

DRAFT

CEPA – Domestic Substance List Post-Categorization and Relevance to the GLBTS

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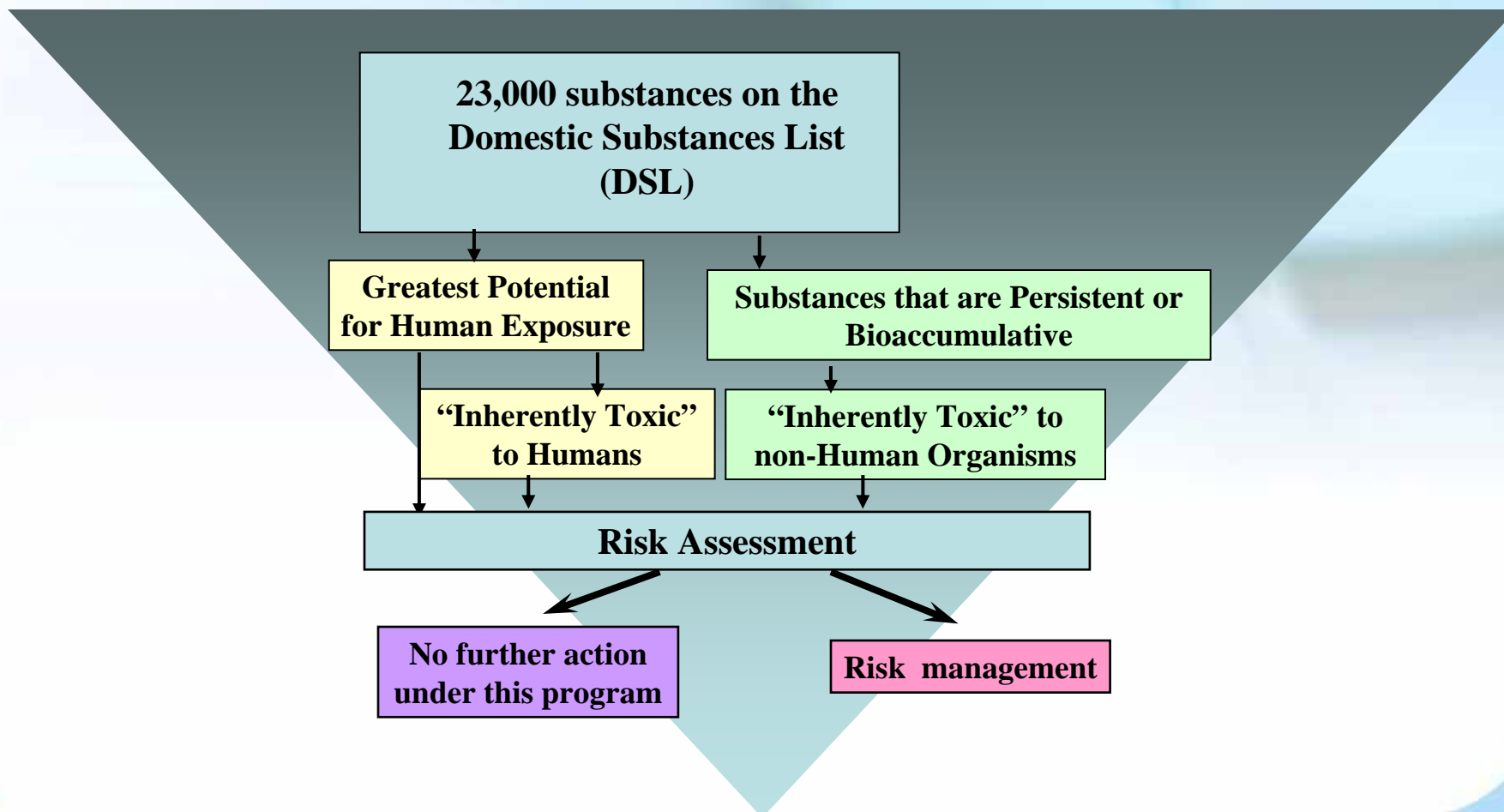
Canada

What is Categorization?

