Categorization of the Canadian Domestic Substances List

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What is the Domestic Substances List (DSL)?

- A list of substances that are “in commerce” in Canada – “existing substances”
- The DSL was created in 1991 - for the purpose of defining a “new substance”
- For categorization, focus on substances nominated as being, between 1984-1986:
  - In Canadian commerce or used for commercial manufacturing in Canada, or;
  - Manufactured or imported in Canada at >100 kg/year
  - Does not include: contaminants, by-products and wastes
Types of Substances on the DSL
(total 23,000 substances)

- Polymers: 20%
- Inorganics: 10%
- UVCBs: 20%
- Discrete Organics: 50%
What is Categorization?

• Mandated under CEPA 1999 (S. 73)
  – Ministers are 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)

• DSL categorization is a precedent setting activity – no other jurisdiction has implemented such a program

• Important considerations:
  – process is scientifically sound but practical
  – allowing sufficient and efficient stakeholder input
What is the Objective of Categorization?

• 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 regs, and inherently toxic to humans or to non-human organisms, as determined by lab or other studies
Human Health Related Aspects

- “Greatest potential for exposure” (GPE)
  - all 23 000 substances on the DSL

- “Inherently Toxic to humans” (iThuman)
  - subset of substances

Which subset?
  - Those that are P or B [but not inherently toxic to non-human organisms (iTeco)]
Approach to Categorization for Human Health

• Use of Tools to maximize efficiency in prioritization of a large number of substances
• It was recognized that multiple stages of prioritization were required
  – First Stage- needed to be simple and pragmatic
  – Subsequent Stages- increased in complexity
The Tools for Categorization

- **Simple Tools**
  - **Simple Exposure Tool (SimET)**
    Relative ranking of all DSL substances based on submitters (S), quantity (Q) and expert ranked use (ERU)
  - **Simple Hazard Tool (SimHaz)**
    Identification of high or low hazard compounds by various International agencies based on weight of evidence for multiple endpoints

- **Complex Tools**
  - **Complex Exposure Tool (ComET)**
    Quantitative estimate of upper bounding environmental and consumer exposure for multiple age groups based on use scenarios
  - **Complex Hazard Tool (ComHaz)**
    Hierarchy of multiple toxicological endpoints and data sources including QSAR
The Draft Maximal List

- Application of the Simple Tools (SimET, SimHaz)
  Exposure – ranked all substances based on greatest potential for exposure and separated into one of three groups
  Greatest Potential for Exposure (GPE)
  Intermediate Potential for Exposure (IPE)
  Lowest Potential for Exposure (LPE)
  Hazard- Identified both High and Low Hazard Substances

- Result
  Draft Maximal List Released in October 2004
  Consisted of a total of 1896 substances
  Requested focused submission of information to fill data gaps
Draft Maximal List Groups

- High Hazard and LPE
- High Hazard and GPE or IPE
- GPE
- IPE, P or B
- IPE, P or B unknown
- Low Hazard
- "other"
Refinement of the Maximal List

- Consideration of new and submitted information
- Identified those substances already assessed and/or managed under CEPA
- Application of the Complex Hazard Tool to the moderate group of substances
# Human Health Categorization Results

## High Hazard Substances

<table>
<thead>
<tr>
<th>High or Intermediate Exposure (~100)</th>
<th>Low Exposure (~160)</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>High/Intermediate Exposure (~160)</th>
<th>Low Exposure (~100)</th>
</tr>
</thead>
</table>

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.
Categorization Criteria for P, B, and non-human iT

**Bioaccumulation**
- **BAF** > 5000
- or
- **BCF** > 5000
- or
- log **Kow** > 5

**iT –non-humans**
- Acute aquatic toxicity of **LC(EC)_{50}** ≤ 1 mg/L,
- or a chronic aquatic toxicity of **NOEC** < 0.1 mg/L

**Persistence**
A substance is considered persistent if its transformation half-life satisfies the criterion in any one environmental medium or if it is subject to long-range transport

<table>
<thead>
<tr>
<th>Medium</th>
<th>Half-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air</td>
<td>&gt; 2 days (or LRT)</td>
</tr>
<tr>
<td>Water</td>
<td>&gt; 6 months</td>
</tr>
<tr>
<td>Sediment</td>
<td>&gt; 1 year</td>
</tr>
<tr>
<td>Soil</td>
<td>&gt; 6 months</td>
</tr>
</tbody>
</table>
Process for Ecological Categorization

1. Define Technical Approach (Guidance Manual)
2. Collection of Empirical Data and Generation of QSAR predictions*
3. Scientific Evaluation of Data
4. Release Preliminary Categorization Decisions*

*released publicly on CD
Process for Ecological Categorization (cont’d)

Voluntary Submission of Data by Stakeholders*

Scientific Evaluation of Data

Issue Final Categorization Results (Sept 2006)

Not Considered P/B and eco iT

Considered P/B and eco iT
## Data Preference for P B iT Profiles

<table>
<thead>
<tr>
<th>Preference</th>
<th>P</th>
<th>B</th>
<th>iT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higher</td>
<td></td>
<td>Experimental</td>
<td></td>
</tr>
<tr>
<td>Medium</td>
<td>Analogue / Groupings / Scientific rationale</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower</td>
<td></td>
<td></td>
<td>Modelled (QSAR)</td>
</tr>
</tbody>
</table>
Stakeholder Submission of Data

• June 2004, Canada launched an 18 month voluntary challenge to industrial stakeholders and interested parties to submit experimental study or other information that could help refine categorization decisions

• We received approx 20 larger data submissions for consideration and more than 400 individual studies addressing P, B or aquatic toxicity

• Approx. 20 submissions have been received covering the human health aspects of categorization
Availability of Experimental Data

• For more than 11,500 organic substances examined,
  – Experimental aquatic toxicity data was found for 1200 substances (80% accepted)
  – Experimental P data was found for 1500 substances (50% accepted)
  – Experimental B data was found for 440 substances (80% accepted)

• 2100 substances on the DSL are also part of the US HPV program and 3140 are part of the OECD HPV program

• The US HPV and OECD HPV programs provided:
  – Aquatic toxicity data for approx. 160 substances (70% accepted)
  – Persistence data for approx. 140 substances (90% accepted)
  – Bioaccumulation data for approx. 10 substances (90% accepted)
Ecological Categorization Results

*Low volume <1T; Med volume> =1T and <1000T; High volume >=1000T
More Information

• Chemical Substances Website:
  http://www.chemicalsubstances.gc.ca

• Health Canada Existing Substances Division Website:
  http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/index_e.html

• Environment Canada Existing Substances Division Website:
  http://www.ec.gc.ca/substances/ese

• CD ROMS available by request