CEPA: LESSONS IN THE REGULATION OF CHEMICALS

Presentation to the House of Commons Standing Committee on Environment and Sustainable Development

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OVERVIEW

- What is CELA? (Slide 1)
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What is CELA?

- Non-profit organization established in 1970 to use existing laws to protect the environment and to advocate environmental law reforms
- Funded by Legal Aid Ontario - Provides free legal advice to the public & legal representation at hearings and in courts on behalf of those otherwise unable to afford legal assistance
- Also undertakes education & research projects

Nature of the Problem

- Over 23,000 chemicals in use in Canada
- Some cause cancer, birth defects, endocrine disruption, neurological & behavioural impacts, etc.
- Ontario: #2 in North America for release of developmental/reproductive toxicants (CEC 2004)
- Ontario: #4 in North America for release of known/suspected carcinogens (CEC 2004)
- Ontario: responsible for 36% of air / 50% of water discharges in Canada (Ontario 2008 Discussion Paper on Toxics Reduction Law)

Nature of the Problem

- Between 2006 & 2012 Canada's release & transfer of pollutants known/suspected to be carcinogenic increased 45% (255 million kg to 468 million kg)
- For same years, Canada's release & transfer of pollutants known/suspected to be reproductive/developmental toxicants increased 10% (230 million kg to 255 million kg) & for PBT pollutants 54% (446 million kg to 685 kg million)
- Source: CEC

Nature of the Problem

Higher GDP does not explain Ontario releases:

- California # 1 GDP in N. America (2004): 3x Ontario's ($1.5 trillion v. $427 billion); but less than ½ Ontario's on-site air releases of carcinogens -1.5 million v. 3.4 million kg
- Massachusetts GDP similar to Ontario ($312 billion); but less than 1/20th Ontario's on-site air releases of carcinogens (0.15 million kg)

Nature of the Problem

More facilities do not explain Ontario releases:

- Ontario facilities reporting to NPRI/CEC in 2004: 1295
- Ohio facilities reporting to TRI/CEC in 2004: 1465
- But Ontario's on-site air releases of carcinogens almost double that of Ohio's (3.4 million kg v. 1.8 million kg)

Nature of the Problem

- Pollution levels in the Great Lakes-St. Lawrence River Basin in 2007 (PollutionWatch 2010):
- **total releases (on and off site) -** Almost 209 million kg of pollutants released on and off site from US and Canadian facilities (Canadian facilities contribute over 66 million kg)
- Releases to air - 75 million kg (Canadian facilities contribute over 31 million kg of toxic pollutants);
- 4 million kg released to air are known carcinogens (almost 2.5 million kg released by Canadian facilities)

Nature of the Problem

2007 statistics on Great Lakes pollution due to toxics also show (PollutionWatch 2010):

- NPRI facilities emitted more carcinogens & reproductive/developmental toxicants to air than TRI facilities though there were ½ as many NPRI facilities reporting
- Per facility, NPRI facilities emitted to air, on average, 3x more carcinogens and 2x the reproductive/developmental toxins TRI facilities did

Canada's Response: CEPA

- Canada has had toxic substance legislation in one form or another since the mid-1970s
- Environmental Contaminants Act (1975 – 1988)
- Canadian Environmental Protection Act (1988 – 1999)
- CEPA,1999 (current law)

Canada's Response: CEPA

- Canadian Environmental Protection Act,1999 – principal law governing manufacture, import, & use of chemicals in Canada
- Primary purpose "to contribute to sustainable development through **pollution prevention**" (CEPA,1999 – Declaration); also
- "**Virtually eliminate** most persistent & bioaccumulative toxic substances" (Preamble)
- Federal government duties include: protection of environment & human health through application of **precautionary principle** (s. 2)

Canada's Response: CEPA

- Under CEPA,1999 a substance must be declared "toxic" before Canada can act to reduce exposure
- "toxic" defined as a substance entering or that may enter the environment in a quantity or concentration or under conditions that:

Canada's Response: CEPA

- Have or may have immediate / long-term effect on environment or its biological diversity;
- Constitute or may constitute danger to environment on which life depends; or
- Constitute or may constitute danger in Canada to human life or health (s. 64)

Canada's Response: CEPA

- If a substance meets s. 64 test it can be added to Schedule 1 of Act (List of Toxic Substances) & become eligible for regulation (following public notice, comment and/or Board of Review hearings)
- For both existing and new chemicals CEPA,1999 applies risk assessment approach to determine whether s. 64 test met

