



Government
of Canada

Gouvernement
du Canada

Overview of Canada's Chemicals Management Plan

Health Canada – PAHO Workshop
Lima, Peru
November 8-10, 2016



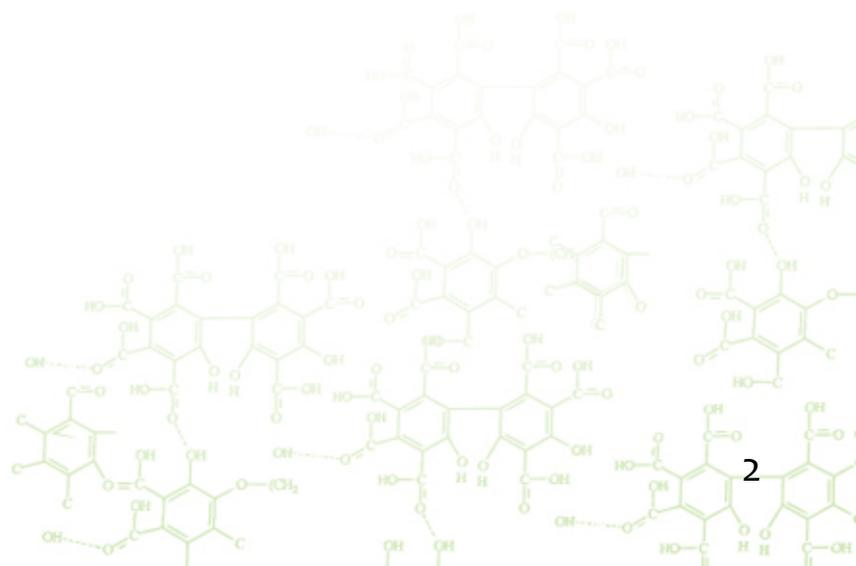
CHEMICALS
MANAGEMENT
PLAN

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Canada 

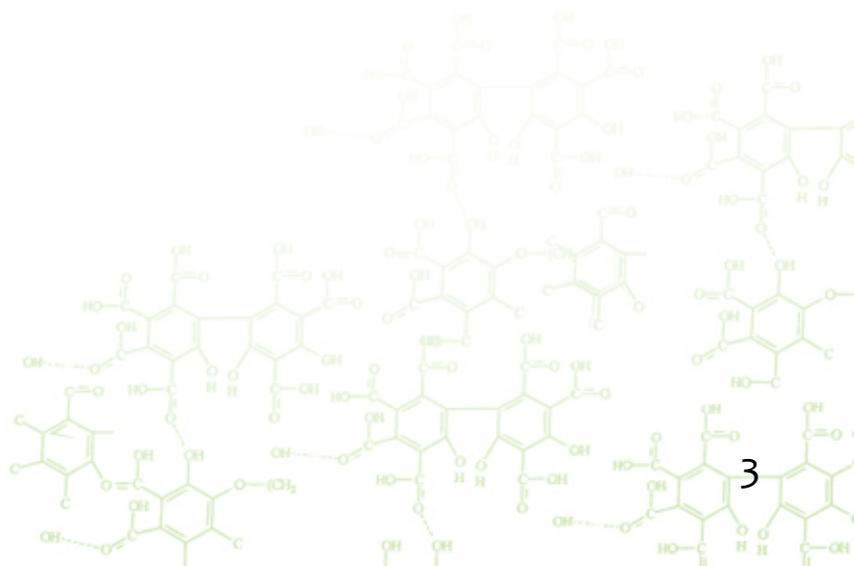
Outline

- Introduction to CMP
- Implementing the CMP
- Activities under the CMP
- Progress To Date



Implications of Results of Categorization

- Categorization of DSL identified 4300 substances for further consideration (September 2006)
- CEPA 1999 required Ministers of the Environment and of Health to conduct screening assessments on substances meeting the categorization criteria and, by extension, implement management controls if applicable



Canada's Chemicals Management Plan

- The Prime Minister of Canada announced the Chemicals Management Plan (CMP) in December 2006
 - The CMP built on categorization initiative to improve protection against hazardous substances
 - Included new, proactive measures to ensure chemical substances are managed properly
- The CMP set clear priorities for assessing and managing chemical substances used in Canada and provided:
 - An integrated, government-wide approach to chemicals
 - Targeted action on chemicals of higher concern
 - Transparent, predictable timelines
 - Integration of Research and Monitoring programs between Environment Canada and Health Canada and aligned to priorities
 - A basis to promote international collaboration
 - Enhanced stakeholder engagement



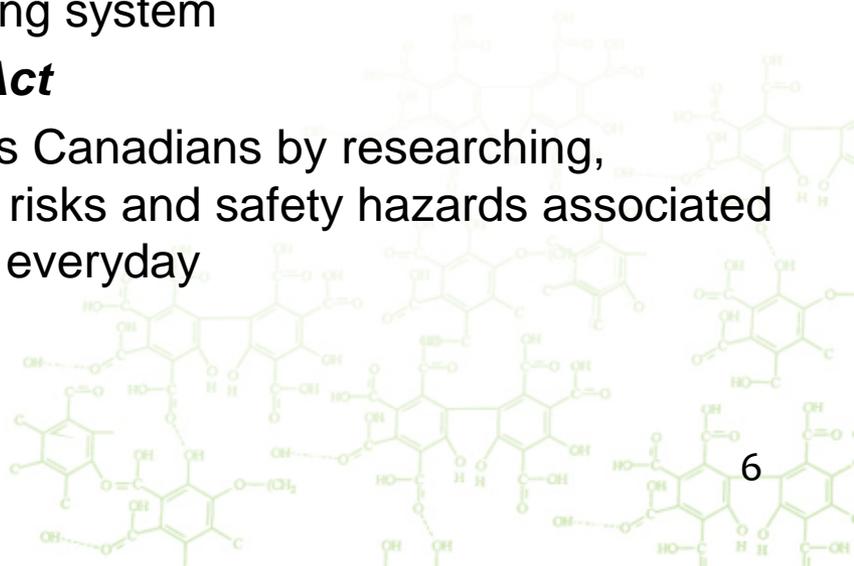
Key Objectives for Canada's CMP

- Canada is a participant to the *Strategic Approach to International Chemicals Management* (SAICM). SAICM is a policy framework adopted in February 2006 to foster the sound management of chemicals.
- The CMP is the Government of Canada's response to SAICM. It is designed to meet the 2020 goals set by the World Summit on Sustainable Development for sound management of chemicals.
- The CMP provides a framework for assessment and management of ~4,300 substances identified through categorization.
- The CMP integrates federal programs into a single strategy to ensure that chemicals are managed appropriately in order to prevent harm to Canadians and their environment.



Integrated Approach

- In addition to CEPA 1999, there are several other Government of Canada programs and agencies involved in assessing and managing the risks from chemical substances, to protect human health and the environment, 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
 - Includes the evaluation of new pesticides; re-evaluation of older pesticides; pesticide incident reporting system
 - **Canada Consumer Products Safety 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

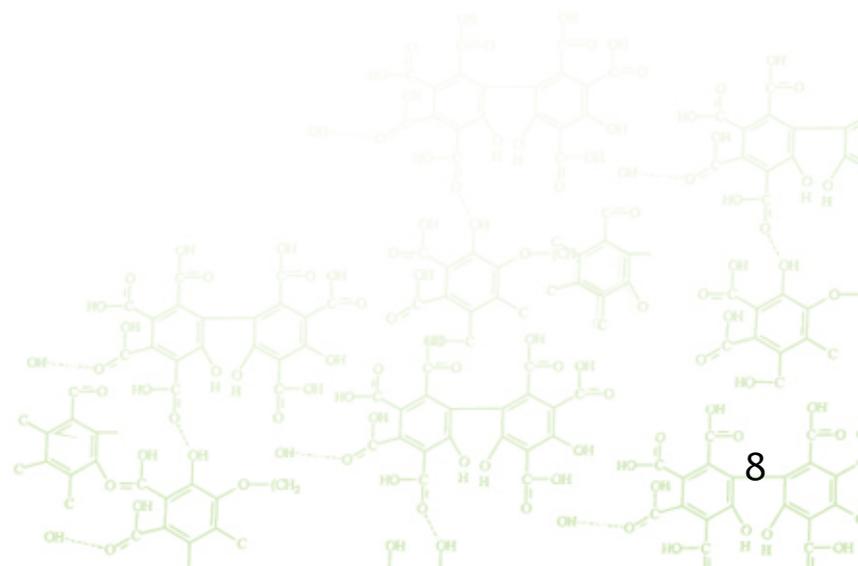


Chemicals Management Plan



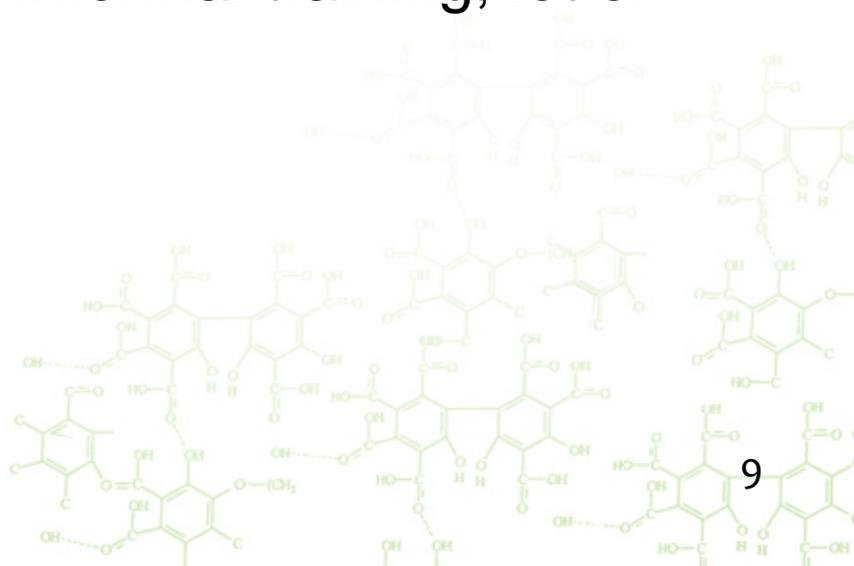
Implementing the CMP Phase I

- Acquire resources
- Establish processes
- Prioritize the priorities



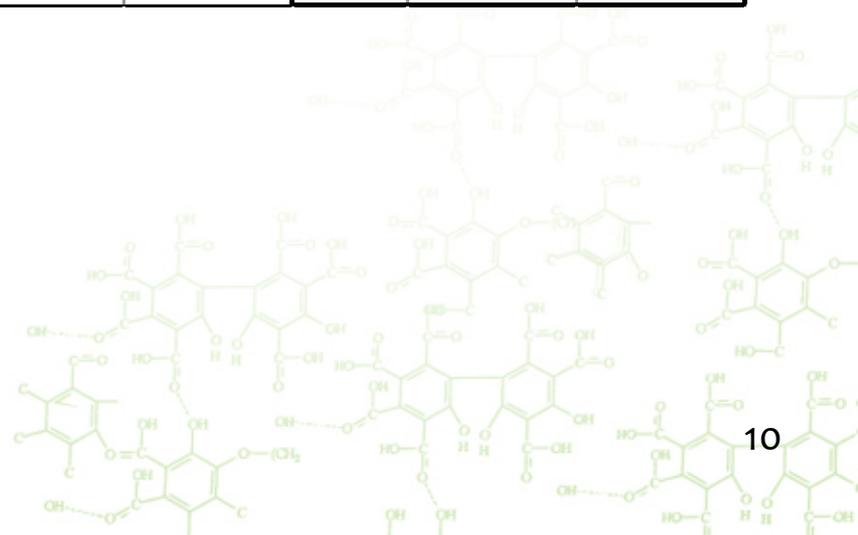
Capacity Building

- Extensive hiring campaign to increase capacity
 - Health Canada
 - Increase from 8-10 assessment staff for PSL to 20-30 for categorization to 70-75 for staff dedicated to risk assessment under CMP
 - Environment and Climate Change Canada
 - 30-40 staff dedicated to risk assessment under CMP
- Organized in-house formal and informal training; lot of “on-the-job learning” required