Mandate under CEPA 1999

- The Canadian Environmental Protection Act, 1999 (CEPA 1999) required the Ministers of Environment and Health to categorize the 23,000 substances on the Domestic Substances List (DSL) by September 14, 2006
- Categorization represented a *priority setting* exercise that involved the systematic identification of substances on the DSL that should be subject to screening assessments
- This included identifying substances, based on available information that:
 - May present, to individuals in Canada, the greatest potential for exposure (GPE); or
 - Are persistent (P) or bioaccumulative (B), in accordance with the P and B regulations, and inherently toxic to humans or to non-human organisms (iT), as determined by lab or other studies

The Categorization Process



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
- Since 1994, Canada has assessed and managed the risks to health and environment from new substances being imported into or created in Canada
- Until now, however, Canada has not had an information base about the thousands of existing substances in commercial use before these requirements came into place, many of which continue to be used
- The Government will use this information base to transform how it protects Canadians and their environment from risks associated with the chemicals we use

Human Health Categorization Results

High Hazard Substances

**High or Intermediate
Exposure (~100)**

Low Exposure (~160)

This group of substances has a high likelihood of human exposure and a high hazard to human health (e.g. carcinogenicity, developmental toxicant)

Petroleum Stream Substances

**High/Intermediate Exposure
(~160)**

Low Exposure (~100)

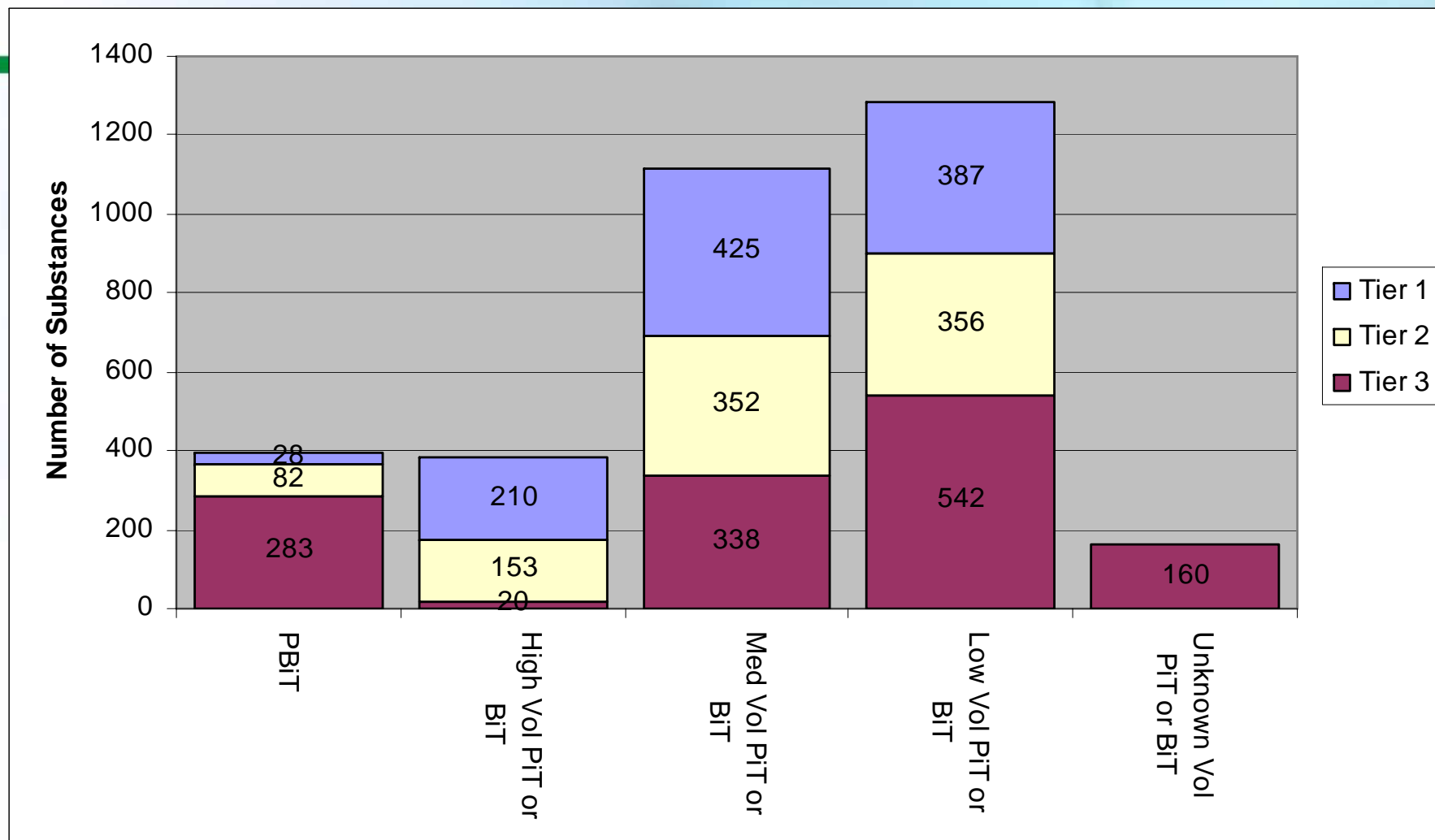
This group of substances has a high hazard to human health; substances are likely contained in plant processes and within the industry

