

Results of DSL Categorization and the Way Forward: Chemicals Management Plan

Task Force Promoting Safer Chemicals in Consumer Products
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Augusta, Maine



Government
of Canada

Gouvernement
du Canada

Canada

Purpose for Today

- Provide a background on Canada's approach on chemical substances
- Provide an overview of the Chemicals Management Plan recently announced by the federal government
- Opportunity to ask questions on implementation of the Chemicals Management Plan



Overview

- Legislation of Chemical Substances in Canada
- Context: Results of DSL Categorization
 - What is DSL Categorization?
 - Consistent way to identify priorities
 - Plan to address “categorized substances”
- Chemicals Management Plan
 - Key Policy Objectives
 - Approaches:
 - Challenge to industry
 - Sector approaches
 - Substances not in use



Chemical Substances in Canada

- In Canada, municipal, provincial, territorial and federal governments all play a role in managing chemical substances.
- The Government of Canada has many laws and programs dedicated to protecting human health and the natural environment from chemical risks.
- Its primary legal tool for assessing and managing chemical substances in the environment is the *Canadian Environmental Protection Act, 1999* (CEPA 1999), jointly administered by Environment Canada and Health Canada.



Other Government of Canada Programs and Agencies...

- 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, including:
- 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



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 big part of CEPA 1999
- Requires every new chemical substance made in Canada or imported from other countries since 1994 be assessed against specific criteria.
- The Domestic Substances List (DSL) is the sole basis for determining whether a substance is "existing" or "new" to Canada.



What is Categorization?

- Mandated under CEPA 1999 (S. 73)
 - Ministers were required to categorize the 23,000 substances on the DSL by September 14, 2006
 - Categorization is a prioritization process that involves the systematic identification of substances on the DSL that should be subject to screening assessment (Section 74, CEPA 1999)
- Identify substances, based on available information, that:
 - May present, to individuals in Canada, the greatest potential for exposure; or
 - Are persistent (P) or bioaccumulative (B), in accordance with the Persistence and Bioaccumulation Regulations under CEPA 1999, and inherently toxic to humans or to non-human organisms, as determined by lab or other studies



Completion of Categorization is an opportunity

- Government of Canada scientists, in co-operation with industry and health and environmental groups, completed the categorization process by the Sept. 14, 2006 deadline
- Until now, Canada has not had a consistent information base on which the thousands of existing substances potentially in commercial use could be compared and prioritized
- The Government will use this information base to transform how it protects Canadians and their environment from risks associated with the chemicals we use
- Since 1994, Canada has assessed and managed the risks to health and environment from new substances being imported into or created in Canada
- Internationally, new initiatives such as REACH and ongoing programs focused on High Production Volume Programs (e.g., OECD, US) provided Canada with an opportunity to identify its own path forward