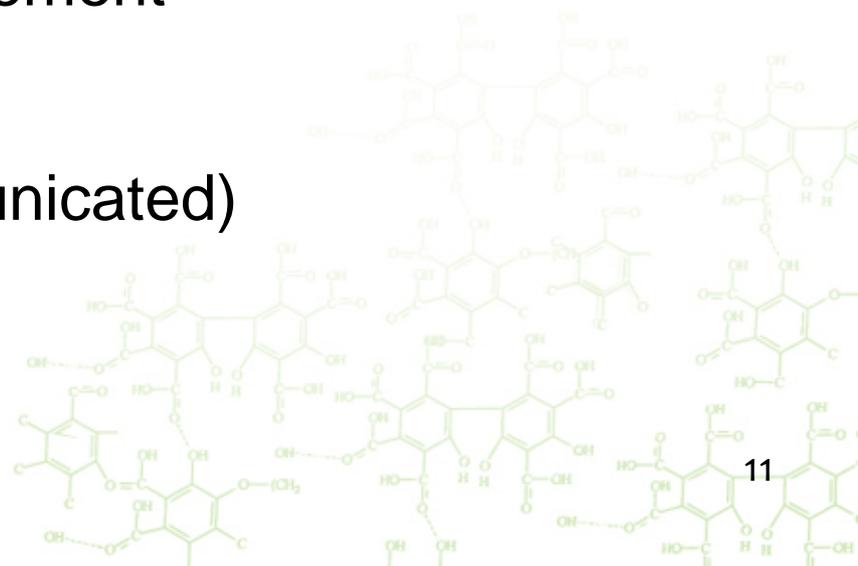
Budget: CMP 1, 2 & 3

		Health Portfolio			Environment Canada			Total		
		FTE	Total (M) annual	Total (M) 4/5 year*	FTE	Total (M) annual	Total (M) 4/5 year*	FTE	Total (M) annual	Total (M) 4/5 year*
CMP3 (TBC)	2016-17 to 2020-21	357.0	65.1	325.3	168.4	29.5	147.5	525.4	94.6	472.8
CMP2	2013-14	376.8	73.628	358.4	168.4	29.5	147.5	539.1	103.2	516.0
CMP1**	2010-11	316.9	91.9	192.7	188.7	32.8	107.3	505.6	124.7	300.0



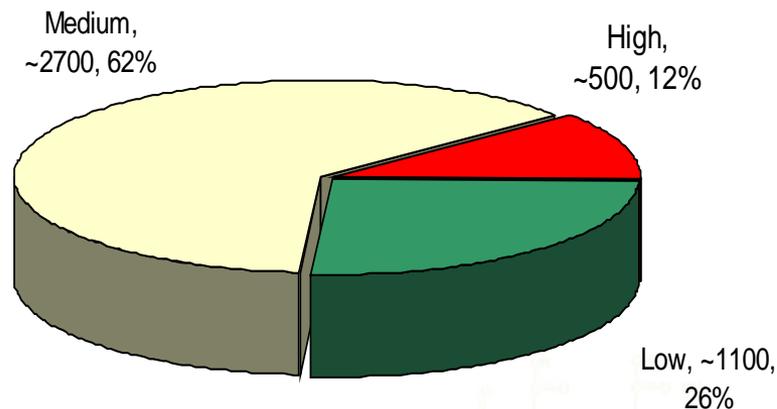
Process

- Key elements
 - Integration of HC & EC work streams
 - Information acquisition
 - Expert input & peer consultation/review
 - Internal reviews & approvals
 - Stakeholder & public engagement
 - Outreach & communication
 - Timelines (publically communicated)

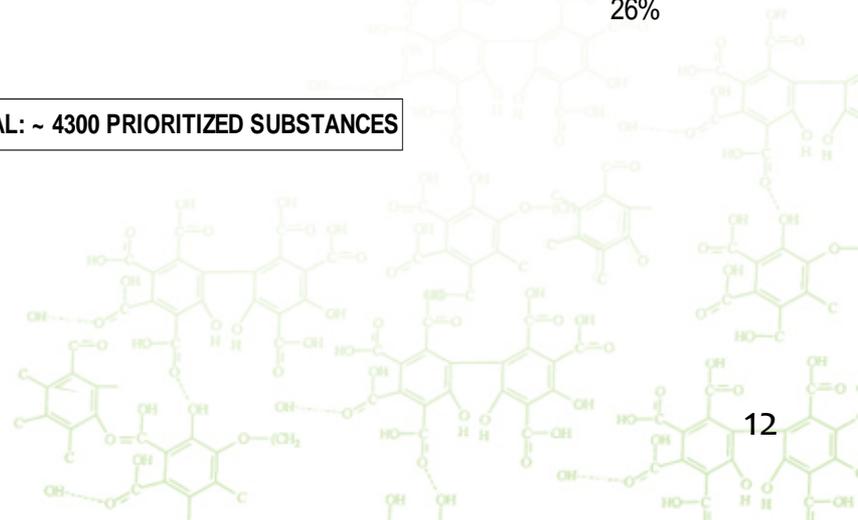


Prioritizing the Priorities

- CMP directed that substances of highest concern of those identified in categorization be addressed initially
 - “Focus attention where attention is due”
 - Substances that were P, B and iTeco, and in commerce in Canada; **and/or** GPE or IPE and “high health hazard” (i.e., classified as carcinogenic, mutagenic, devo/repro toxic)
 - Capitalized on information gathered during categorization process
- Further prioritized substances based on consideration of:
 - 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

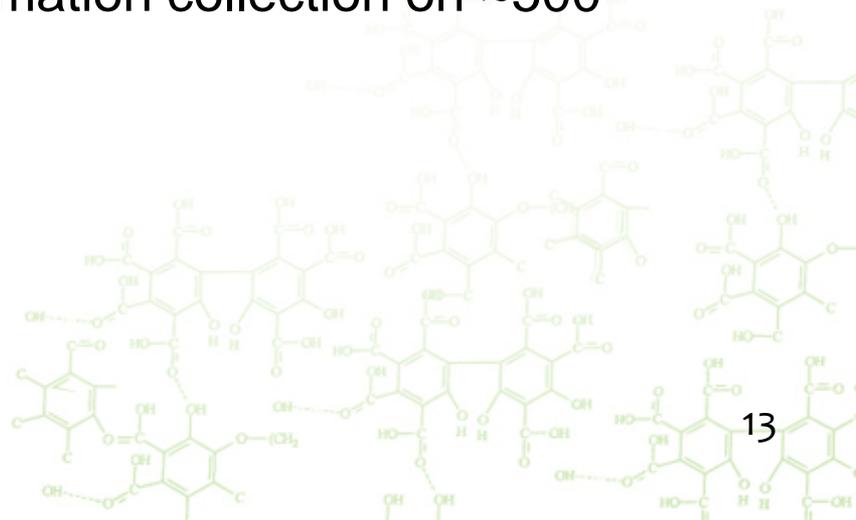


TOTAL: ~ 4300 PRIORITIZED SUBSTANCES



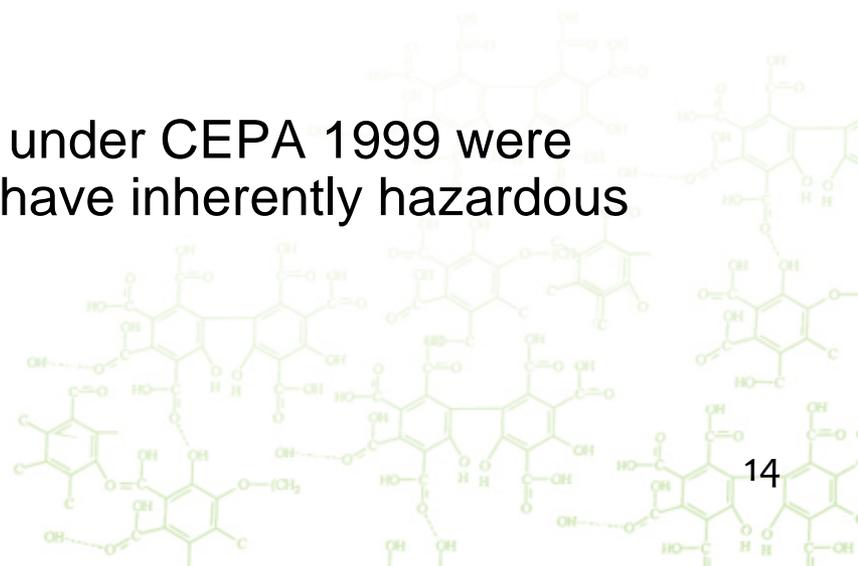
CMP Phase 1 Activities

- Key Assessment Activities to Address CMP1 Priorities:
 - Significant New Activity (SNACs) for substances believed to not be in commerce
 - Rapid screening
 - Targeted Sectoral Stream Approach (Petroleum)
 - The Ministers' Challenge Program
- DSL Inventory Update Phase 1 (information collection on ~500 substances)



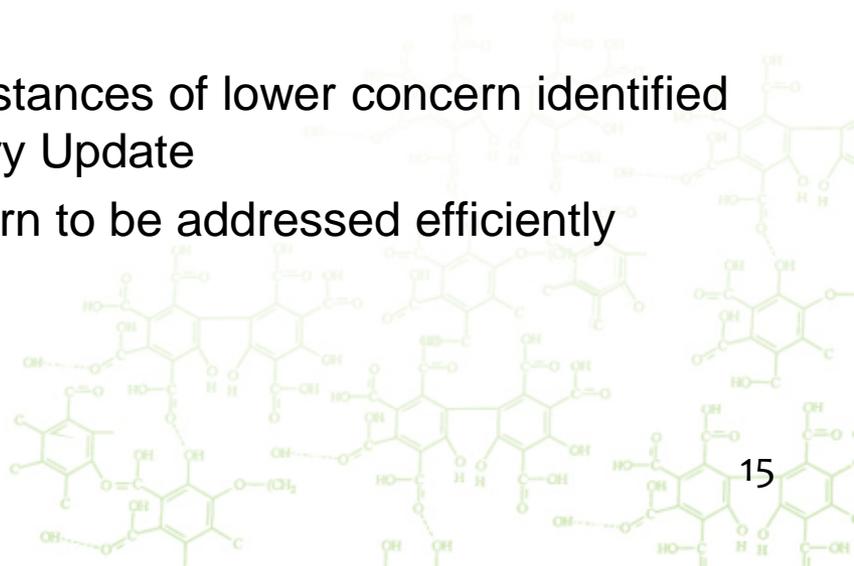
Restrictions on Re-introductions and New Uses (SNAcs)

- 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 affected approximately 150 high-hazard (PBiT) chemical substances not in use in Canada at that time as per survey results.
- The notices meant 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 were proposed for some substances that have inherently hazardous properties for humans.