High Exposure Substances

Moderate Priorities – High or intermediate exposure and persistent or bioaccumulative (~680)

This group of substances has a high likelihood of human exposure and persists or bioaccumulates in the body

Ecological Categorization Results



*Low volume <1T; Med volume \geq 1T and <1000T; High volume \geq 1000T



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

- 4300 substances have been identified as requiring further work/action:
 - Where to start?
 - How to deal with a large number of substances?
 - How to deal with ecological and human health concerns?
 - How to make the process transparent?
 - What substances will be the Government’s highest priority for assessment?
 - How long will this take?
 - What resources are needed to complete the task?
- **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

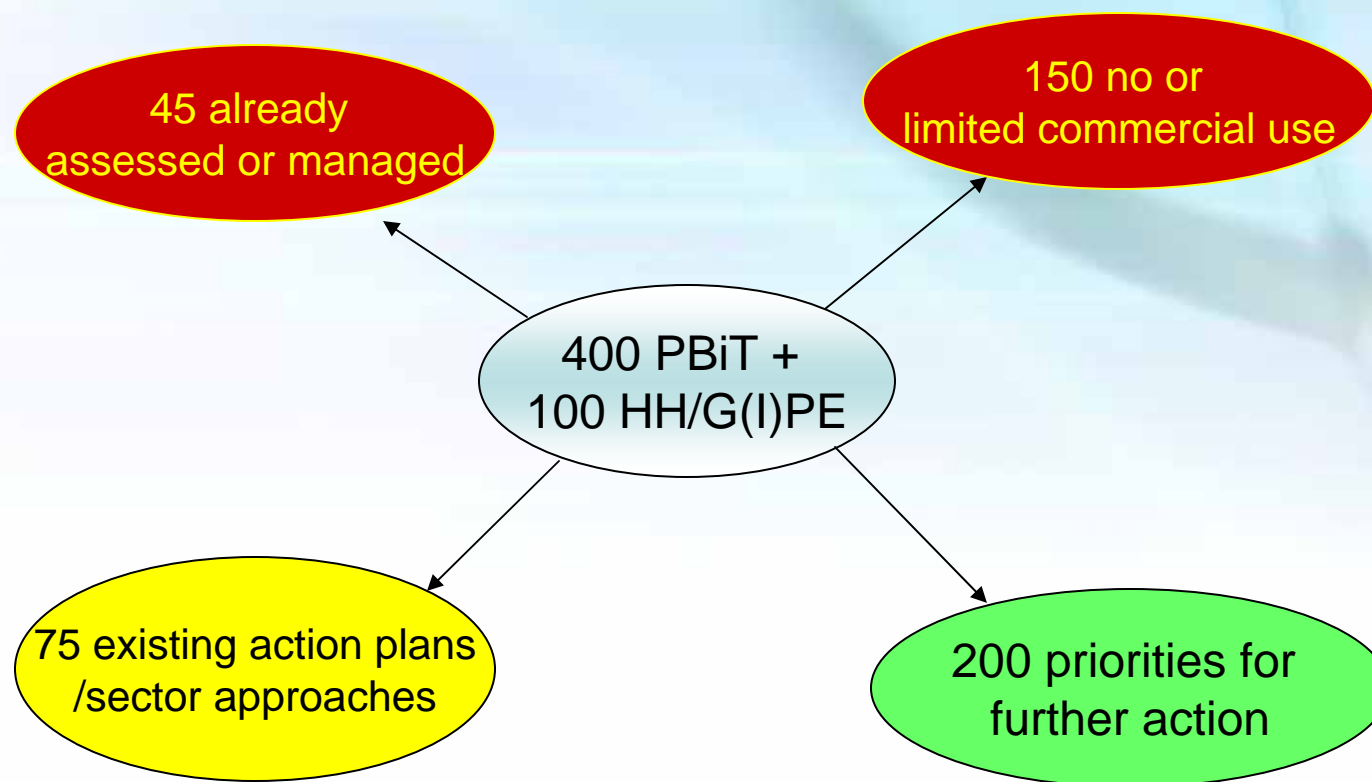
Highest Concern

- **P and B substances:**
 - 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
- **Potential for exposure and inherently toxic to humans**
 - Greatest Potential for Exposure or Intermediate Potential for Exposure and high human health hazard

S.71 Notice with Respect to Selected Substances identified as Priority for Action

