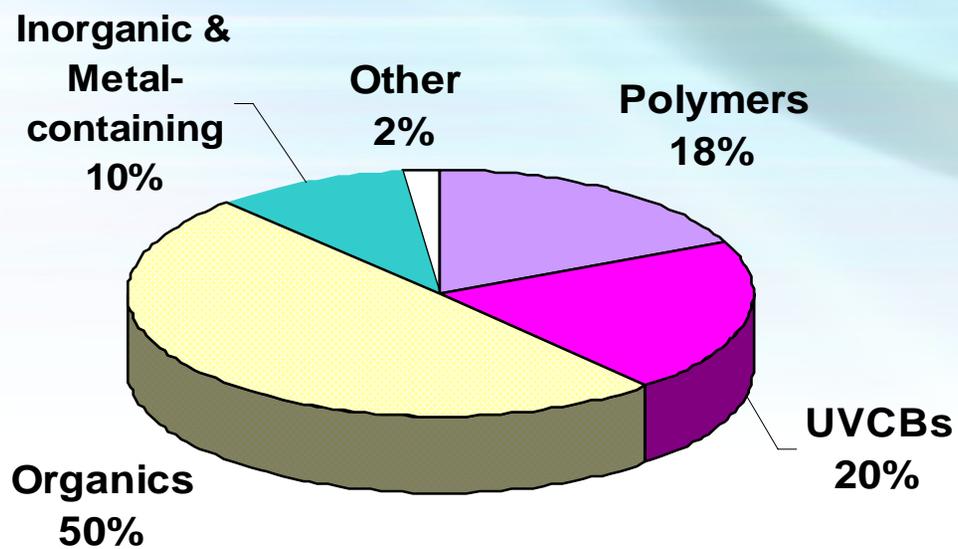
What is the Domestic Substances List?

- A list of substances that are “in commerce” in Canada – “existing substances”
- It was created in 1991 with a list of substances which were between 1984-1986:
 - In Canadian commerce or used for commercial manufacturing in Canada, or;
 - Manufactured or imported in Canada at >100 kg/year
- The DSL does not include: contaminants, by-products and wastes
- If a substance is not on the DSL, it is a “new substance”, thus subject to data submission and review prior to introduction to Canadian commerce



Types of Substances on the DSL

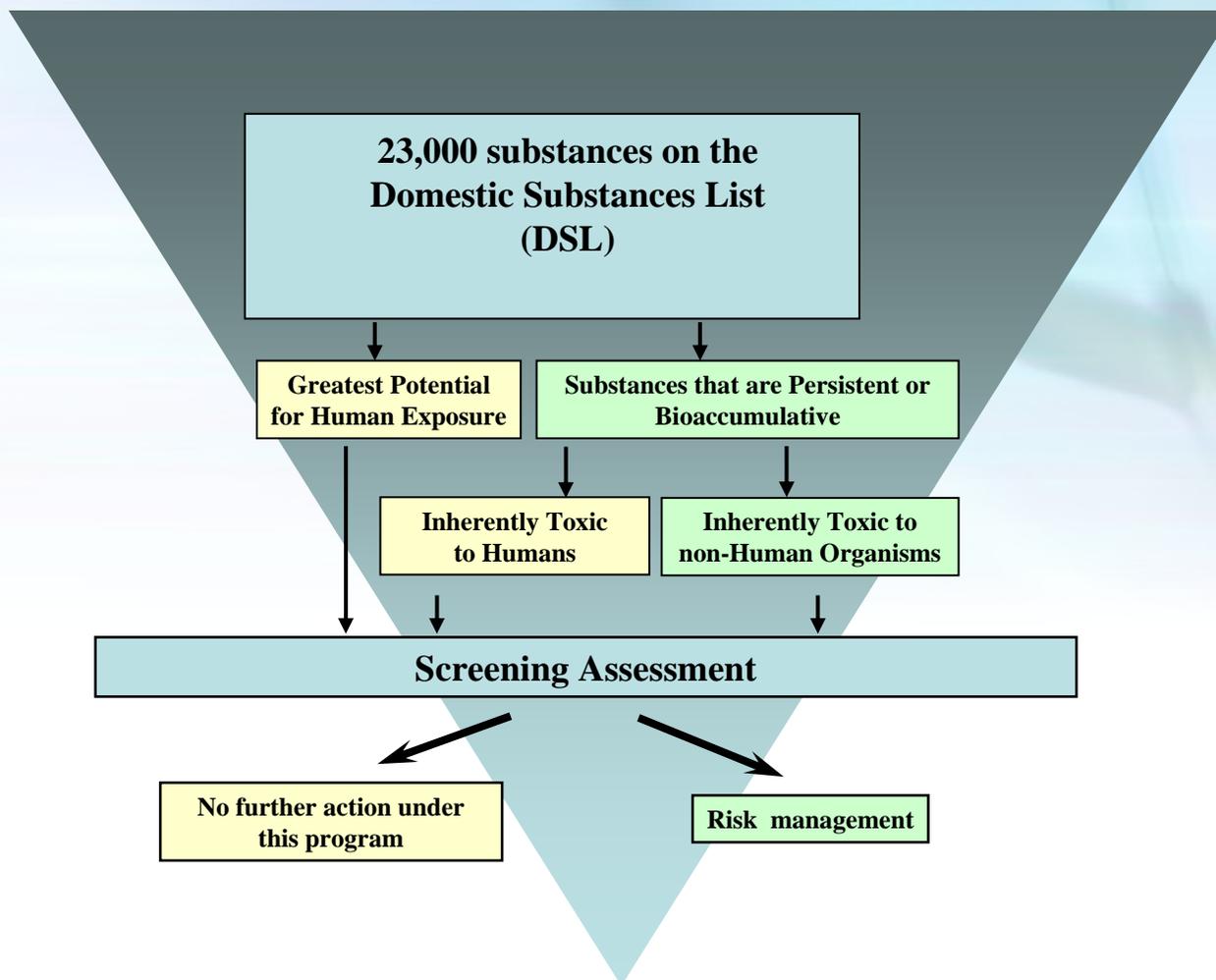
(~23,000 Substances)