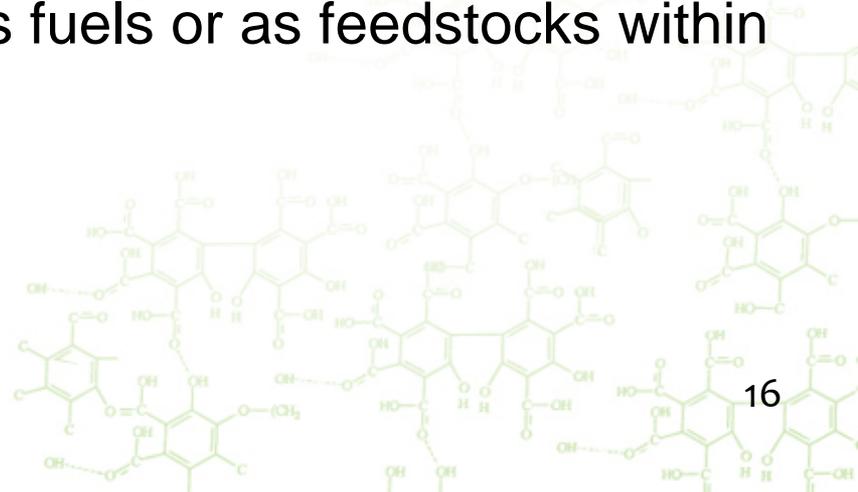
Rapid Screening Approach

- Approach uses a series of qualitative and quantitative steps to evaluate the likelihood that a substance may cause harm based on conservative exposure estimates
- A substance will be:
 - Identified as requiring further assessment if at any time during the process it appears to present potential harm
 - Concluded as unlikely to meet the criteria under S.64 of CEPA 1999 if it passes each step successfully
- As the CMP continued:
 - This approach was further used for substances of lower concern identified from Phase 1 and 2 of the DSL Inventory Update
 - This allows for substances of low concern to be addressed efficiently



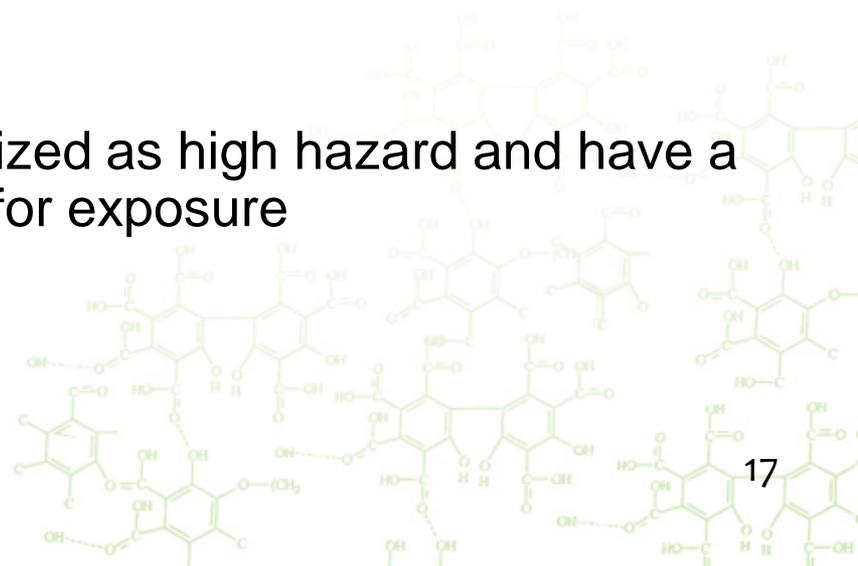
Petroleum Sector Stream Approach (PSSA)

- A sector approach was taken for ~160 high priority substances PSSA substances (divided into categories or “Streams”)
- These substances were chosen to be addressed under an approach specific to the petroleum sector because they were:
 - primarily, if not exclusively, related to the petroleum sector
 - complex mixtures that may need to be considered differently from discrete substances
- It was expected that a large portion of the PSSA substances are limited to petroleum sector facility sites, meaning that they are used for blending into finished marketed products; confined within an oil & gas facility; or consumed as fuels or as feedstocks within a petroleum sector facility.



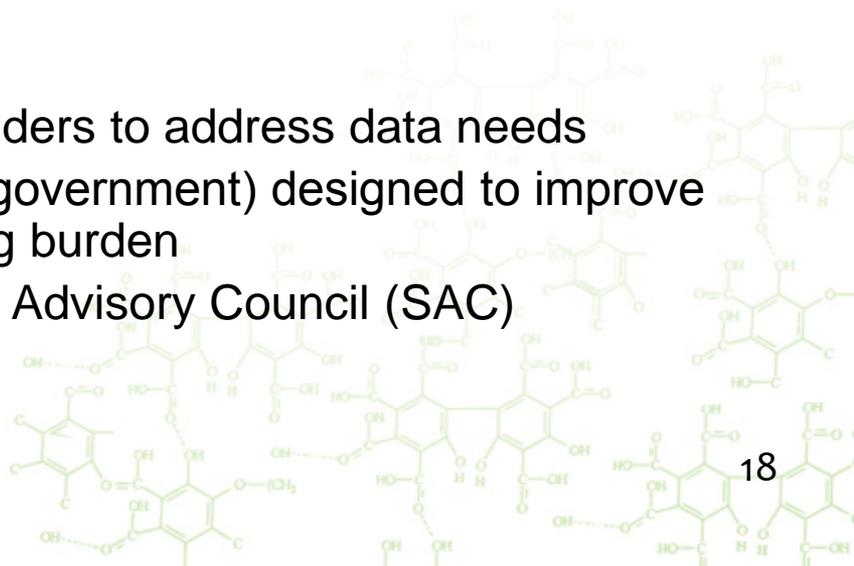
The Challenge Initiative

- 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
- The Challenge focuses on those substances that have been identified as ecological and human health priorities
 - Ecological:
 - Substances that were categorized as Persistent (P) and Bioaccumulative (B) and inherently toxic to non-human organisms (iT):
 - Human Health:
 - Substances that were categorized as high hazard and have a high or intermediate potential for exposure



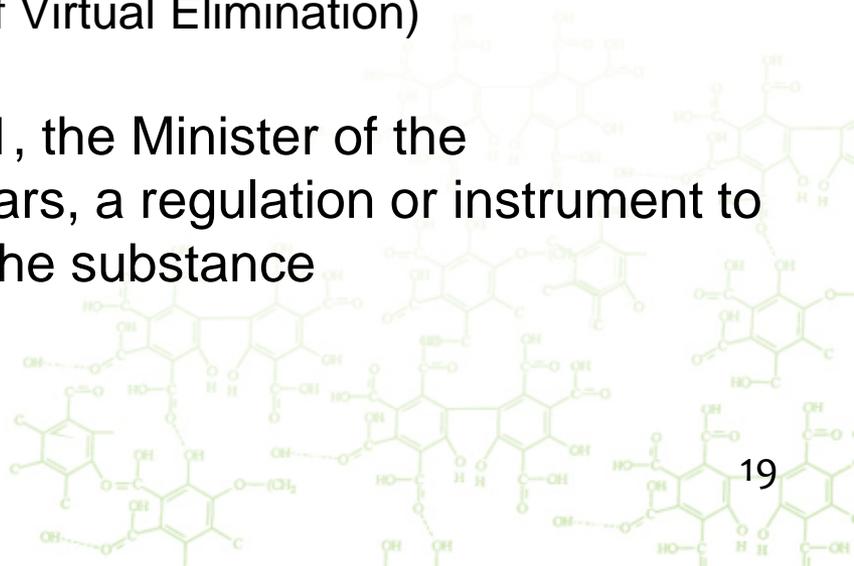
Challenge Process

- 200 substances were separated into 12 batches. Batches were released every 3 months and contained ~15-20 substances/batch
- Each batch of the Challenge followed these steps:
 - Information gathering (survey every 3 months, voluntary questionnaires etc)
 - Risk Assessment
 - To determine if the substance was toxic as defined under s.64 of CEPA
 - Risk Management (as required)
 - If a substance was determined to be CEPA Toxic, risk management options were to be proposed within 24 months and finalized within an additional 18 months
- Consultation with Challenge Advisory Panel
- Stakeholder consultation throughout
 - Work with associations and key stakeholders to address data needs
 - Engagement methods (stakeholders ↔ government) designed to improve exchange of information while minimizing burden
 - Foster dialogue through the Stakeholder Advisory Council (SAC)