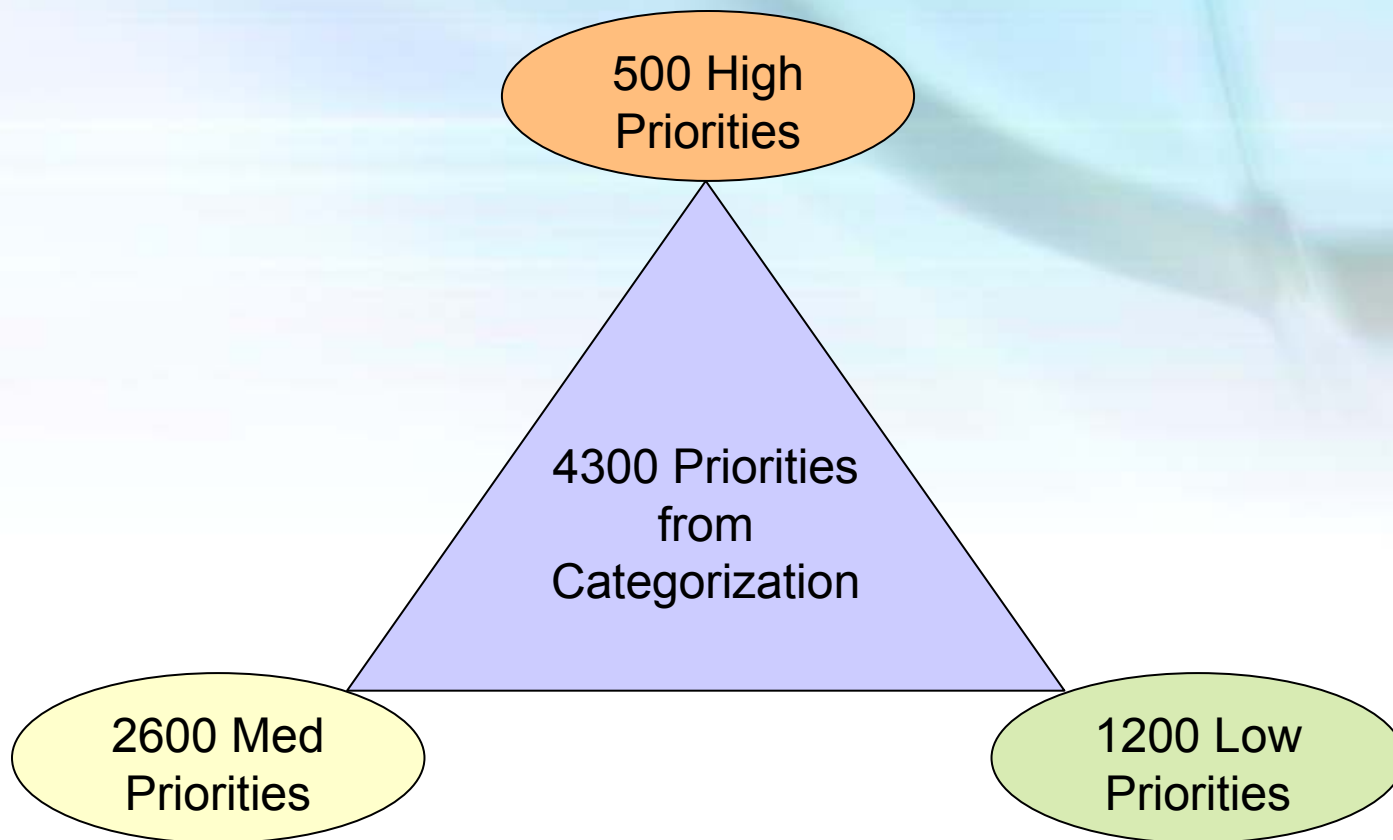


Results of Categorization brings a challenge: how to distinguish “Priorities among Priorities”

- 4300 substances on Canada’s Domestic Substances List have been identified as requiring further work/action
 - 4000 met the categorization criteria
 - 300 warrant further attention from a human health perspective
- Considerations for the first round of priority setting and upcoming actions :
 - The degree of hazard/risk
 - Commercial activity in Canada
 - Existing/ongoing risk assessment and risk management activities
 - Opportunities to engage internationally and “share the work” for a global issue



From 23,000 to 4300 Substances



Key Objectives of the Chemicals Management Plan

- **Significantly strengthen the existing substances regime:** Categorization has established a new information baseline that sets clear priorities for action
- **Integrate Governments Activities:** 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 includes regulations that will draw on:
 - Enhanced monitoring and surveillance activities
 - Increased research activities
 - Enhanced risk communications to Canadians
 - A cyclical update of the Domestic Substances List
 - Public web portal
- **Strengthening industry's role in proactively identifying and safely managing risks associated with chemicals they produce and use.**



Chemicals Management Plan

Canada's Chemicals Management Plan includes:

- Prohibitions;
- Virtual Elimination;
- Challenge Program;
- Restrictions on re-introduction and new uses (SNACs);
- Rapid screening of lower risk chemical substances;
- Monitoring & Surveillance and Research; and
- Integrating Government's Chemical Activities
 - mandatory ingredient labelling of cosmetics;
 - regulations to address environmental risks posed by pharmaceuticals and personal care products;
 - enhanced management of environmental contaminants in food;
- Performance agreements recognizing industry leadership



Prohibitions on Five Categories of Toxic Substances

2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes

Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes) will come into force on February 9, 2007.