- Notice issued in Canada Gazette on March 4, 2006
- Compliance deadline June 22, 2006
- Required Canadian companies who manufactured or imported >100 kg of listed substances in 2005 to respond
- ~500 substances in the notice
- Courtesy copies mailed to ~6000 companies and industry associations
- Survey designed to:
 - Identify which substances are in commerce in Canada
 - Identify stakeholders and sectors before action is taken on these substances
- Included substances found in “manufactured items”
- Reporting of information that companies “reasonably may be expected to have access to”

Top 500 Priorities



Top 200 Priorities for Action

- List has yet to be released
- The PBiT substances cover mainly substances within the chemical industry – ie pigments/dyes, plastics, printing, textile, adhesives
- The G(I)PE/HH substances cover a wider range of uses and industries - ie chemical, pulp and paper, agricultural, cosmetic

Subset of PBiTs

Siloxanes:

- Cyclohexasiloxane, dodecamethyl-, CAS# 540-97-6
- Cyclotetrasiloxane, octamethyl-, CAS# 556-67-2
- Cyclotetrasiloxane, heptamethylphenyl-, CAS# 10448-09-6
- Siloxanes and Silicones, di-Me, hydrogen-terminated, CAS# 70900-21-9

Azo Pigments:

- 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt, CAS# 1937-37-7
- 2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy-, CAS#6410-41-9
- 2-Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy-, CAS#12236-64-5
- Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[(4-methoxyphenyl)amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1), CAS#43035-18-3
- 2-Naphthalenecarboxamide, 4-[[5-[[4-(aminocarbonyl)phenyl]amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy-, CAS#59487-23-9

Subset of PBiTs (cont'd)

Anthracenediones:

- Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt, CAS#4474-24-2
- Benzenesulfonic acid, [(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)bis(imino-4,1-phenyleneoxy)]bis-, disodium salt, CAS#70161-19-2
- Benzenesulfonic acid, 2,2 -[(9,10-dihydro-5,8-dihydroxy-9,10-dioxo-1,4-anthracenediyl)diimino]bis[5-(1,1-dimethylethyl)-, disodium salt, CAS#83006-67-1
- 9,10-Anthracenedione, 1,4-bis[(4-methylphenyl)amino]-, sulfonated, potassium salts, CAS#125351-99-7

Rosin/Rosin Acids:

- Rosin, hydrogenated, CAS# 65997-06-0
- Resin acids and Rosin acids, fumarated, barium salts, CAS#124751-15-1

Miscellaneous:

- Phenol, 2,4,6-tris(1,1-dimethylethyl)-, CAS#732-26-3
- Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl), CAS#6731-36-8
- 2,9,11,13-Tetraazanonadecanethioic acid, 19-isocyanato-11-(6-isocyanatohexyl)-10,12-dioxo-, S-[3-(trimethoxysilyl)propyl] ester, CAS#85702-90-5

Many substances meeting Categorization criteria are not high priorities for assessment

- 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
 - Low volume (<1 tonne) substances are subject to cursory assessment and reduced testing requirements in new substance program, or are exempt from review in other jurisdictions (such as EU) therefore there is little opportunity for cooperation for these substances
 - We will communicate that while these are potentially hazardous chemicals, their risk is low
 - We will conduct limited assessments in order to demonstrate in a transparent manner the risk potential of these substances
 - This work will be conducted soon after 2006 in order to reduce the number of substances under consideration in order to focus attention on substances with greater potential risk
 - It is expected that 1200 substances meeting categorization are in fact low priorities. This will leave approximately 3100 categorized substances, the subject of further review

Many substances have minimal or conflicting Categorization data

- In addition to the 4300 substances meeting the categorization criteria, 1200 substances have minimal or conflicting data despite our efforts to collect available data, use computer models and requests to industry for voluntary submissions of data
 - 200 of which are in high volume (>1000 tonnes)
- Further work by industry or other jurisdictions would face the same scientific challenges.
- The program has exhausted all “available information” and international programs have been generating limited data prior to 2006
- Additional work could focus on comparison of program results over time as they become available

An Action Plan for Research is needed

- A group of substances are emerging as priorities for data generation
 - We are proposing that Canadian industry fill some of the data gaps – this can be completed in conjunction with global partners or international High Production Volume programs
- For others we must identify and prioritize research needs for information critical to assessment and management activities.
Potential data gaps to be filled:
 - Uncertain categorization parameters
 - Substance characteristics and fate processes
 - Analytical method development and monitoring data
 - Broader research themes
- Our research must identify potential partners for engagement

Key Outcomes of Categorization

- For those substances meeting the categorization criteria:
 - Some substances can proceed immediately to risk assessment – key actions will be announced shortly
 - While, other substances require additional data generation to reduce uncertainty in their categorization decision
 - New research needs to be conducted particularly in the area of environmental monitoring, and model development
 - Progress from the US & OECD HPV programs and pending EU REACH program will continue to be taken into consideration