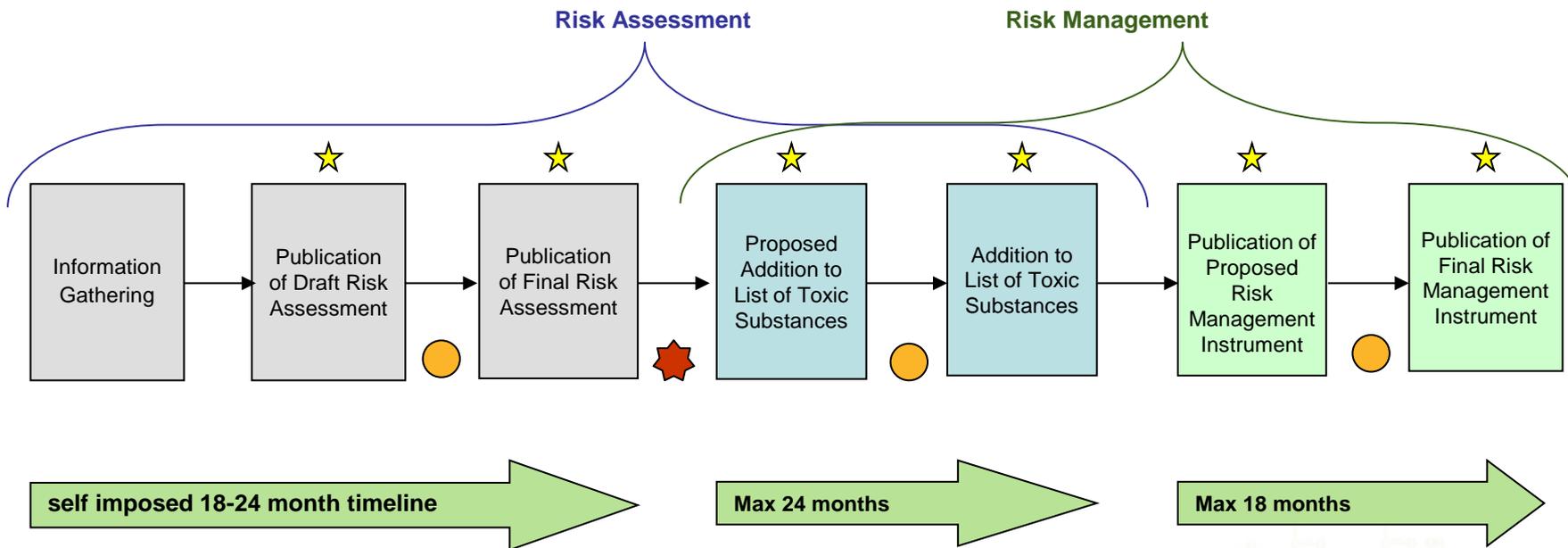


Key Steps After Risk Assessment

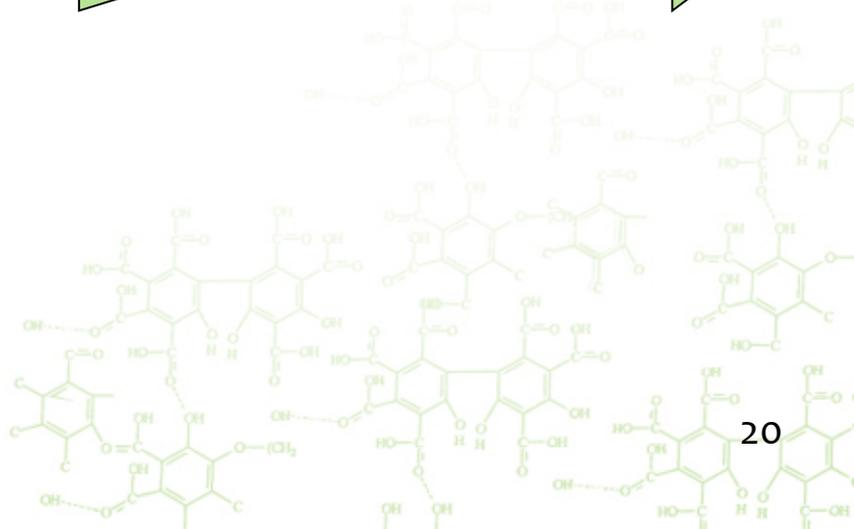
- Ministers must publish in the *Canada Gazette*
 - Summary of the assessment
 - 60 day public consultation period on the draft assessment
 - Statement indicating which of the following measures they propose
 - No further action (i.e., no formal risk management action under CEPA)
 - Add to Priority Substance List (i.e. further risk assessment required)
 - Recommend addition to List of Toxic Substances (Schedule 1) (and, where applicable, implementation of Virtual Elimination)
- If recommending addition to Schedule 1, the Minister of the Environment must propose, within 2 years, a regulation or instrument to prevent or control the risk(s) posed by the substance



Existing Substances Assessment & Management

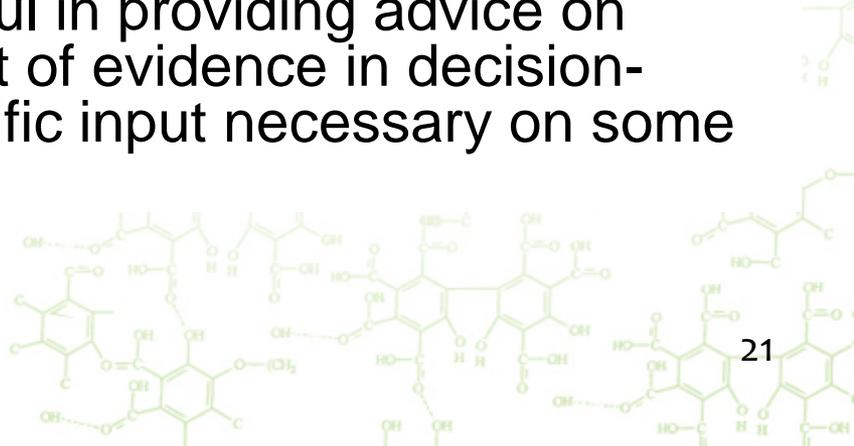


- ★ Official publication in *Canada Gazette*
- Denotes a 60 day public comment period
- ★ If substance is not toxic, process stops here



Some Key Lessons Learned from CMP1

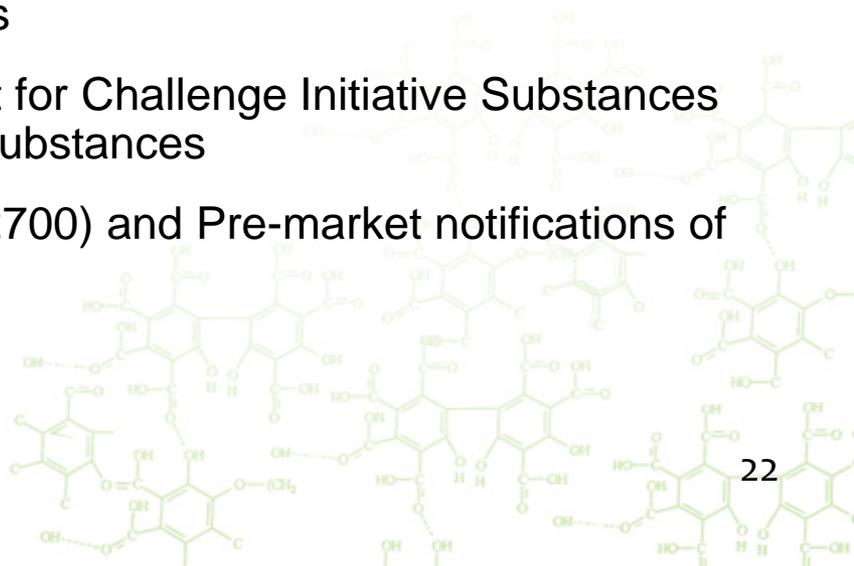
- Transparent and predictable work plan for the Challenge was critical in managing capacity internally to deliver and externally to respond
- Inventory update important in setting priorities
- Industry data important in decision-making
- Direct exposures from use of consumer products were frequently a key driver in assessment outcomes
- Substance-by-substance approach limits ability to consider aggregate exposure and cumulative risk
- Challenge Advisory Panel was useful in providing advice on application of precaution and weight of evidence in decision-making, but broader external scientific input necessary on some issues



CMP Phase 2

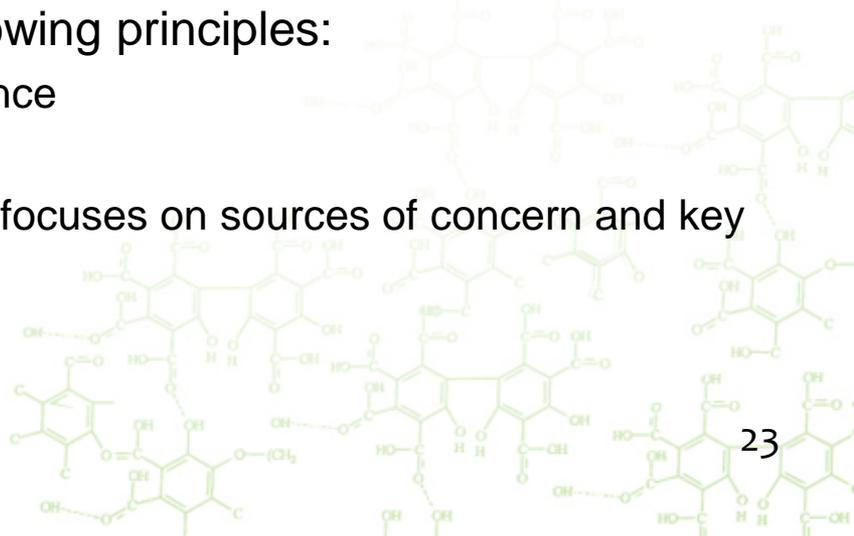
CMP Phase 2 Activities (2011-2016):

- Building upon success and lessons learned of the first CMP, the second phase was announced on October 3, 2011
- Substance Groupings Initiative and other Chemical Substances of Interest (~500) based on structural or functional similarities and were assembled based on considerations related to
 - risk assessment and risk management efficiencies
 - the ability to support informed substitution decisions
 - timing of international actions
 - stakeholder engagement
- Rapid Screening and Polymer approaches
- Risk assessment and/or risk management for Challenge Initiative Substances and Petroleum Sector Stream Approach substances
- Phase 2 of the DSL Inventory Update (~2700) and Pre-market notifications of new substances to Canadian marketplace



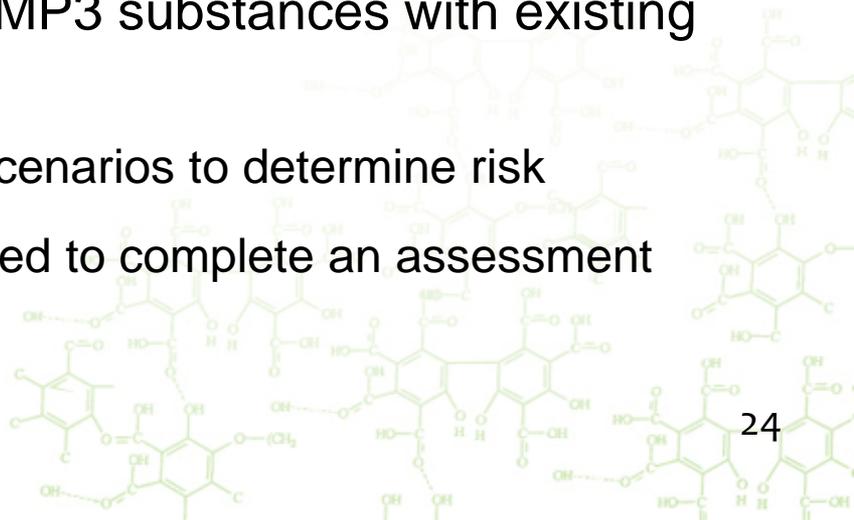
CMP Phase 3

- Remaining Priorities
- Ambitious task
 - ~1550 remaining priorities to cover to 2020
- Includes a cross section of known high hazard compounds, known high volume compounds as well as substances with varying levels of hazard or exposure potential;
- Heterogeneous
 - singletons, small groups, large groups;
 - simple to complex assessments.
- Various approaches may be used to appropriately focus resources, but all approaches continue to incorporate the following principles:
 - Application of precaution and weight of evidence
 - Strong science
 - “Tailored” approach – where the assessment focuses on sources of concern and key hazard properties



Principles for Gaining Efficiencies

- Tiered Assessments
 - “right-sized” approach – i.e., doing only what is required to make a sound decision
 - Using exposure data from DSL Inventory Update to inform level of assessment required
 - Focus on getting the right conclusion, more than comprehensiveness in the characterization of risk
 - Aim to have complexity of the assessment commensurate with level of risk
 - May result in different depths of assessment for environment and health
- Adoption of existing hazard characterizations from international partners where available (e.g., ~220 CMP3 substances with existing OECD initial assessment reports)
 - Supplement with Canadian exposure scenarios to determine risk
 - Reduces the resources and time required to complete an assessment