→ restrict the manufacture, use, sale, offer for sale and import of these substances

Perfluorooctane Sulfonate, its Salts and Certain Other Compounds (PFOS)

Proposed *Perfluorooctane Sulfonate, its Salts and Certain Other Compounds Regulations Regulations* will shortly be published in the *Canada Gazette*, Part I.

→ prohibit PFOS and products containing PFOS with a limited number of exemptions proposed

Polybrominated Diphenyl Ethers (PBDEs)

Proposed *Polybrominated Diphenyl Ethers Regulations* will shortly be published in the *Canada Gazette*, Part I as a first step in the risk management of PBDEs in Canada.

→ focus on the three PBDEs that pose the greatest threat to the environment



Virtual Elimination (VE)

- 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 meet the following criteria
 - Persistent
 - Bioaccumulative
 - Toxic under CEPA 1999
 - Predominantly anthropogenic
- Substances that meet these criteria will follow the CEPA 1999 process for addition to the VE List
- The VE List was established on December 13th with the addition of the substance Hexachlorobutadiene (HCBD) .



Top 500 Priorities

Within the Chemicals Management Plan, the top 500 priorities are addressed through 4 components:

- Challenge Program
- Significant New Activity Controls (SNACs)
- Petroleum Sector Stream
- Substances that are already in the assessment or management stream



Top 200 Priorities for Action - Challenge

- There are three products to the Challenge:
 - substances profiles,
 - mandatory s.71 surveys, and
 - a questionnaire.
- 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.
- Starting early in 2007, the federal government will publish, in batches of 15-30 substances every three months, profiles of chemical substances and complementary mandatory surveys. Industry and other stakeholders will be asked to provide information in their possession pertaining to the questions outlined in the survey. All challenge substances will be released within 3 years.
- In addition, relevant parties will be challenged to further submit the specific information detailed in the challenge questionnaire within a ***maximum of 6 months***, after which government scientists will have a ***maximum of 6 months*** to review the information provided.
- 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.
- If the requisite information is not provided or does not respond to the information sought, the Government of Canada will nevertheless take action to safeguard human health and protect the environment in accordance with CEPA processes.