What was CEPA Categorization?

- The *Canadian Environmental Protection Act, 1999* (CEPA 1999) required Ministers of the Environment and Health to categorize the 23,000 substances on Canada's Domestic Substances List (DSL) according to specific criteria
- The criteria for categorization were:
 - May present, to individuals in Canada, the greatest potential for exposure; or
 - Are persistent (P) or bioaccumulative (B), in accordance with the regulations, and inherently toxic to humans or to non-human organisms, as determined by laboratory or other studies
- Categorization represented a **priority setting exercise** that involved the identification of substances that should be subject to screening assessments and by extension, management controls if applicable

The Categorization Process



Categorization Criteria for P, B, and Non-Human iT

Bioaccumulation (B)

BAF ≥ 5000 or
BCF ≥ 5000 or
log Kow ≥ 5

Inherent toxicity (iT) – non-humans

Acute aquatic toxicity of LC(EC)₅₀ ≤ 1 mg/L, or a chronic aquatic toxicity of NOEC ≤ 0.1 mg/L

Persistence (P)

A substance is considered persistent if its transformation half-life satisfies the criterion in any one environmental medium or if it is subject to long-range transport

Medium	Half-life
Air	≥ 2 days
Water	≥ 6 months
Sediment	≥ 1 year
Soil	≥ 6 months
(or LRT)	

Categorization Criteria for Human Exposure and Human iT

Greatest Potential for Exposure

- **Simple Exposure Tool (SimET)**

Relative ranking of all DSL substances based on number of submitters, quantity in commerce and sum of expert ranked use codes. Ranking separated into one of three groups