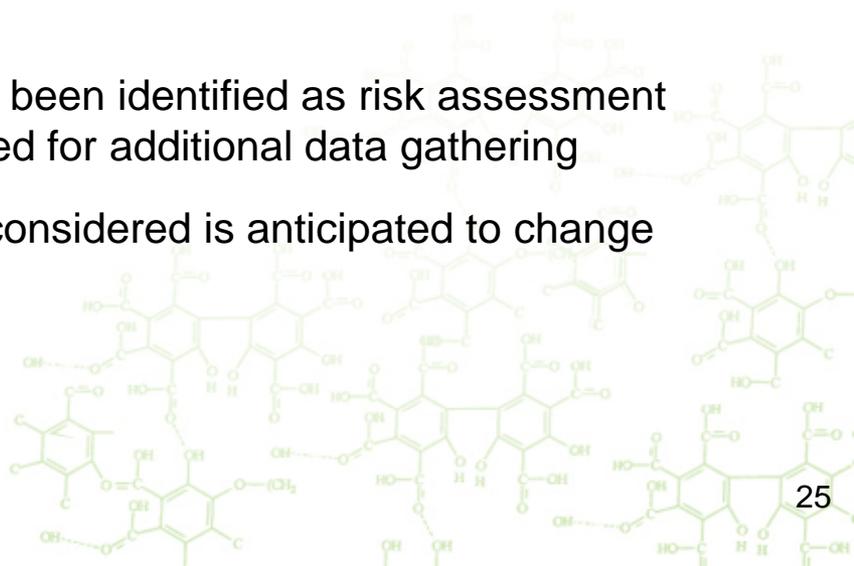
Identification of Risk Assessment Priorities

- **Experience To Date and Moving Forward**

- The Government of Canada has recently taken steps to enhance the way new information from the other feeders is acquired, evaluated and incorporated into forward work planning.
- Enables the government to be better positioned to recognize concerns, to track emerging issues, and to identify and prioritize substances requiring further work.
- Helps to increase transparency in the process of identifying new priorities.
- The Approach for the Identification of Risk Assessment Priorities was published for comment; results published on May 31, 2016

<http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-proche/chem-pol-priori-eng.php>

- Result: 28 non-categorized substances have been identified as risk assessment priorities and > 100 substances were identified for additional data gathering
- The scope of substances and data sources considered is anticipated to change with future iterations of review



Mechanisms to identify future priorities

Mechanisms

Addition to
DSL
Inventory
Update or
other survey

Emerging
science and
monitoring

Information
submitted
under
Section 70
of CEPA

Data from
domestic and
international
organizations

Review of
decisions of
other
jurisdictions,
including
section 75 of
CEPA

Issues
flagged via
New
Substances
Program

Results of
previous
CMP
assessment
activities

Significant
New Activity
Notice
(SNAN) on
substance
that was
subject to a
SNAC
provision

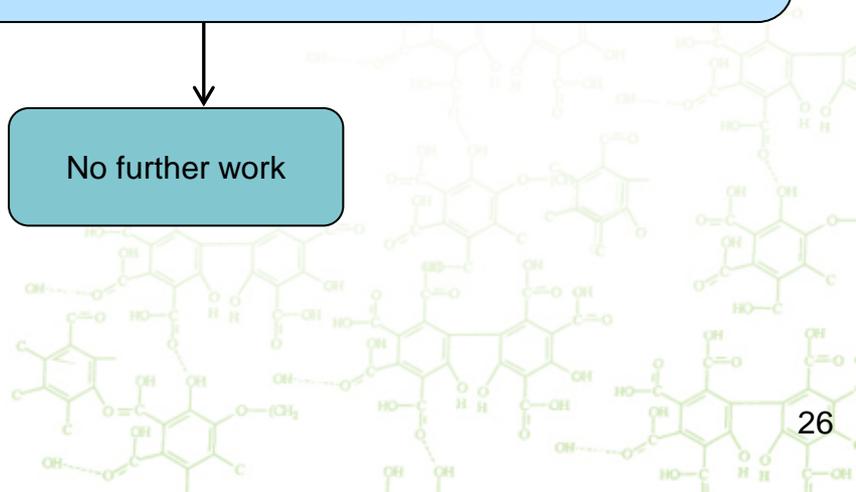
Annual application of the *Approach for Identification of Chemicals and Polymers as Risk Assessment Priorities under CEPA 1999* (i.e., IRAP)

Data sources include international hazard classifications and assessment activities, NPRI, international quantity data, etc.

Risk assessment

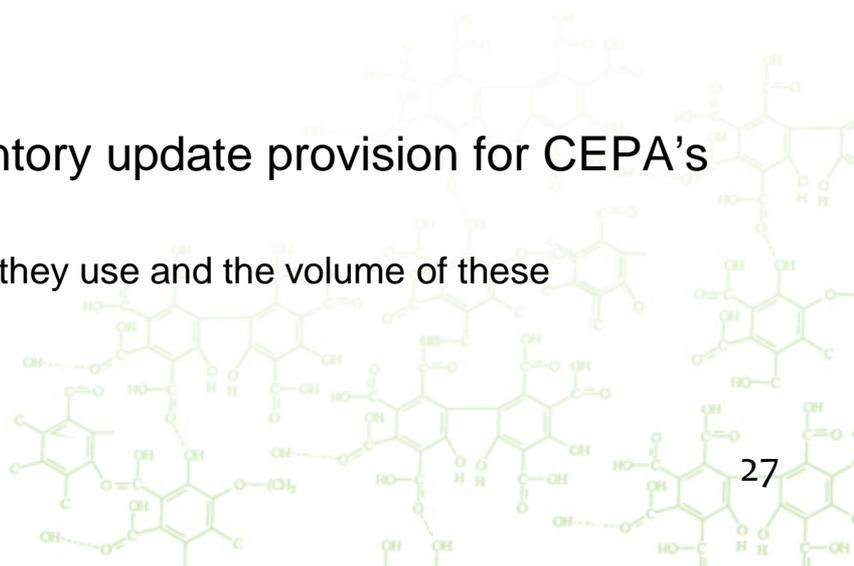
Further data
collection/generation

No further work

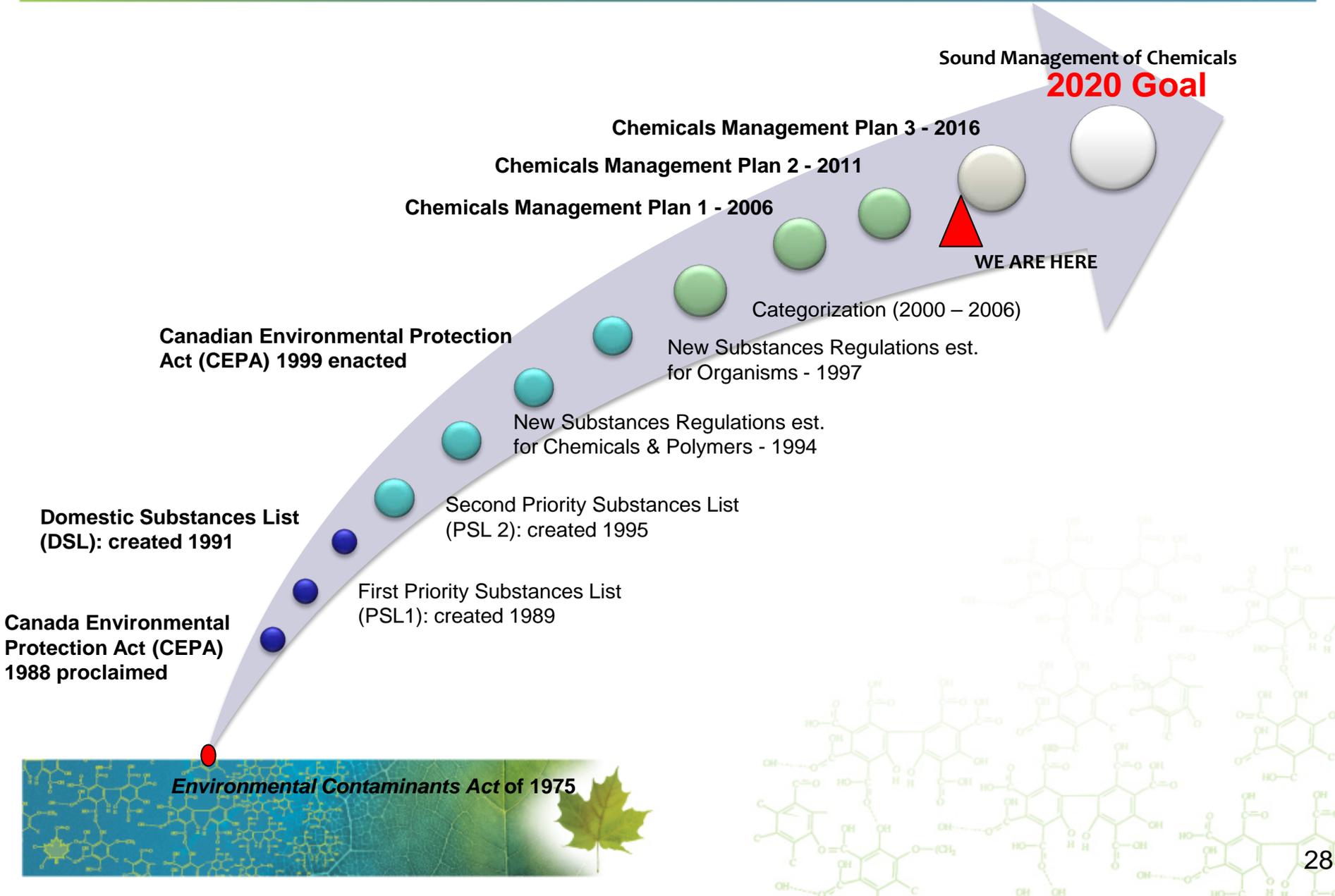


The CMP Continuum

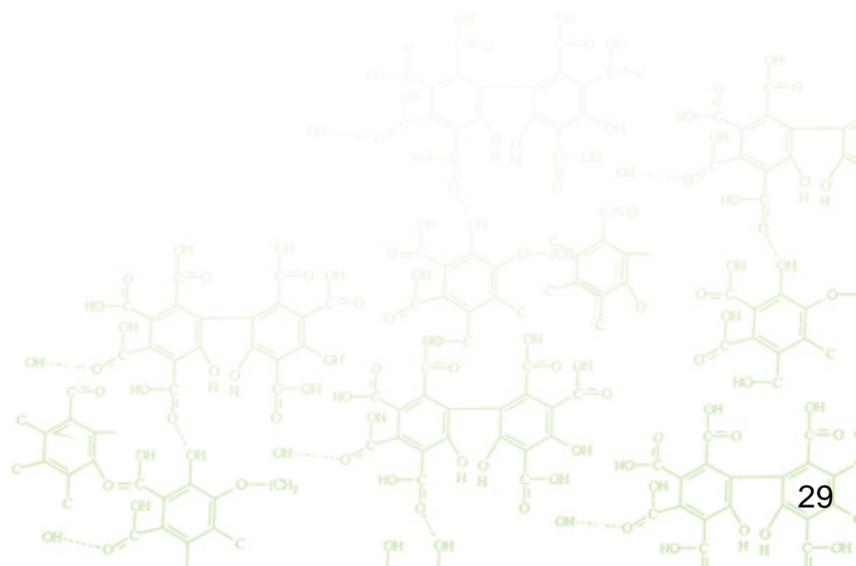
- Key to an efficient science-based regulatory regime for chemicals
- Support for Research
 - Enhancing regulatory science by leading research and partnering with external research bodies to inform risk assessments and regulatory interventions
 - Ensures that actions are informed by the best science
- Integrated Monitoring
 - Implement 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
 - Develop and implement a cyclical inventory update provision for CEPA's Domestic Substances List
 - Require industry to report on the substances they use and the volume of these substances on the Canadian market