CEPA: Existing Chemicals

- If a substance is on the Domestic Substances List it is deemed an existing substance; & would be on that list if it was used, manufactured, imported for commercial purposes in volumes greater than 100 kg between January 1, 1984 & December 31, 1986 (s. 66, CEPA,1999)
- Approximately 23,000 substances on DSL

CEPA: Existing Chemicals

- Substances on DSL categorized as to persistence, bioaccumulative, toxic, & exposure potential to humans & environment within 7 years after CEPA,1999 became law (s. 73)
- Substances not on DSL placed in non-DSL list & cannot be manufactured or imported unless information first provided to government of Canada (essentially deemed to be new substances)

CEPA: Existing Chemicals

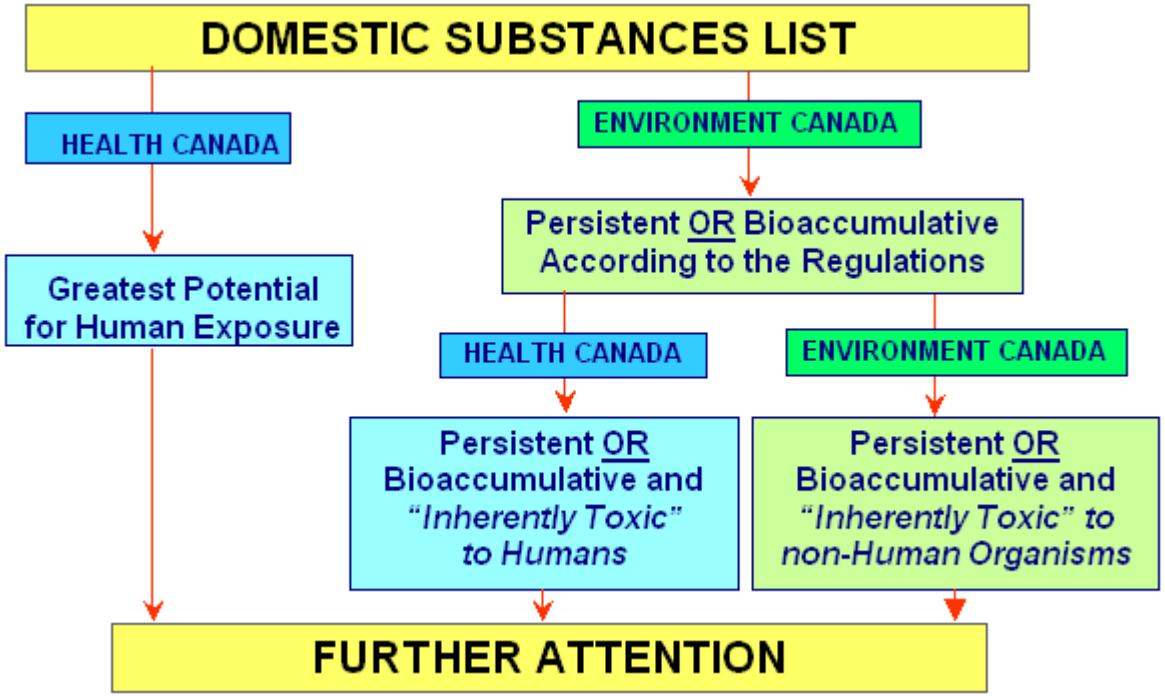
- Assessment of DSL substances to determine which should be deemed toxic & placed in Schedule 1 has been on-going under CEPA,1999 & predecessor law
- To expedite review of existing substances categorization process authorized under s. 73 to identify chemicals that should be subjected to screening level risk assessment (s. 74)

CEPA: Existing Chemicals

- Under categorization, chemicals were assessed on:
  - **Environmental criteria** (3): persistence (P); bioaccumulation (B) and; inherent toxicity (iTe) to aquatic organisms; &
  - **Health criteria** (2): greatest potential for exposure (GPE); and inherent toxicity to humans (iTh)
  - Canada completed categorization process by September 2006

What is Categorization?