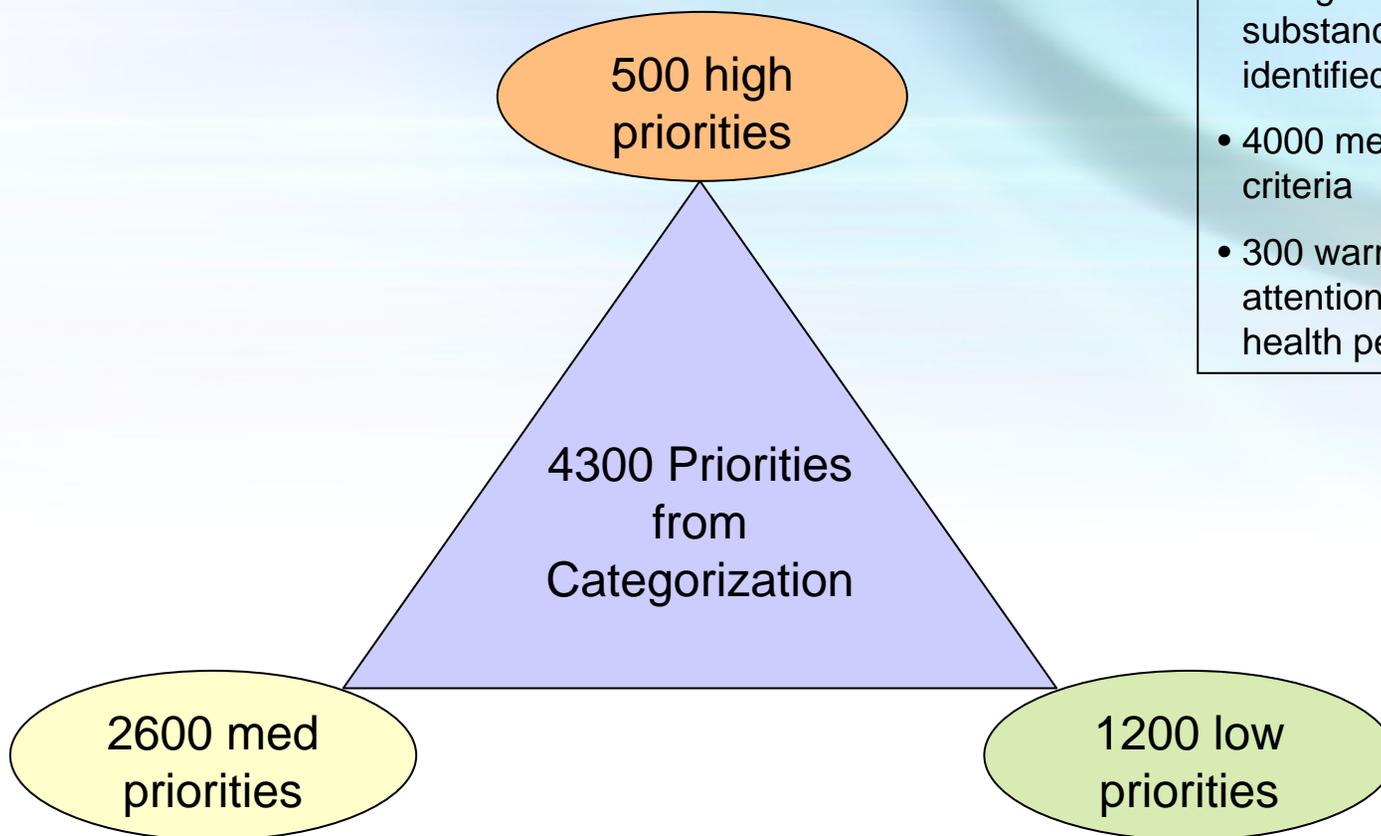
- 1) Greatest Potential for Exposure (GPE)
- 2) Intermediate Potential for Exposure (IPE)
- 3) Lowest Potential for Exposure (LPE)

Inherent toxicity to humans (iT)

- **Simple Hazard Tool (SimHaz)**

- Identification of high or low hazard compounds by various International agencies based on weight of evidence for multiple endpoints

Results of Prioritization



Through categorization, 4300 substances on the DSL were identified for further action

- 4000 met the categorization criteria
- 300 warranted further attention from a human health perspective

Completion of categorization presented an opportunity

- Government of Canada scientists, in co-operation with industry and health and environmental groups, completed **categorization** of the Domestic Substances List (DSL) by the September 2006 deadline.
- As a result, Canada has an **information base** on which existing substances can be compared and prioritized. The Government is using this information to:
 - Inform completion of obligatory risk assessments
 - Launch new programs under the Chemicals Management Plan
 - (e.g. Challenge)
 - Transform how it protects Canadians and their environment from risks associated with chemicals

Key Objectives of the Canada's Chemicals Management Plan (CMP)

- **Significantly strengthen the existing substances regime:** Categorization established a new information baseline that sets clear priorities for action that are science based
- **Integrate government activities:** The Chemicals Management Plan will strengthen CEPA's coordination with other federal statutes, including: *Hazardous Products Act, Food & Drugs Act, and Pest Control Products Act*
- **Establish government accountability:** The Plan draws on:
 - Enhanced monitoring and surveillance activities to identify priorities and measure effectiveness of regulatory actions
 - Increased research activities to ensure that action is informed by best available science
 - Enhanced risk communications to Canadians
 - Public web portal to ensure consistent access to information
 - A cyclical update of the Domestic Substances List that will require industry to report on use and volume of substances on the Canadian market
- **Strengthen industry's role by proactively identifying and safely managing risks associated with chemicals they produce and use**

Chemicals Management Plan: Program Elements

- Stakeholder feedback during design indicated a clear preference for a phased approach driven by priorities
- The initial focus of the Chemicals Management Plan is addressed through (**high priorities**):
 - **Challenge** Initiative for high concern substances in commerce
 - **Significant new activity controls (SNACs)** for high concern substances no longer in commerce
 - **Petroleum sector** as a priority with unique risk assessment and management circumstances
 - **Prohibitions** on a set of substances and creation of the virtual elimination list to demonstrate commitment and action by government
 - **Rapid screening** of lower risk chemical substances for market certainty
 - Foundational work (international engagement, research and science, monitoring, inventory update) to inform and **set priorities for next phase of priority substances**

What is the Challenge?