Evolution of Chemicals Management Federally

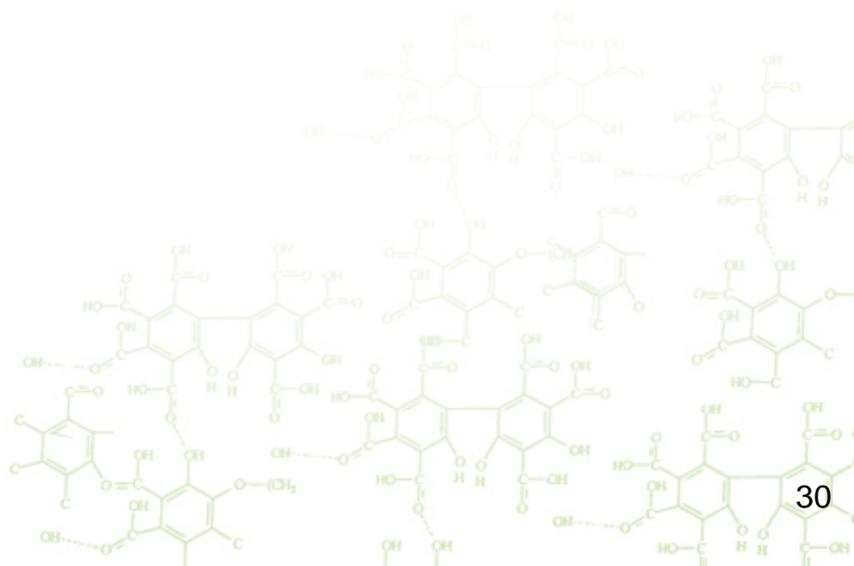


Progress under the CMP to date



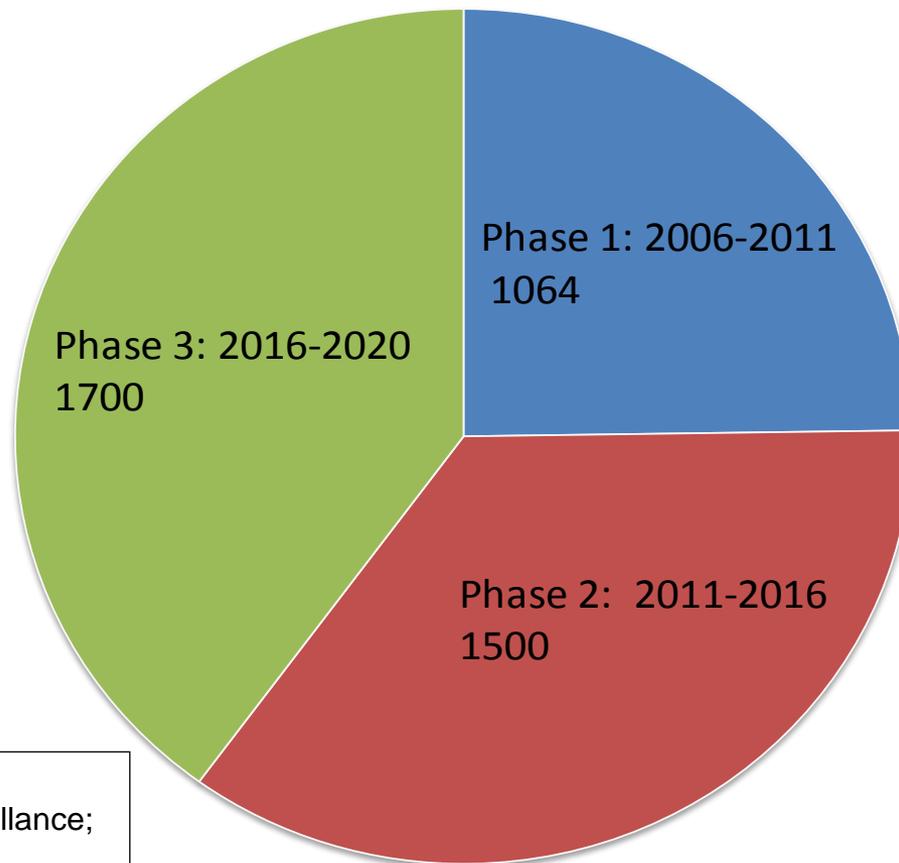
Taking Stock – Progress Made To Date

- Risk Assessment
 - Existing Substances
 - New Substances
 - In Commerce List Substances
 - Older Pesticides
- Information Gathering
- Monitoring and Surveillance - Biomonitoring
- Risk Management
- Multilateral and Bilateral Activities
- Outreach
- Stakeholder Contributions



Priorities Within CMP

~ 4300 Substances Addressed by 2020



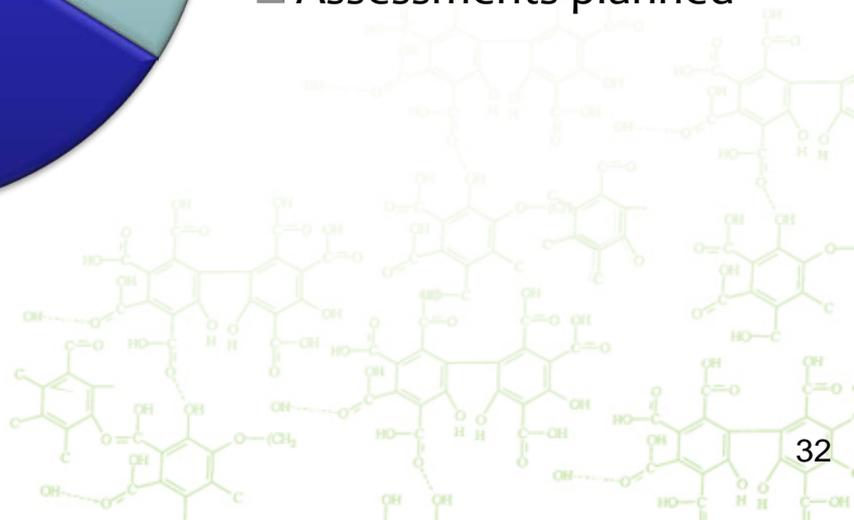
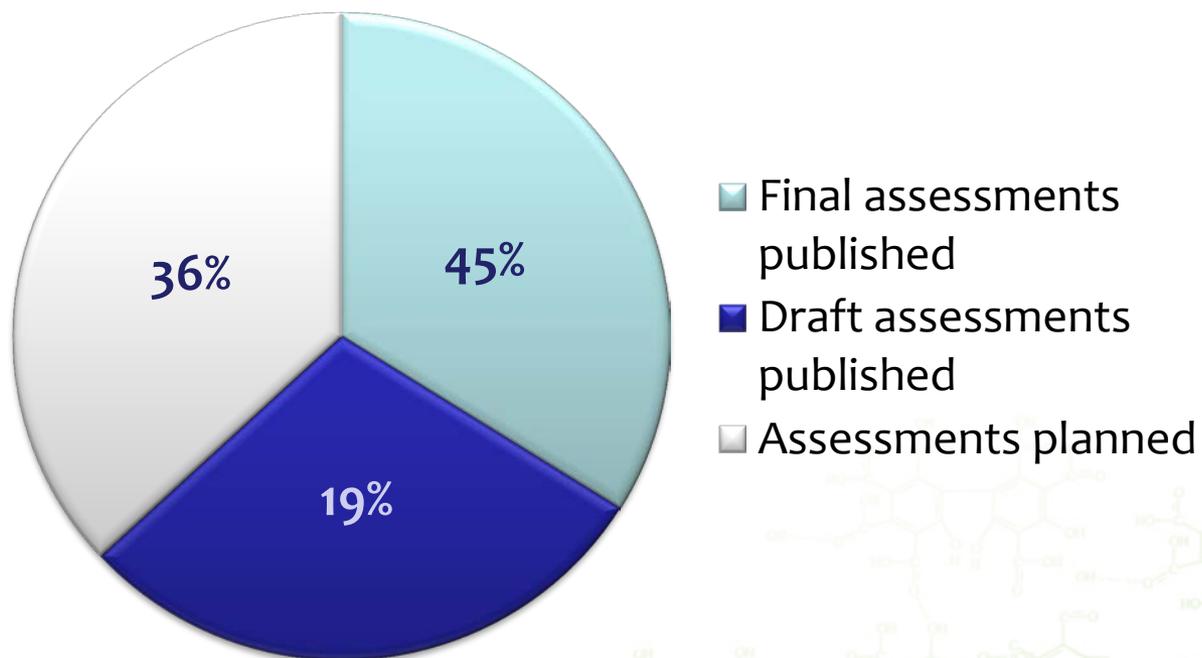
Support through:

- Research, monitoring, surveillance;
- Inventory update;
- International collaboration.



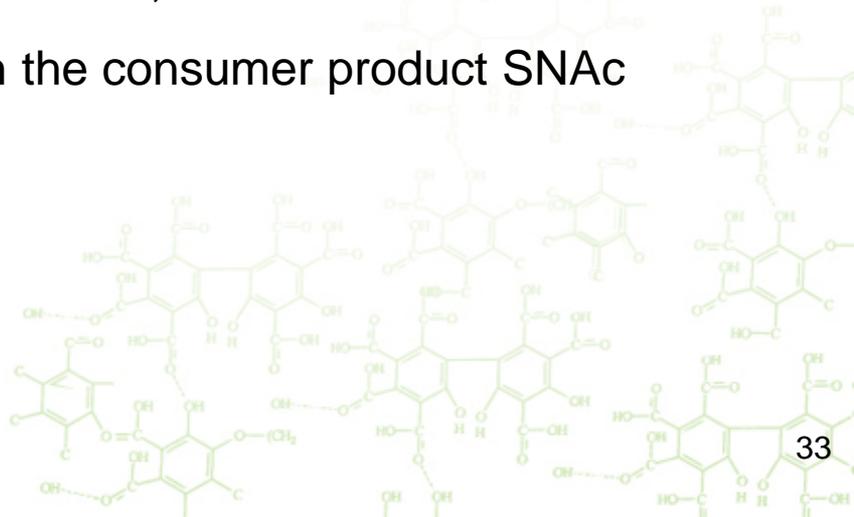
Risk Assessment - Existing Substances

Progress to date on the 4,300 substances identified for action
(as of July 25, 2016)



