Use of Informational Resources on Hazard and Exposure to Support Chemical Risk Assessment in Canada

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Overview

• Canada’s Chemicals Management Plan (CMP)
  – Categorization:
    • Process
    • Data Used to Inform Health-Related Components of Categorization
    • Results

• Chemical Human Health Risk Assessment Search Tools
  – Hazard and Exposure Information Sources
  – Canadian Specific Information Sources
Chemicals Assessment & Management in Canada

- **Chemicals Management Plan (CMP):**
  - The Government of Canada’s response to the Strategic Approach to International Chemicals Management (SAICM).
  - Designed to meet the 2020 goals set by the World Summit on Sustainable Development for Sound Management of Chemicals.
  - Provides a framework for the assessment and management of approximately 4,300 substances identified as priorities through categorization.
Domestic Substances List (DSL):

- List of substances that, between January 1, 1984 and December 31, 1986 were in Canadian commerce; used for manufacturing purposes; or manufactured in or imported to Canada in a quantity of 100 kg or more in any calendar year.
- Contains approximately 23,000 substances and is amended regularly to include additional substances that have been deemed eligible following their assessment under the new substances notification and assessment regime.
- Includes discrete organic compounds, inorganic substances, organometallic substances, polymers, and unknown or variable composition complex reaction products or biological material such as acetone or iron.
CEPA 1999 required the Ministers of Environment and Health to categorize the 23,000 substances on the Domestic Substances List (DSL) within a 7-year timeframe, according to specific criteria (completed in 2006).
Categorization of the Canadian Inventory

- A priority-setting exercise
- Based on simple tools (SimET and SimHaz)
- SimET: a relative ranking of all substances based on 3 lines of evidence
  - Quantity in commerce
  - Number of submitters, and
  - Sum of expert ranked use codes
- Based on initial compilation data for the DSL (1984-1986) – only data available for ALL substances on the DSL
- Resulted in substances either grouped as
  - Greatest potential for exposure (GPE)
  - Intermediate potential for exposure (IPE)
  - Lowest potential for exposure (LPE)
Results of Health-Related Components of Categorization

Below is an excerpt from the list of human health priorities:

High Health Priorities for Action

Results based on July 27, 2006 and persistent and bioaccumulative status as of July 2006

<table>
<thead>
<tr>
<th>ID</th>
<th>CAS RN</th>
<th>Chemical Name</th>
<th>Maximal List Subgroup</th>
<th>Status</th>
<th>SimHaz Result Carcinogenicity</th>
<th>SimHaz Result Developmental Toxicity</th>
<th>SimHaz Result Genotoxicity</th>
<th>SimHaz Result Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>62-56-6</td>
<td>Thiourea</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2</td>
<td>74-87-3</td>
<td>Methane, chloro-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3</td>
<td>75-28-5</td>
<td>Propane, 2-methyl-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>4</td>
<td>75-56-9</td>
<td>Oxirane, methyl-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>5</td>
<td>78-59-1</td>
<td>2-Cyclohexen-1-one, 3,5,5-trimethyl-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>6</td>
<td>78-79-5</td>
<td>1,3-Butadiene, 2-methyl-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>7</td>
<td>79-06-1</td>
<td>2-Propenamide</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>8</td>
<td>80-05-7</td>
<td>Phenol, 4,4'-(1-methyl ethyldene) bis-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>9</td>
<td>91-20-3</td>
<td>Naphthalene</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>10</td>
<td>96-29-7</td>
<td>2-Butanone, oxime</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>11</td>
<td>98-01-1</td>
<td>2-Furancarboxaldehyde</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>12</td>
<td>100-41-4</td>
<td>Benzene, ethyl-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>13</td>
<td>100-44-7</td>
<td>Benzene, (chloromethyl)-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>14</td>
<td>103-23-1</td>
<td>Hexanedioic acid, bis(2-ethylhexyl) ester</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>15</td>
<td>106-89-1</td>
<td>Oxirane, (chloromethyl)-</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>16</td>
<td>106-97-8</td>
<td>Butane</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>17</td>
<td>108-05-4</td>
<td>Acetic acid ethenyl ester</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>18</td>
<td>110-54-3</td>
<td>Hexane</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>19</td>
<td>111-15-9</td>
<td>Ethanol, 2-ethoxy-, acetate</td>
<td>High - GPE</td>
<td>GPE</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Results of Health-Related Components of Categorization