- It is a plan for the assessment and management of substances believed to be in-commerce and identified as high priorities for action as a result of Categorization

This included substances:

- That met each of the ecological categorization criteria (persistence (P), bioaccumulation (B) and inherent toxicity to aquatic organisms (iT), and believed to be in commerce in Canada and/or;
 - That met the criteria for greatest or intermediate potential for exposure (GPE or IPE) and were identified as posing a high hazard to human health (evidence of carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity)
 - This was complemented with industry survey data to indicate that these substances were still in commerce today
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- A Notice was published in the *Canada Gazette*, Part I December 2006 outlining the Government of Canada's intended action for the Challenge

Why Canada is using a Challenge initiative to deal with the 200 priorities for action?

- The Chemicals Management Plan relies on strong stewardship from Canadian industry.
- The Government of Canada will use existing legal tools and the regulatory process to challenge industry to provide new information about how it is managing 200 chemical substances that are potentially harmful to human health or the environment.
- Challenge to stakeholders to provide information that:
 - Improves, where possible, information for risk assessment
 - Identifies industrial best practices in order to set benchmarks for risk management and product stewardship; and
 - Collects environmental release, exposure, substance and/or product use information.
- The absence of information will not preclude government from taking action that safeguards human health and the environment.

Process for the Challenge

- The Government will publish, in 12 batches of 15-30 substances every three months, **profiles of chemical substances** and complementary **mandatory surveys**. All Challenge substances will be released within 3 years.
- Industry and other stakeholders will be asked to provide, by the specified deadline, information they may have in their possession pertaining to the questions outlined in the **survey**.
- In addition, relevant parties will be challenged to submit the specific information detailed in the **challenge questionnaire**, and comment on **substance profiles**, within 6 months.
- Completed mandatory surveys and questionnaires will be reviewed by Government of Canada scientists to determine what further actions may be necessary to ensure that the health of Canadians and their environment are protected.
- Government scientists will have a **maximum of 6 months** to publish a screening level risk assessment.

Regulatory Actions to date

Proposed prohibitions were announced in December 2006:

- *Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes)* came into force on February 9, 2007
- Proposed ***Perfluorooctane Sulfonate, its Salts and Certain Other Compounds Regulations*** were published in the *Canada Gazette*, Part I in December 2006
- Proposed ***Polybrominated Diphenyl Ethers Regulations*** were published in the *Canada Gazette*, Part I in December 2006 as a first step in the risk management of PBDEs in Canada

The Virtual Elimination (VE) List was created:

- VE is the reduction of the quantity or concentration of a toxic substance in a release into the environment below concentrations that can be accurately measured.
- VE applies to substances that are persistent, bioaccumulative, toxic under CEPA 1999 and are predominantly anthropogenic
- The VE List was established on December 13, 2007 with the addition of the substance Hexachlorobutadiene (HCBd)

Restrictions on Re-introductions and New Uses (SNACs)

- A survey of the domestic chemical industry indicated that some of the priority substances were no longer in commerce in Canada
- The Government is **controlling the re-introduction** of 148 high-hazard substances from categorization not currently in use in Canada through the Significant New Activity (SNAC) provisions of the New Substances Program
 - A SNAC notice requires industry to provide data – to be reviewed by Environment Canada and Health Canada – before the substance can be re-introduced into Canada
- A further grouping of substances of interest (human health, low exposure) will be the subject of SNACs in the coming months

Petroleum Sector Stream

- High priority petroleum substances were set aside from the Challenge because of the large number of substances that are primarily, if not exclusively, related to the petroleum sector. In addition, most of these substances are **complex mixtures** that may need to be considered differently from discrete substances.
- These substances will be addressed according to the same timeline as the Challenge (risk assessment in three years, with control measure if appropriate within CEPA timelines)
- The Government is currently developing a **work plan** and will **consult** with stakeholders in fall 2007