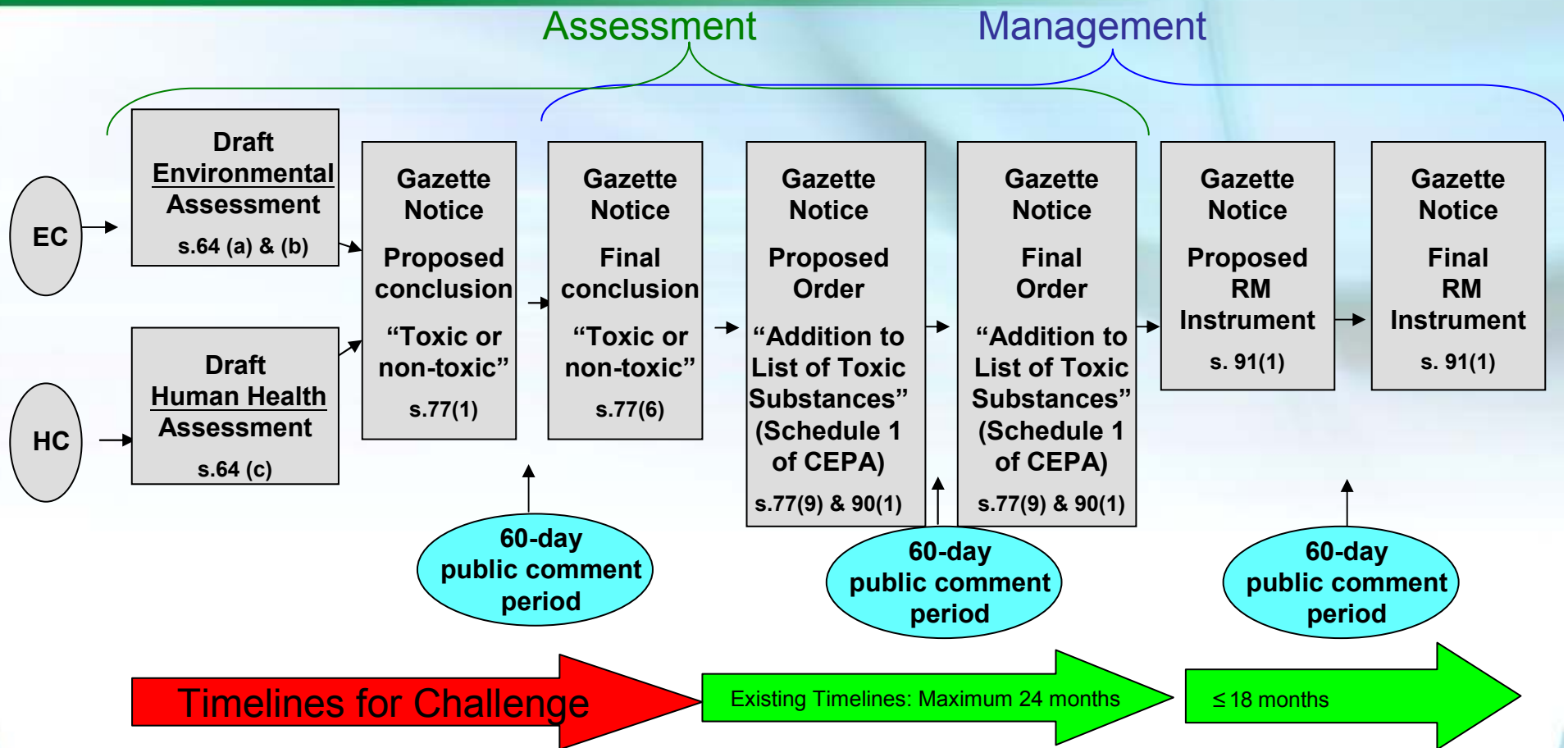


Challenge continued...

- The mandatory s.71 survey is targeted to Canadian companies that imported or manufactured ≥ 100 kg for all Batch 1 substances except Naphthalene and cyclohexylphenoxy dinitrile.
- Information requested for 2006 calendar year
 - Manufacture, Import and Use Quantities
 - Use Codes
 - Customer List
 - Release Data
 - Concentration
- If information has already been provided to the Government of Canada (i.e. through NPRI) stakeholder are asked to specify to which department.



Risk Assessment and Risk Management Process under CEPA 1999



Restrictions on Re-introductions and New Uses (SNAcs)

- Evidence of commercial activity in Canada was obtained through the results of a S.71 Notice (survey) issued in March 2006.
- In December 2006, the Government of Canada began issuing Significant New Activity requirements under CEPA 1999. These will affect approximately 150 high-hazard (PBiT) chemical substances not currently in use in Canada as per survey results.
- These notices mean industry must provide data (under the New Substances Program) to be reviewed by Environment Canada and Health Canada before any of the chemical substances on the list can be re-introduced into Canada.
- In the spring 2007, these provisions under CEPA 1999 will be proposed for some substances that have inherently hazardous properties for humans.



Rapid Screening of low hazard, low risk substances

- Some substances met categorization criteria based on hazard despite the fact that many may not be priorities for assessment based on their low potential for risk
- We believe that these substances, are not likely to pose a risk to the environment in the amounts at which they are found.
- The accelerated screening approach will apply a worst-case scenario to determine whether further assessment is necessary.
- It is expected that 1200 substances meeting categorization are in fact low priorities.
- Results will be released for public comment in the Spring of 2007.