Chemical Hazard based on tool → SimHaz (data available prior to 2006)

- Carcinogenicity* was determined by one or more the following criteria:

<table>
<thead>
<tr>
<th>Organization</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Community</td>
<td>Category 1 (Known to be carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Category 2 (Regarded as if carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Category 3 (Causes concern for humans owing to possible carcinogenic effects)</td>
</tr>
<tr>
<td>Health Canada (Guidelines for Canadian Drinking Water Quality)</td>
<td>Group I (Carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Group II (Probably carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Groups IIIA and IIIB (Possibly carcinogenic to humans)</td>
</tr>
<tr>
<td>International Agency for Research on Cancer</td>
<td>Group 1 (Carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Group 2A (Probably carcinogenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Group 2B (Possibly carcinogenic to humans)</td>
</tr>
<tr>
<td>National Toxicology Program</td>
<td>Known to be a human carcinogen</td>
</tr>
<tr>
<td></td>
<td>Reasonably anticipated to be a human carcinogen</td>
</tr>
<tr>
<td>United States Environmental Protection Agency (US EPA) 1986 Carcinogenicity Guidelines</td>
<td>Group A (Human carcinogen)</td>
</tr>
<tr>
<td></td>
<td>Groups B1 and B2 (Probable human carcinogen)</td>
</tr>
<tr>
<td></td>
<td>Group C (Possible human carcinogen)</td>
</tr>
<tr>
<td>US EPA 2003 Carcinogenicity Guidelines</td>
<td>Carcinogenic to humans</td>
</tr>
<tr>
<td></td>
<td>Likely to be carcinogenic to humans</td>
</tr>
<tr>
<td></td>
<td>Suggestive evidence of carcinogenicity, but not sufficient to assess</td>
</tr>
<tr>
<td></td>
<td>Human carcinogenic potential</td>
</tr>
</tbody>
</table>

*Note: Some substances are identified as a carcinogen or mutagen because the substance may contain substances of concern (eg. ≥ 0.1 % w/w benzene)
Results of Health-Related Components of Categorization

Chemical Hazard based on tool → SimHaz (data available prior to 2006)

**Developmental Toxicity was determined by one of the following criteria:**

<table>
<thead>
<tr>
<th>European Community</th>
<th>Category 1 (Known to cause developmental toxicity in humans)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Category 2 (Regarded as if they cause developmental toxicity in humans)</td>
</tr>
<tr>
<td></td>
<td>Category 3 (Causes concern for humans owing to possible developmental toxic effects)</td>
</tr>
</tbody>
</table>

**Genotoxicity was determined by one of the following criteria:**

<table>
<thead>
<tr>
<th>European Community</th>
<th>Category 1 (Known to be mutagenic to humans)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Category 2 (Regarded as if mutagenic to humans)</td>
</tr>
<tr>
<td></td>
<td>Category 3 (Causes concern for humans owing to possible mutagenic effects)</td>
</tr>
</tbody>
</table>

**Reproductive Toxicity was determined by one of the following criteria:**

<table>
<thead>
<tr>
<th>European Community</th>
<th>Category 1 (Known to impair fertility in humans)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Category 2 (Regarded as if they impair fertility in humans)</td>
</tr>
<tr>
<td></td>
<td>Category 3 (Causes concern for human fertility)</td>
</tr>
</tbody>
</table>

Final results of categorization (human health and eco):

The Categorization Process

CEPA 1999 required the Ministers of Environment and Health to categorize the 23,000 substances on the DSL within a 7-year timeframe, according to specific criteria (completed in 2006)
Where we are in the process of assessing and managing existing chemical substances under CEPA

4300 existing chemical substances to be addressed by 2020:

- Included in Rapid Screening: 545
- Addressed through PBiT SNAcs: 145
- Being addressed in Petroleum Sector Stream Approach: 164
- Addressed in the Challenge: 200
- Remaining priorities to be addressed by 2020: 3200

~1500 to be addressed by 2016 through the groupings initiative, rapid screening and other approaches

http://www.chemicalsubstanceschimiques.gc.ca/plan/status_prioritized_sub-statut_substances_priorisees-eng.php
Chemical Risk Assessment Search Tools