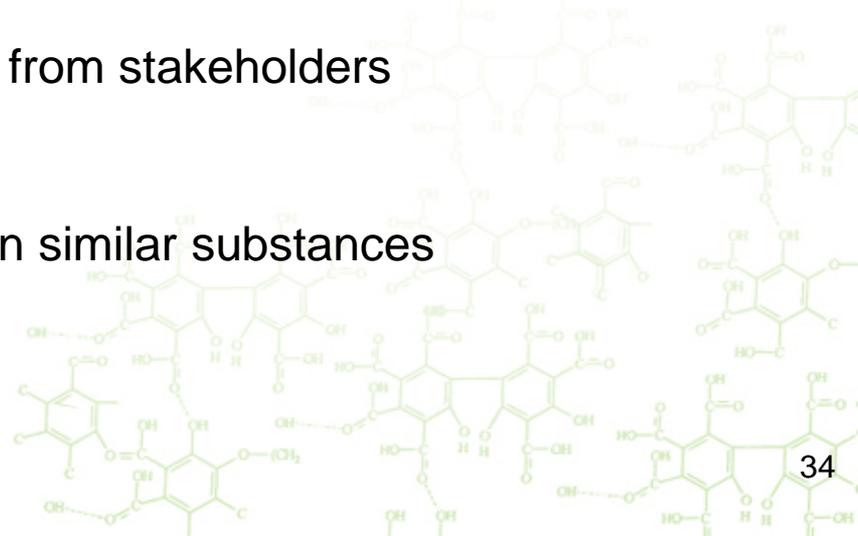
Risk Assessment - New Substances

- Approximately 500 new substances assessed each year
 - Includes chemicals, polymers, products of biotechnology, nanomaterials and substances in *Food and Drugs Act* regulated products
- Approximately 315 control measures have been put in place to address concerns from new substance assessments since the New Substances Notification Regulations first came into force in July 1994
 - Includes Significant New Activities (SNACs), Ministerial Conditions, Ministerial Requests for Additional Information, and Ministerial Prohibitions
 - Work on SNACs includes progress with the consumer product SNAC review and Nanomaterial SNACs



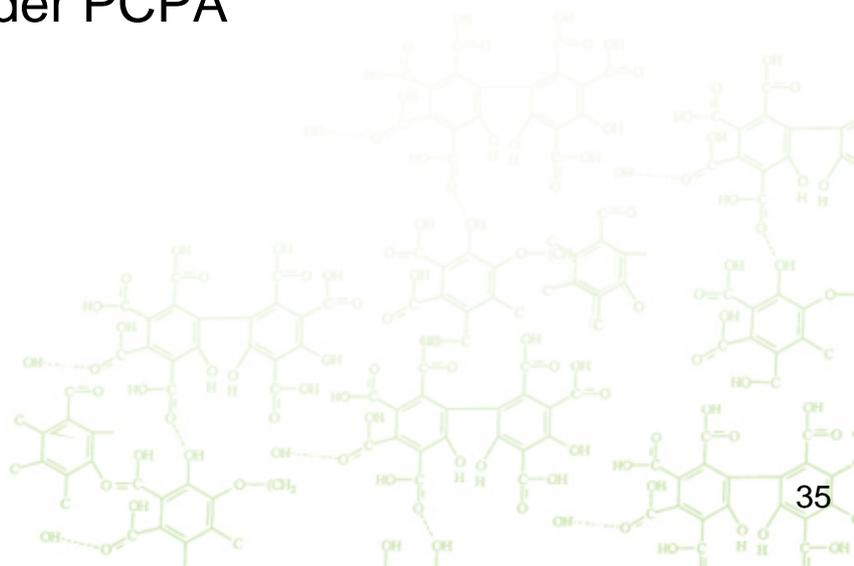
Risk Assessment – In Commerce List Substances

- ICL is an administrative list of substances in Canadian commerce used in products regulated by the *Food and Drugs Act* between 1987-2001
- Approx. 3,500 substances, including pharmaceuticals, veterinary drugs, cosmetics, biologics, food products, natural health products, and medical devices
- CMP2 commitment to prioritize substances on the revised ICL
- Approach for Prioritization was published in November, 2015
- Prioritization identified approx. 850 substances for further consideration
 - Further information gathering, including from stakeholders
 - Sponsored research or monitoring
 - Leverage work in progress elsewhere on similar substances

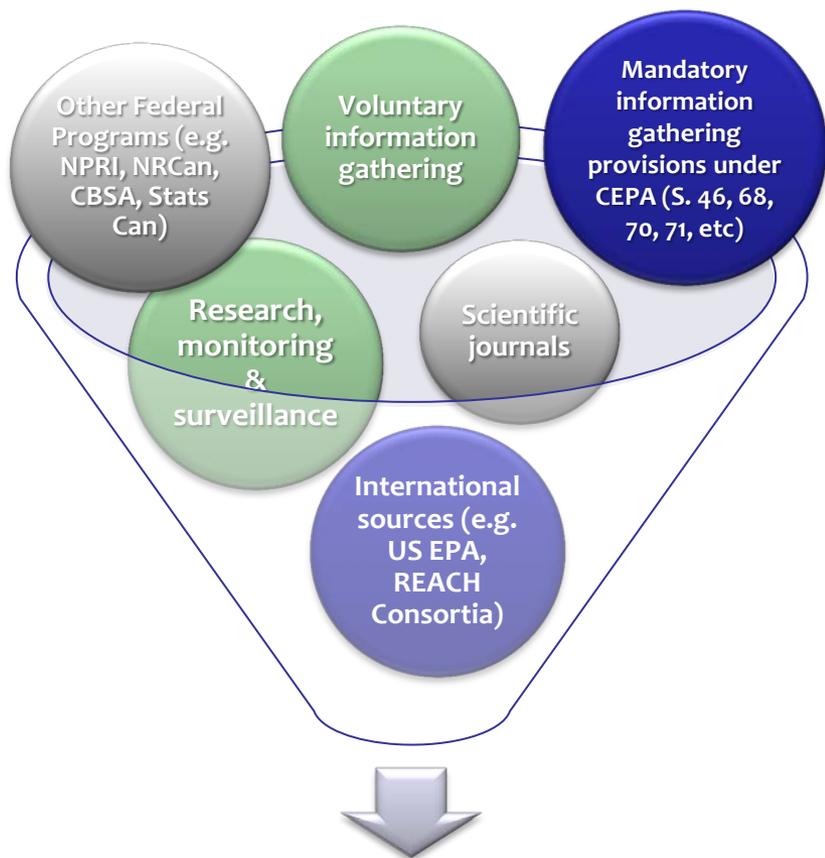


Risk Assessment - Older Pesticides

- Risk management decisions (for both re-evaluations and special reviews) made on 379 pesticides, including discontinued products
- Since the launch of CMP3, have initiated:
 - Re-evaluation of approximately 88 active ingredients registered under the *Pest Control Products Act* (PCPA)
 - Special reviews as required under PCPA



Information Gathering



Inventory Update (IU)

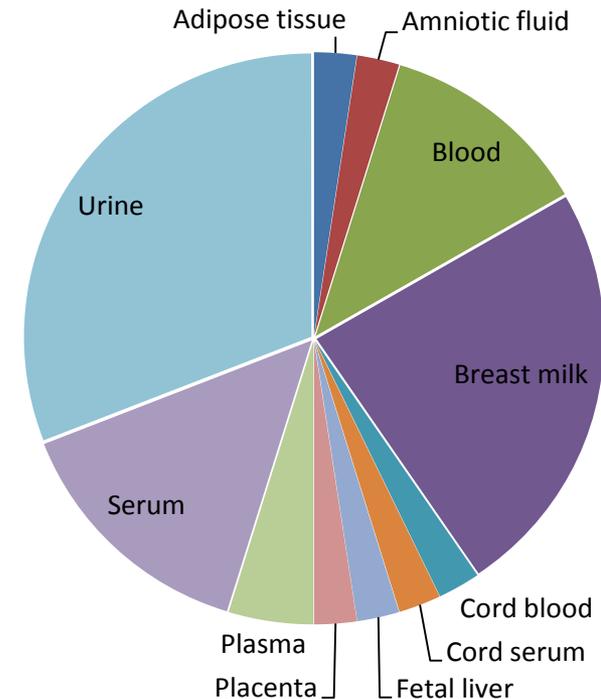
- Proposed launch in Fall 2016, requesting information on 1000 - 1500 substances
- On-going cyclical approach with reporting every 4 years to maintain up-to-date information of substances in Canada which is critical to inform risk assessment and risk management activities
- Lessons learned and feedback from stakeholders were considered in developing the notice

NPRI = National Pollutant Release Inventory
NRCan = Natural Resources Canada
CBSA = Canadian Border Services Agency
Stats Can = Statistics Canada
US EPA = United States Environmental Protection Agency
REACH = Registration Evaluation Authorisation Restriction

Monitoring and Surveillance - Biomonitoring

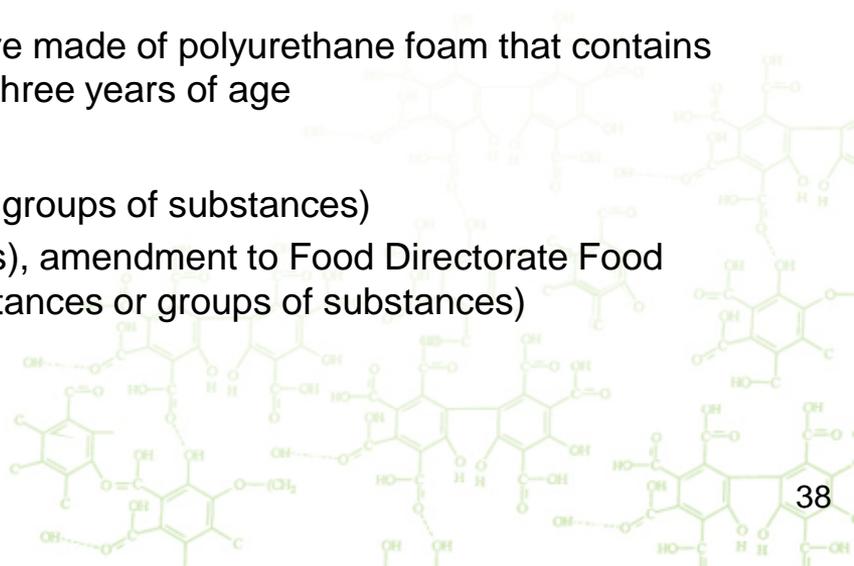
- Of the ~2700 substances assessed to date:
 - ~10% (or ~250 substances) had human biomonitoring data
- Examples of CMP assessments that have used biomonitoring data to propose conclusions about the potential for risk to human health:
 - PBDEs, HBCD, BPA (breast milk)
 - PFOA and PFOS (blood)
 - Lead (blood)
 - Triclosan (urine)
 - Selenium (blood)
 - Phthalates (urine)
 - Boron (blood)