Focus attention where attention is due: Criteria used to establish the list of substances of Highest Concern

- Substances that are Persistent (P) and Bioaccumulative (B) and inherently toxic to non-human organisms (iT):
 - For substances that are P, exposure can not easily be reduced by discontinuing production. Problems caused by persistent chemicals are, therefore, long-lasting
 - Persistent substances that are bioaccumulative concentrate up to several orders of magnitude. They can reach concentrations where adverse effects occur even at low levels of exposure in the environment
- Substances that are high hazard and a high potential for human exposure
 - Greatest Potential for Exposure or Intermediate Potential for Exposure and high human health hazard



Integrating the Government's Chemical Activities

- The information base provided by categorization will enable greater integration across current federal chemicals regimes
- We now know more about the hazards, exposures, uses, sectors, and regulatory regimes associated with chemicals in Canada
- Activity undertaken under these regimes will ensure that the risks posed to Canadians and the environment are lessened
 - Older pesticides will be reviewed and the review process for newer, safer pesticides will be accelerated
 - Control measures will be developed to ensure that Canadians' food is safe from the risks associated with chemicals
 - Regulations will be developed to address risks to Canadians and Canada's ecosystems posed by pharmaceuticals and personal care products that are released into the environment
 - Cosmetics products will require content labels



Working from a systems perspective to deliver the Chemicals Management Plan

- **Categorization highlights the advantages of establishing a strong information base from which to advance a regulatory agenda**
- **The Government will build on this information base 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**
- **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**
- **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**



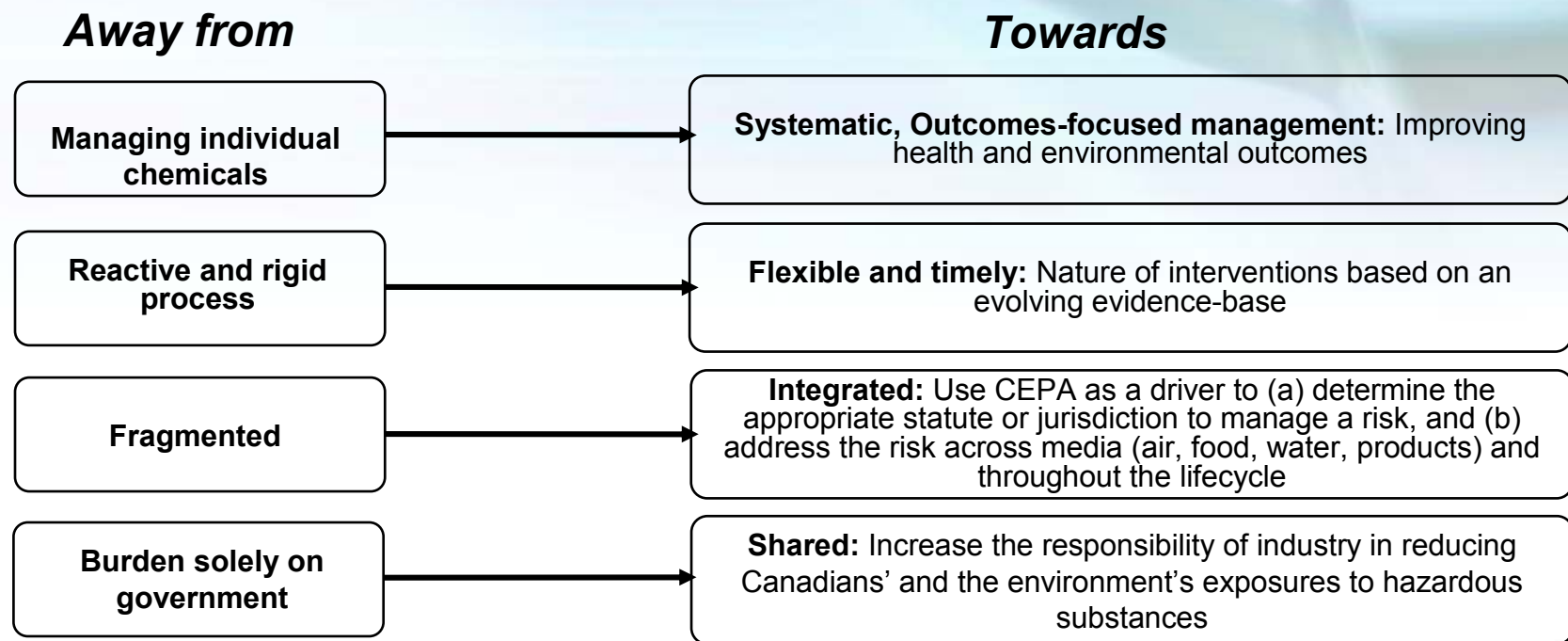
Additional work on the current and next round of Priorities:

- International Actions:
 - Approximately 600 of the 4300 substances are being addressed under international programs (e.g., HPV) and with coming passage of REACH, new information will become available over time
 - Canada must determine its role, priorities and delivery schedule in the international arena
 - Opportunity to fill a niche overlooked outside HPV programming
 - Explore opportunities for advancing domestic priorities through international programmes
 - Examine procedures to complement existing programs
- Research and monitoring must be aligned to support ongoing program priorities through measuring performance and improving tools, as well as identifying emerging issues and trends
- Working with priority sectors to negotiate and implement performance agreements
- Continued consideration of remaining feeder groups to adjust and refine priorities



New information will promote an evolution in how chemicals are managed in Canada

- With domestic and international programs generating much more information on chemical safety, there can be a shift



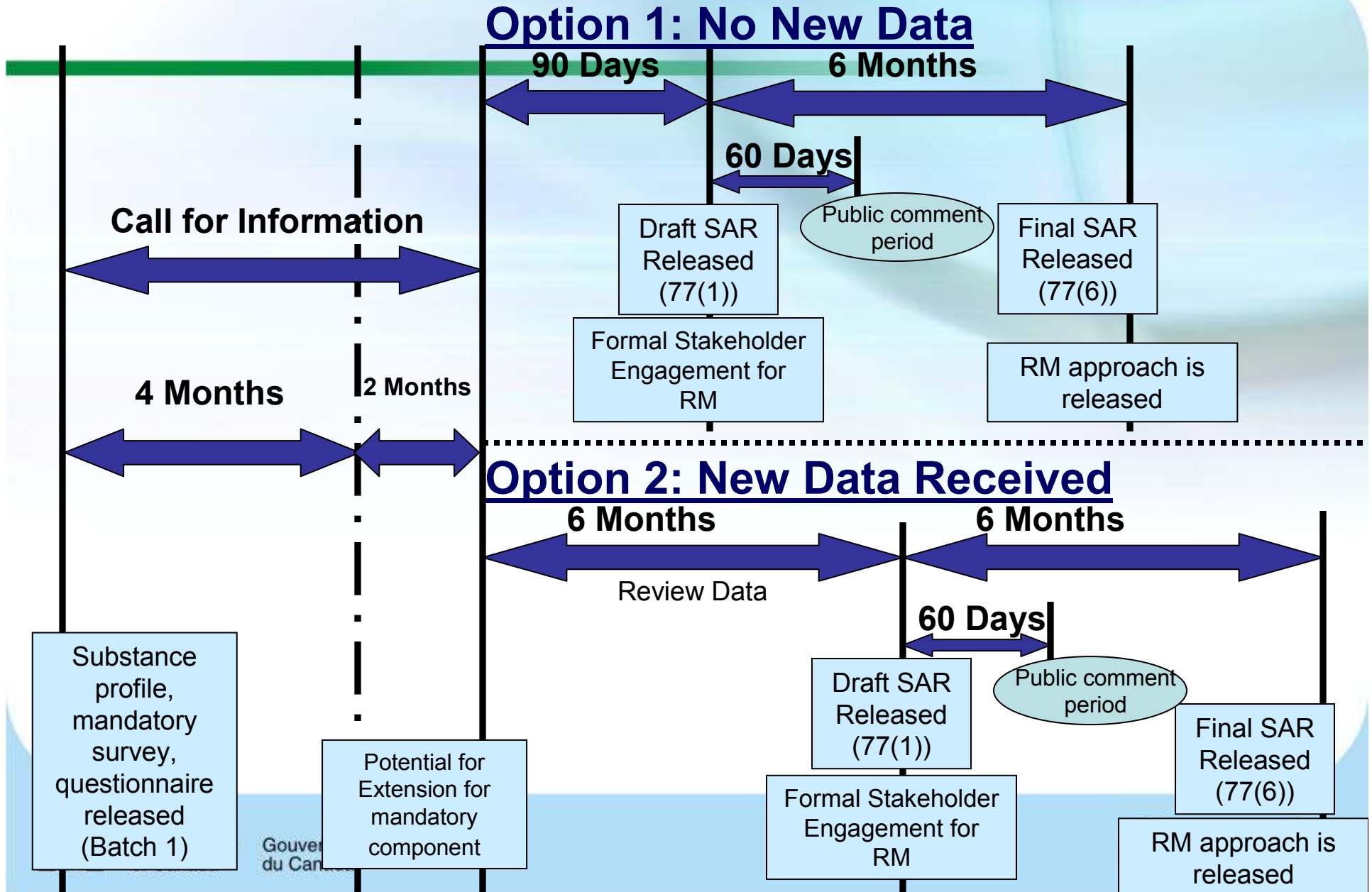
Contact Information

Website:

- **Chemical Substances Web Portal:**
<http://www.chemicalsubstances.gc.ca>
- **Challenge:**
http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index_e.html
- **CD ROMS with results of DSL Categorization are available upon request.**



Timelines for the Challenge



Batch 1 Substances

CAS#	Chemical Name
75-56-9	Oxirane, methyl-
78-63-7	Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)
91-08-7	Benzene, 1,3-diisocyanato-2-methyl-
91-20-3	Naphthalene
106-88-7	Oxirane, ethyl-
120-80-9	1,2-Benzenediol