Medium priority substances

- The remaining medium priority substances are expected to be **addressed in total by 2020**.
- International programs, support for the research and monitoring community, and development and update of a cyclical inventory update will help the Government set priorities.
- In addition, we will work with **priority sectors** to negotiate and implement performance agreements
- The Government will consult on the approach and proposed “next round” of priorities for medium-priority substances starting in the fall/winter of 2007/2008

Low hazard, low risk substances

- A number of substances identified through categorization have a **low potential for risk**.
- The rapid screening employed for risk assessment used a worst-case scenario model to confirm the likelihood that a substance may not cause ecological harm
 - Results were released for public comment on June 23, 2007.
 - 1066 substances were subject to this approach
 - 754 substances were proposed to be “not toxic” for the criteria set out under section 64 of CEPA 1999
 - The government proposes to include the substances in the future inventory update to validate assumptions, conducting monitoring where appropriate and revisit some of the substances as part of assessments of “families of chemicals” at a later date.
 - 312 substances have been identified as requiring further assessment and have therefore been re-prioritized into the group of medium priority substances

The CMP continuum: key to an efficient science-based regulatory regime for chemicals

Support for Research:

- The Government will **enhance regulatory science** by leading research and partnering with external research bodies in order to inform risk assessments and regulatory interventions
 - Thus ensuring that action on the part of governments, Canadians, and industry are informed by the best available science

Integrated Monitoring:

- The Government will build on the new baseline of information from categorization by implementing a **national health and environment monitoring and surveillance program** that:
 - Identifies emerging priorities and tracks Canadians' exposure to toxic substances; and,
 - Measures the effectiveness of our regulatory actions so that we know what works best

Inventory Update

- The Government will **develop and implement a cyclical inventory update** provision for CEPA's Domestic Substances List
 - This will require industry to report on the substances they use, and the volume of these substances on the Canadian market

Considerations for Breakout Session: Sharing of the Canadian Experience

- **Some Key Contributors to success**

- Mandated program, accountability through legislated deadline helped to create a focus on priorities while remaining grounded in risk-based, science driven approaches
- Commitment to engage stakeholders early in process
- Engaging international expertise in development of technical approaches to ensure future sharing and management of work
- The development of an information base from Categorization has allowed the development and launch of the CMP which will advance new, proactive measures to ensure chemical substances are managed safely using the best available tools for required control measures
- Shifting burden of proof to industry to establish assurance of safety
- Not just limited to chemicals for which there is a large database

- **Key Challenges or obstacles encountered**

- Was a precedent setting exercise, no models out there to follow
- Data
 - Availability of empirical data for substances
 - Original data reported on uses and quantities of DSL was dated
 - Use of QSARs and modelled data
- Required the development of technical approaches and strategic guidance
 - Inorganics, Polymers, UVCBs, QSARs
- Two organizations needed to converge to provide one path forward based on outcomes
- Required development of approaches for different regulatory groups to work together to assess and manage chemicals (co-ordination, different methods, different tools)

Other potential considerations

- Canada is largely an 'importer' with much more manufacturing occurring in US
- While CEPA provides regulatory tools to obtain information, finding balance with other approaches was necessary to leverage voluntary programs that can often prove to be more effective or efficient
- Future work will help refine and validate previous work promoting improvement within programs. For example:
 - Concept of Challenge to discover best/latest information
 - Introduction of Inventory Update
- Program expertise, experienced stakeholder engagement relationships and targeted legislative design will ensure the most efficient and effective management outcomes to best protect Canadians and their environment
- Use of precaution in the risk based decision-making process

Contact Information

Chemical Substances Web Site:

- www.chemicalsubstanceschimiques.gc.ca

***CD-ROMS with results of DSL Categorization available upon request**



ANNEX

Timeframe for implementing the CMP

Canadian Environmental Protection Act

Prohibitions
Apply significant new activity provisions
Notice of Intent for Challenge, DSL Corrections, and Rapid Screening
Implement Assessment Challenge (rolling deadlines decisions)
Negotiated performance agreements
Generic rapid screening
Assessment of medium priorities

Pest Control Products Act

Accelerate re-evaluation of older pesticides
Review and Registration of New Products (ongoing)
Pesticide Risk Indicators, Incident Reporting System

Food and Drugs Act

Cosmetics Regulations: Mandatory Ingredient Labelling
PPCP Regulations
Pharmaceuticals disposal guidelines

Program Activity

Research, monitoring and surveillance, inventory updates, risk communication

Dec 06

Mar 07

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2008

2009

2010

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2020