- Developed guidance to streamline and build consistency in data collection for human health exposure and hazard chemical risk screening assessments under CEPA 1999

- Identifies databases/sources that contain important substance:
  - Toxicology
  - Pharmacokinetics
  - Emissions
  - Epidemiology
    - Phys/chem property
    - Use patterns
    - Concentration

- Currently updated monthly & include 2 phases (tiered approach)
Search Strategy: Targeted Approach for Data Collection

Phase I

• Aim to identify important substance characteristics
  – Regulatory Status and Assessment Activity
  – In Commerce Status and Use Patterns
  – Bureau Assessment and Data Collection Activities
  – Phys/Chem Property Databases/Sources
  – Search Engines & Databases

Phase II

• Utilizes information gathered from phase I to perform targeted searches of Product and Monitoring Databases
  – Emissions and Monitoring Sources/Databases
  – Food Sources/Databases
  – Biomonitoring Sources/Databases
  – Product Databases/Sources
Key Exposure and Tox Sources: Phase I

Internal Databases:
- Use Profiles
- Exposure Files Databases
- Section 71 Survey
- Toxicity profiles

OECD eChemPortal:
- ACTor EnviChem
- HSDB
- OECD HPV
- EDEXIM (Import/Export of Dangerous Chemicals)

Search Engines:
- SciFinder
- Scopus
- ChemIDPlus

Phys/Chem Property Databases:
- Merck
- Hawleys
- CRC Handbook of Phys/Chem Properties and Environmental Fate
Key Exposure Sources: Phase II

Emissions:
- Canada’s National Pollutant Release Inventory
- Great Lakes Commission Inventory
- US EPA Toxic Release Inventory
- N.A & European Pollutant Release and Transfer Register

Environmental Monitoring:
- Canada’s National Air Pollution Surveillance
- Hamilton Air Monitoring Network
- Canadian DW Guidelines
- Canadian House Dust Study
- UNEC’s European Monitoring & Evaluation Program

Product Databases:
- US Household Products Database
- SPIN
- Canada’s Cosmetic Ingredient Hotlist & Notification System
- Canada’s Drug & Natural Health Product Databases
- Canadian Centre for Occupational Health and Safety MSDS Database

Biomonitoring:
- Canadian Health Measures Survey
- National Health & Nutrition Examination Survey
- German Environmental Survey
- California Environmental Contaminant Biomonitoring Program
Key Toxicological Sources: Phase II

Canadian, US Data:
- Health Canada DW Guidelines
- Ontario Ambient Air Quality Criteria
- Natural Health Products Monographs & Dietary Reference Intakes
- California OEHHA Unit Risk

Foods:
- US FDA
- European Food Safety Authority
- WHO Food Safety Reviews

Pesticides:
- US EPA Pesticides
- PMRA Formulants List
- EU Pesticide Database
- Human & Environmental Risk Assessment on Household Cleaning Products

Petroleum:
- American Petroleum Institute
- Tech Street
- Concawe
Canadian Specific Information Sources

Chemical Risk Assessment documents:

• Priority Substances Assessment Program

• Government of Canada “Challenge” for chemical substances that are a high priority for action
  www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php

• Petroleum Sector Stream Approach
  www.chemicalsubstanceschimiques.gc.ca/petrole/index-eng.php

• Substance Groupings Initiative
  www.chemicalsubstanceschimiques.gc.ca/group/index-eng.php

• Other substances of interest
  www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/other_chem-autres_sub-eng.php
Canadian Specific Information Sources

- **Canadian Monitoring Programs for Industrial Chemicals:**
  - National Pollutant Release Inventory (NPRI)
    - Canada’s legislated, publicly accessible inventory of pollutant releases (to air, water and land), disposals and transfers for recycling
  - Chemistry Industry Association of Canada (CIAC)
    - Conducts environmental surveys of member facilities
  - Commission for Environmental Cooperation, North American Pollutant Release and Transfer Register (NAPRTR)
    - Provides information on industrial pollutant releases and transfers, drawing on the CEC’s integrated North American PRTR database which brings together data from the Canadian, US and Mexican PRTR programs. Also reports Chemical Export Data for the 3 countries.
Canadian Specific Information Sources