123-31-9	1,4-Benzenediol
584-84-9	Benzene, 2,4-diisocyanato-1-methyl-
1068-27-5	Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl)
6731-36-8	Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl)
12236-64-5	2-Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy-
26471-62-5	Benzene, 1,3-diisocyanatomethyl-
43035-18-3	Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[[4-methoxyphenyl]amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1)
54079-53-7	Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl]ethylamino]-2-methylphenyl]methylene]-
59487-23-9	2-Naphthalenecarboxamide, 4-[[5-[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-



Batch 2 Substances

62-56-6	Thiourea
78-79-5	1,3-Butadiene, 2-methyl-
80-05-7	Phenol, 4,4 -(1-methylethylidene)bis-
106-89-8	Oxirane, (chloromethyl)-
108-05-4	Acetic acid ethenyl ester
540-97-6	Cyclohexasiloxane, dodecamethyl-
541-02-6	Cyclopentasiloxane, decamethyl-
556-67-2	Cyclotetrasiloxane, octamethyl-
732-26-3	Phenol, 2,4,6-tris(1,1-dimethylethyl)-
1344-37-2	C.I. Pigment Yellow 34
2778-42-9	Benzene, 1,3-bis(1-isocyanato-1-methylethyl)-
4474-24-2	Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt
12656-85-8	C.I. Pigment Red 104
15086-94-9	Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-3',6'-dihydroxy-
70161-19-2	Benzenesulfonic acid, [(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)bis(imino-4,1-phenyleneoxy)]bis-, disodium salt
83006-67-1	Benzenesulfonic acid, 2,2 -[(9,10-dihydro-5,8-dihydroxy-9,10-dioxo-1,4-anthracenediyl)diimino]bis[5-(1,1-dimethylethyl)-, disodium salt
125351-99-7	9,10-Anthracenedione, 1,4-bis[(4-methylphenyl)amino]-, sulfonated, potassium salts