Source: EC, 2006



Categorization Results

- Categorization of 23,000 DSL chemicals resulted in Canada finding that 4,300 required further evaluation organized into 3 groups:
- High priority – PBiTs, GPE/IPE and high hazard to humans (500)
- Medium priority – P/BiT, GPE/IPE and medium hazard (2600)
- Low priority – P/BiT to aquatic environment, mainly low volume (1200); Source: GC, 2009

CEPA: Existing Chemicals - CMP

- In December 2006, Canada announced new approach known as the Chemicals Management Plan, to address results of categorization by 2020
- Major focus of CMP is to collect additional information from industry and develop risk management tools on approximately 200 chemicals within high priority group – dubbed “Challenge Chemicals”

CEPA: Existing Chemicals - CMP

- The Challenge Chemicals have been subjected to screening level risk assessments in batches based on information provided by industry and other stakeholders
- In 2016, there are still several “challenge chemicals” that have not had their assessments finalized (e.g. triclosan)

CEPA: Existing Chemicals – Risk Management

- CEPA-toxic chemicals go on Schedule 1 of Act & are eligible for risk management
- Risk management options include:
  - Regulation (prohibit, restrict use or release, etc.)
  - Pollution prevention (requiring minimization / avoidance of waste creation, etc.)
  - Significant new activity (SNAC) (notification by industry beyond current uses)
  - Voluntary environmental performance agreement

CEPA: Existing Chemicals – CMP Summary

- CMP Focus:
  - Data collection – updates to inventories (DSL & NPRI) & Challenge on high priority substances (HPS)
  - Risk assessment – screening level risk assessments on HPS
  - Risk management measures for industrial & consumer applications of substances considered CEPA-toxic

CEPA: Existing Chemicals – CMP Summary

- CMP2 Focus:
  - grouping substances, completing assessments, on-going risk management from industry challenge, & DSL inventory update
- CMP3 Focus:
  - to be initiated 2016 & focus on remaining substances for assessment with completion by 2020

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 1- A chemical considered P & B does not meet categorization environment criteria & is not considered for further screening or reduction action
  - Must also be inherently toxic
  - Over 250 DSL substances P & B but not iTe
  - Therefore, not assessed or managed under CMP

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 2 – Many substances not meet very high CMP PBT criteria (e.g. P if ½ life in water =/> 26 weeks); if CMP applied criteria from other jurisdictions, more chemicals would be PBT under CEPA:
  - GLWQA (Can-US) (P if ½ life water 8 weeks)
  - REACH (Europe) (5.7 weeks)
  - PBT (USEPA) (8.5 weeks)
  - Stockholm POPs Convention (8.5 weeks)

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 3 – Categorization health effects assessments considered carcinogenicity, genotoxicity, reproductive toxicity, developmental toxicity, and mutagenicity, but did not consider endocrine toxicity (where effects may only be observed at very low doses)

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 4 – DSL over 20 years old and subject to inaccuracies (update of full DSL needed):
  - 2001 Health Canada study found quantities of 7 of 110 chemicals surveyed were order of magnitude greater than 1986 base year
  - NPRI data can update release information for chemicals on both lists but NPRI only reports on roughly 350 chemicals from large facilities
  - Can lead to wrong conclusions about exposure and incorrect management action

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 5 – Uncertainty regarding categorization results due to data gaps:
  - Categorization relied on existing data
  - Missing information & data gaps filled by use of models (QSAR) & analogues (information from a similar but not identical chemical)
  - Categorization made limited use of surveys to gather data from industry; did not consider breakdown products of parent chemicals or toxicity for parent chemicals' full life cycle

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 6 – Canada does not propose any further action on chemicals under CMP already found to be CEPA-toxic & placed in Schedule 1 under earlier processes
  - Already considered managed under CEPA though some still pose problems (e.g. lead, cadmium, arsenic, particulate matter, benzene, & nonylphenol ethoxylates)
  - Re-evaluation authority under PCPA a precedent for correcting this problem

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 7 – Risk management options do not focus on use of safer alternatives
  - CEPA, 1999 silent on issue
  - REACH program a precedent for examining alternatives

CEPA: Existing Chemicals – Categorization / CMP Gaps

- Gap # 8 – Little correspondence between categorization results and mandatory reporting requirements under NPRI
  - NPRI is CEPA's main inventory for annual tracking of releases & transfer of chemicals
  - But all chemicals identified through categorization not listed for NPRI reporting
  - Canada has yet to resolve issue
  - Need to amend Act re NPRI nature, scope, process

CEPA: New Chemicals

- A chemical is “new” if not listed on DSL as having been in Canadian commerce between January 1, 1984 & December 31, 1986
- Two means by which new chemicals enter Canadian market:
  - New Substance Notification Regulations (NSNR); &
  - Non-DSL

CEPA: New Chemicals - NSNR

- Government assesses new substance following notice by company of intention to manufacture or import to Canada (PMN)
- Company must submit different types of data depending on volume of proposed new substance to be manufactured or imported (# of NSNR Schedules)
- Substances assessed on basis of risk – not automatically prohibited even if PBT