• Canadian Monitoring Programs for Industrial Chemicals:
  – Canadian Importers Database
    • [www.ic.gc.ca/cgi-bin/sc_mrkti/cid/cid_e.cgi?func=start_search&search_type=by_product](http://www.ic.gc.ca/cgi-bin/sc_mrkti/cid/cid_e.cgi?func=start_search&search_type=by_product)
  – Great Lakes Commission Inventory of Toxic Air Emissions
    • This database provides values for emissions from point, area, on-road and off-road sources for 82 toxic air pollutants in Ontario and the eight Great Lake states.
    • [www.glc.org/air/inventory/1999/](http://www.glc.org/air/inventory/1999/)
  – Environment Canada National Air Pollution Surveillance (NAPS)
    • The NAPS Network was established in 1969 as a joint program of the federal and provincial governments to monitor and assess ambient air in Canadian urban centres.
  – Health Canada Drinking Water Guidelines
    • The Guidelines for Canadian Drinking Water Quality are published by Health Canada on behalf of the Federal-Provincial-Territorial Committee on Drinking Water (CDW).
Canadian Specific Information Sources

• Canadian Monitoring Programs for Industrial Chemicals:
  – Hamilton Air Monitoring Network
    • Collaborative initiative with industry to monitor ambient air in the Hamilton Region (Key industrial region). Companies participating in the MOE's Source Emissions Monitoring program are required to submit an annual summary report of their air quality monitoring results obtained in the previous calendar year.
    • [www.hamnair.ca](http://www.hamnair.ca)
  – Statistics Canada Canadian Health Measures Survey
    • Report provides biomonitoring results from the CHMS Cycle I survey which was conducted between the years 2007 to 2009.
  – Government of Canada Food & Drugs Regulations (Food Additive Table)
    • GOC’s Food and Drug Regulations: provide list of additives that are approved for use in Canada
Canadian Specific Information Sources

• Product Databases:
  – Health Canada’s Cosmetic Hotlist
    • Health Canada list of substances that are restricted and prohibited in cosmetics
  – Health Canada’s Drug Products Database
    • DPD contains product specific information on drugs approved for use in Canada. The database is managed by Health Canada and includes human pharmaceutical and biological drugs, veterinary drugs and disinfectant products.
    • [http://webprod3 hc-sc.gc.ca/dpd-bdpp/index-eng.jsp](http://webprod3 hc-sc.gc.ca/dpd-bdpp/index-eng.jsp)
  – Health Canada’s Licensed Natural Health Products Database
    • Licensed Natural Health Products Database contains product specific information on those natural health products that have been issued a product licence by Health Canada.
    • [http://webprod3 hc-sc.gc.ca/lnhd-dbpsnh/index-eng.jsp](http://webprod3 hc-sc.gc.ca/lnhd-dbpsnh/index-eng.jsp)
Canadian Specific Information Sources

• Product Databases:
  – Health Canada’s Natural Health Products Ingredients Database
    • Database enables access to acceptable medicinal and non-medicinal ingredients in NHP's, standard terminology used by the Natural Health Products Online System, and single ingredient and product monographs
  – PMRA Product Label Search Database
    • Tool used to gather pesticide product information by searching the available Product Information Elements, or the full textual content of the entire label collection from the PMRA Registered Products Database.
  – PMRA Formulants List
    • Document contains a revised list of formulants that are found in pest control products currently registered in Canada under the Pest Control Products Act and Regulations
Canadian Specific Information Sources

- Canadian Centre for Occupational Health & Safety
  - MSDS
  - ChemInfo
  - CHEMpendium
  - CESARS

www.ccohs.ca
Canadian Specific Information Sources

• Substances Lists
  – Export Control List: Substances whose export is controlled because their use in Canada is prohibited or severely restricted or because Canada has agreed, through an international agreement, to control their export.
  – Non-Domestic Substances List: An inventory of substances that are not on the Domestic Substances List, but are in commercial use internationally.
  – Priority Substances List: Substances that require investigation on a priority basis to determine whether they meet any of the criteria set out in section 64 of the Act.
  – List of Toxic Substances: Substances that meet at least one of the criteria set out in section 64 of the Act, and that were added to Schedule 1 of the Act by the Governor in Council.
  – Virtual Elimination List: Substances designated for virtual elimination.

www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=EE479482-1
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