Availability of Biomonitoring Data in CMP



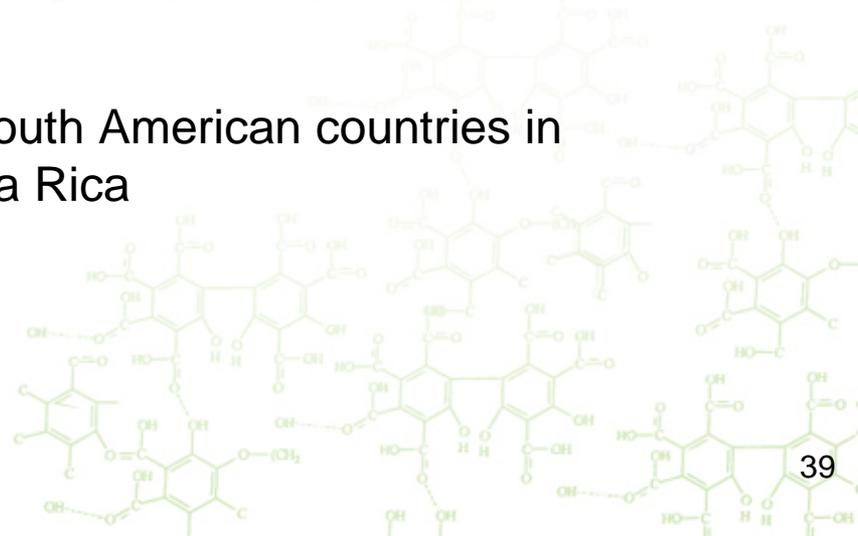
Risk Management – Progress to Date

- Consulted on risk management options for over 200 substances proposed and/or concluded toxic between 2006-2016
 - 70+ Risk Management Scope documents on proposed toxics
 - 50+ Risk Management Approach documents on final toxics
- Continued to implement over 180 instruments controlling 132 toxic substances
- Will continue to select the best placed act, to manage the risks associated with a toxic substance
 - *Canadian Environmental Protection Act*
 - Regulations (27), significant new activity provisions (finalized for 27 substances), pollution prevention plans (9), codes of practice, etc.
 - *Canada Consumer Product Safety Act*
 - Schedule II prohibition e.g. on products that are made of polyurethane foam that contains TCEP and that are intended for a child under three years of age
 - *Food and Drugs Act*
 - Cosmetic Ingredient Hotlist (19 substances or groups of substances)
 - Lists of permitted food additives (3 substances), amendment to Food Directorate Food Packaging Submission Review Policy (7 substances or groups of substances)



Multilateral Activities

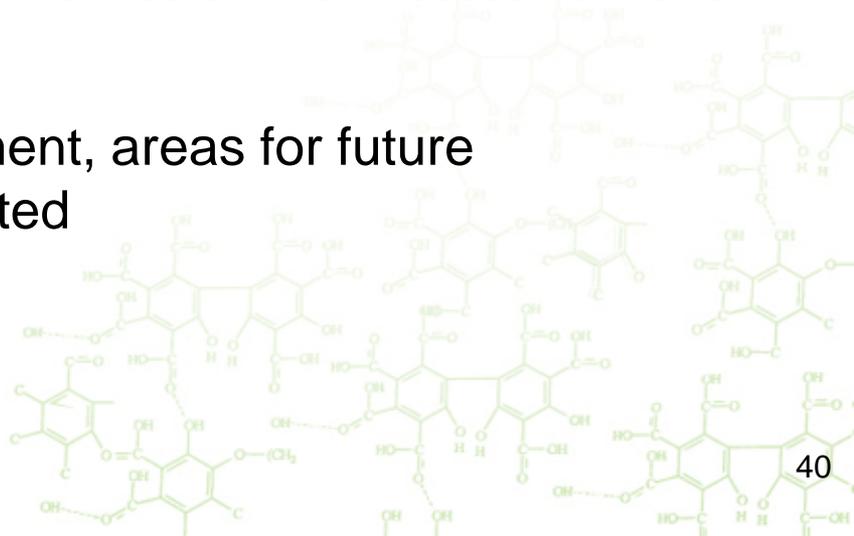
- Continued commitment to protecting Canadians and their environment from pollutants coming from abroad and sharing our experience and expertise to advance global efforts.
- **Organisation for Economic Co-operation and Development (OECD)**
 - Helped guide the transformation of the chemicals programme at the OECD
 - Development of tools, approaches and methodologies have been truly beneficial to assessments under CMP and allowed us to share experience
 - Assisting in capacity building with South American countries in accession including Columbia, Costa Rica



Bilateral and Regional Activities

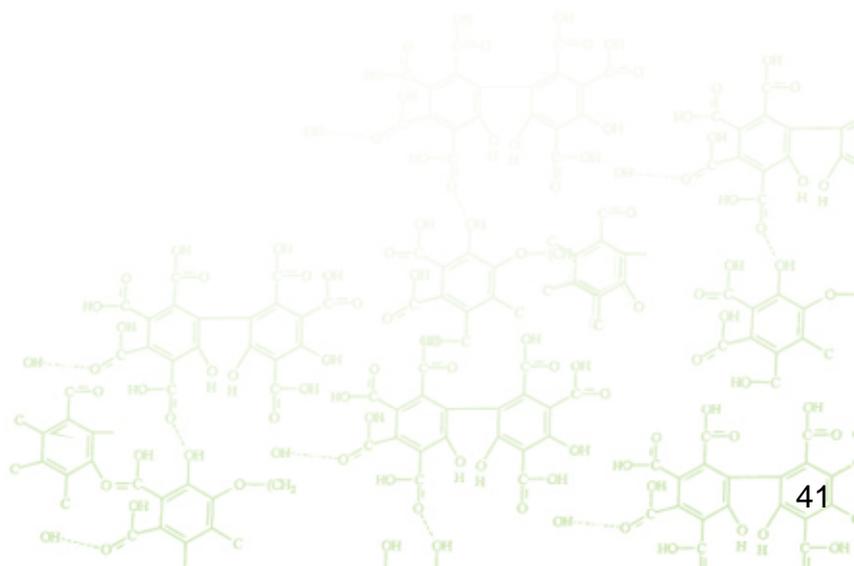
Regulatory Cooperation Council (RCC)

- Canada-U.S. initiative that seeks to facilitate closer regulatory cooperation across a large number of areas with the aim to enhance economic competitiveness
 - U.S. Environmental Protection Agency, Health Canada and Environment and Climate Change Canada have collaborated under two RCC phases
 - Initial Joint Action Plan (2011-2014) - Nanomaterials
 - Joint Forward Plan (2014 – present) – Current Chemicals Management work plan includes initiatives on Risk Assessment and SNAc/SNUR
- Under Regulatory Partnership Statement, areas for future collaboration continue to be investigated



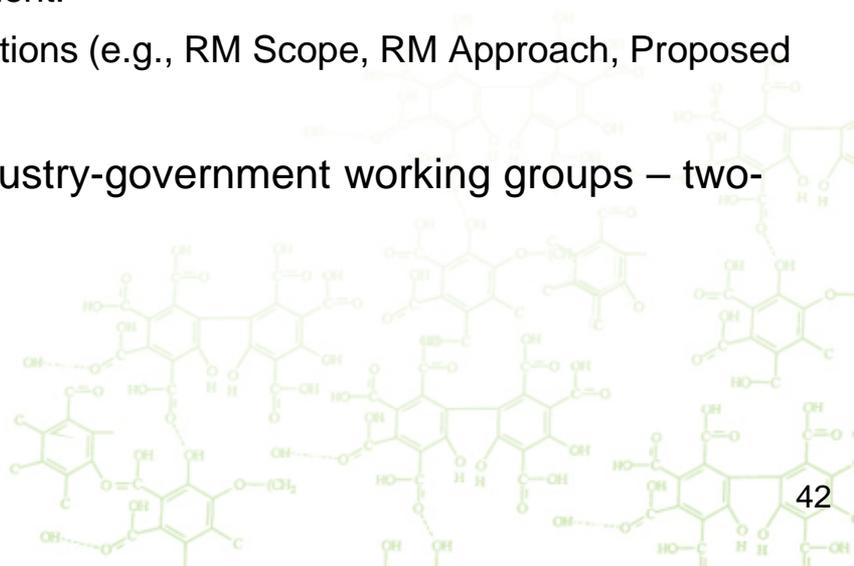
Outreach

- Building public confidence
- Public outreach and stakeholder engagement is well established
- Supported by publications (Hazardcheck, Factsheets, Seniors guide) and websites (Chemical Substances)
- Creation of Stakeholder Advisory Council subcommittee on outreach



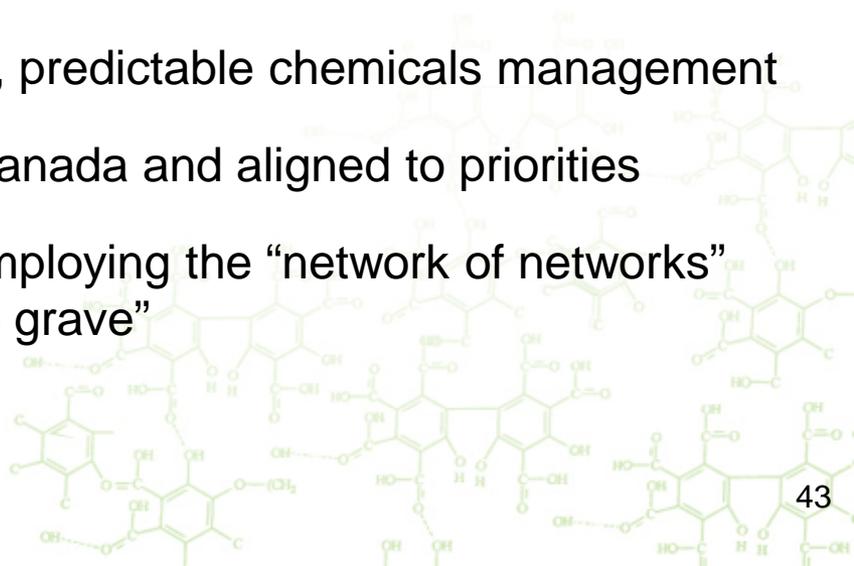
Stakeholder Contributions

- Important shared role in building public confidence in chemicals management
- Contribution to program design
 - Created Stakeholder Advisory Council
 - CMP Science Committee
 - Industry Coordinating Group
 - Series of multi-stakeholder meetings
- Participation in information gathering initiatives
- Important element for the development and design of risk management instruments
 - Informs instrument selection, design, compliance promotion, effectiveness evaluation
 - Opportunities to provide input begin as soon as a substance is proposed to be toxic, and continues through administration and performance measurement.
 - Input via public comment periods and pre-consultations (e.g., RM Scope, RM Approach, Proposed instrument)
- Ongoing opportunities through sector specific industry-government working groups – two-way information exchange



Summary of CMP Results

- Have met or are on track to meet all targets
 - Approximately 64% of the 4,300 substances identified for action under the CMP have been addressed by government scientists
 - 363 substances or groups of substances have been concluded to be toxic since the launch of the CMP
 - 78 final risk management actions have been developed to manage manage the risks in a range of substances and applications, since the CMP was first launched
- Program supported by industry and NGOs
- Consistent, Government-wide approach to chemicals
- Stimulated preventive measures by industry
- Enhanced Canada's reputation for effective, predictable chemicals management
- Research program integrated with Health Canada and aligned to priorities
- Monitoring programs for the environment employing the “network of networks” model looking at substances from “cradle to grave”



Links to More information

- Chemicals Management Plan
 - <http://www.chemicalsubstanceschimiques.gc.ca>
- Categorization
 - <http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=1695F8D0-5CC4-EDA1-AF63-6F23A94064DD>
- Categorization Guidance and Results
 - <http://webnet.oecd.org/ccrweb/Default.aspx>
- Rapid Screening
 - <http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/rapid-eng.php>
- Petroleum Sector Stream Approach
 - <http://www.chemicalsubstanceschimiques.gc.ca/petrole/index-eng.php>