CEPA: New Chemicals - NSNR

- If proposing to import or manufacture 100 to 1000 kg per year of a substance new to Canada, information required includes:
  - MSDS
  - Intended use
  - Human health environmental hazard information in possession
  - No toxicity information explicitly required
  - Short government assessment period after which may enter Canadian commerce

CEPA: New Chemicals - NSNR

- If proposing to import or manufacture 1000 to 10000 kg per year of a substance new to Canada, information required includes:
  - Physical / chemical data
  - Acute toxicity / mutagenicity testing
  - Exposure information
  - Whether chemical will be used in products for children
  - 60 day assessment period unless otherwise notified

CEPA: New Chemicals - NSNR

- If proposing to import or manufacture more than10000 kg per year of a substance new to Canada, information required includes:
  - Skin irritation / skin sensitization testing
  - Repeated dose toxicity
  - Additional mutagenicity test data
  - Minimum 75-day assessment applies during which Canada may ask for more information

CEPA: New Chemicals – NDSL

- NDSL = substances in use internationally but not on DSL; are subject to NSNR requirements but benefit from reduced information requirements under NSNR than would be required for a “brand new” substance introduced to Canada
- NDSL primarily based on US TSCA inventory
- NDSL substances assigned less onerous data & assessment time frame requirements under NSNR (e.g. only need meet 1000 kg reqs where 10000 kg reqs otherwise apply) but also submit USEPA assessment & management information

CEPA: New Chemicals – Gaps

- Gap # 1 – Inadequate data required for new substances
  - NSNR regulations & schedules silent on need for carcinogenicity, neurodevelopmental toxicity, & endocrine disruption data even for highest volumes of new chemicals being introduced (though Canada does have authority to request such information)
  - With some exceptions, NSNR regulations & schedules silent on need for P & B data

CEPA: New Chemicals – Gaps

- Gap # 1 – Inadequate data - continued
  - NDSL reliance on reduced NSNR requirements because such substances on TSCA inventory may be a problem
  - 85% of new chemicals introduced in US have no health test data ("Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program" GAO 2005, page 11)

CEPA: New Chemicals – Gaps

- Gap # 1 – Inadequate data – continued
  - "TSCA does not require chemical companies to test new chemicals for toxicity & to gauge exposure levels before they are submitted for review and, according to EPA officials, chemical companies typically do not voluntarily perform such testing" (GAO 2005, page 10)

CEPA: New Chemicals – Gaps

- Gap # 1 – Inadequate data – continued
  - Hinders Canada's ability to assess effectively new substances entering Canada by lowering the bar for chemicals already on US market
  - Chemicals at higher volumes of import or use that are on TSCA inventory & NDSL do not have to meet same criteria as other chemicals not on DSL
  - Allows chemicals to enter Canada with less data than otherwise required by NSNR

CEPA: New Chemicals – Gaps

- Gap # 2 – Lack of public participation & transparency on new substances
  - For existing chemicals, assessments are made public & include public comment period
  - But no notice & comment occurs for new chemicals unless Canada determines chemical is toxic & imposes use conditions or SNAC requirements

Looking Forward: Recommendations

- Improvements to CEPA necessary for:
  - Risk assessments (RA)
  - Risk management strategies (RMS)

Looking Forward: Recommendations

- RA improvements (to Act, regulations):
  - Address data gaps, establish timelines
  - Consider potential for harm at lower exposure
  - Focus more on vulnerable populations
  - Address cumulative / synergistic effects
  - Consider more health endpoints (e.g. endocrine disruption) and substance types (e.g. nanomaterials)
  - Focus more on requiring environmental fate, life cycle & long-range transport information from industry

Looking Forward: Recommendations

- RMS improvements (to Act, regulations):
  - Enhance pollution prevention authority
  - Authorize substitution planning (i.e. to identify / use safer alternatives)
  - Enhance monitoring authority
  - Improve transparency, reporting, public participation, and timelines
  - Better application of precautionary principle where data absent
  - Reform virtual elimination authority

Looking Forward: Recommendations

- 31 recommendations of House of Commons Standing Committee on Environment & Sustainable Development (April 2007)
- 24 recommendations of Senate Standing Committee on Energy, Environment, & Natural Resources (March 2008)
- Arise from s. 343 CEPA: 5-year review
- None recommending reforms to Act adopted by Parliament

Looking Forward: Conclusions

- Are Ontario toxic substance emission levels advertisement for CEPA as law reform model?
- High emissions in Ontario may be function of inadequate Ontario law, but query whether CEPA part of problem
- Gaps in CEPA regarding existing & new chemicals suggest room for improvement that would aid Ontario, rest of Canada, & serve as true law reform model beyond national borders in protecting health & environment

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