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

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Types of Substances on the DSL
(total 23,000 substances)

Inorganics 10%

Polymers 20%

Discrete Organics 50%

UVCBs 20%
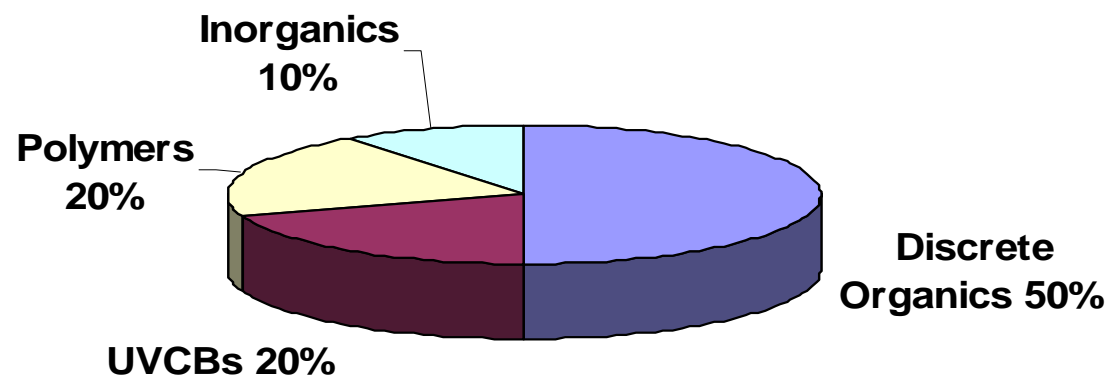
What is Categorization?

- 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

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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)

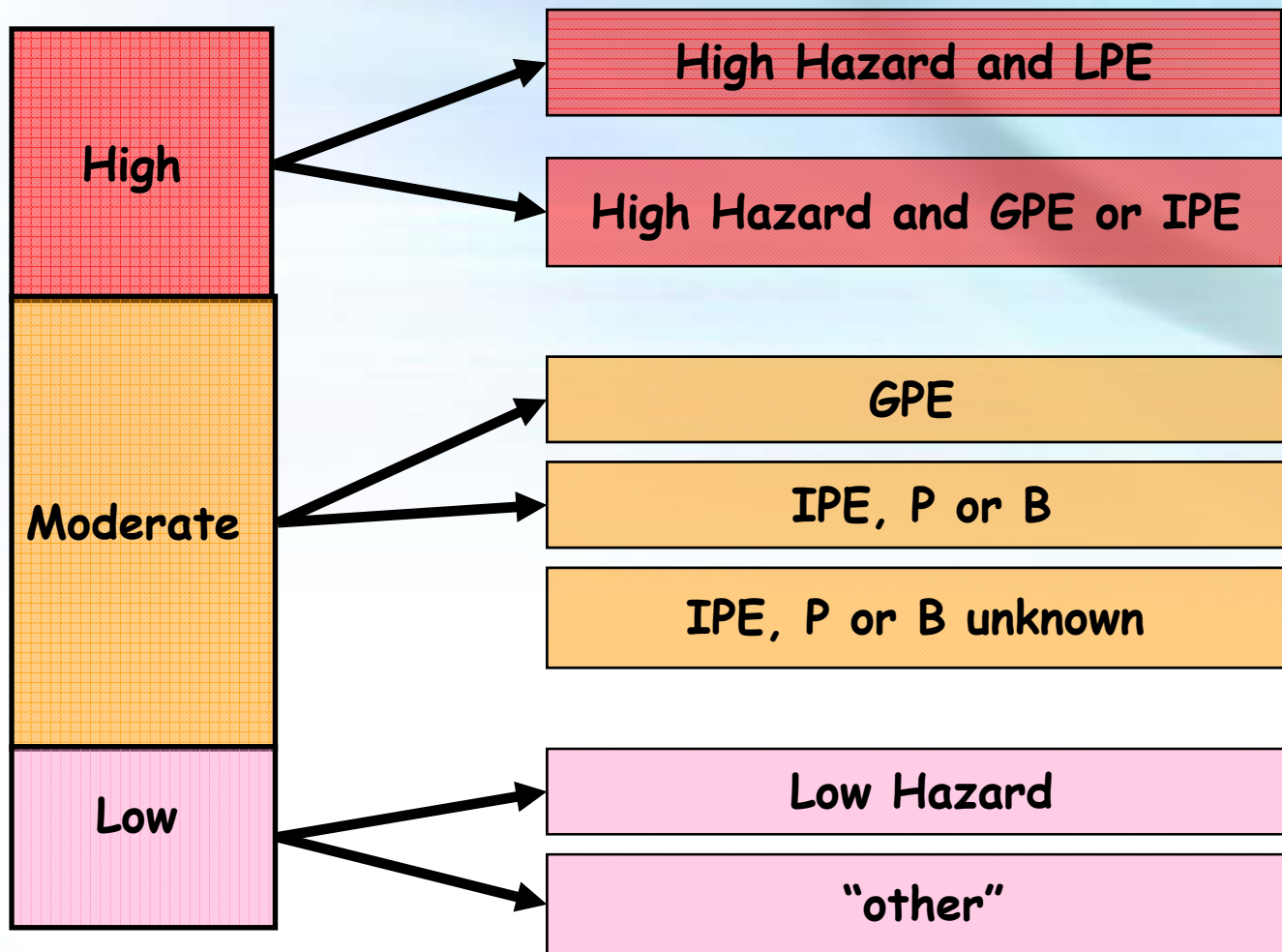Hierarchy of multiple toxicological endpoints and data sources including QSAR

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
- High Hazard and LPE
- High Hazard and GPE or IPE

Moderate
- GPE
- IPE, P or B
- IPE, P or B unknown

Low
- 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

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

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

Bioaccumulation

BAF $\geq$ 5000
or
BCF $\geq$ 5000
or
log Kow $\geq$ 5

iT –non-humans

Acute aquatic toxicity of LC(EC)$_{50}$ $\leq$ 1mg/L, or a chronic aquatic toxicity of NOEC $\leq$ 0.1 mg/L
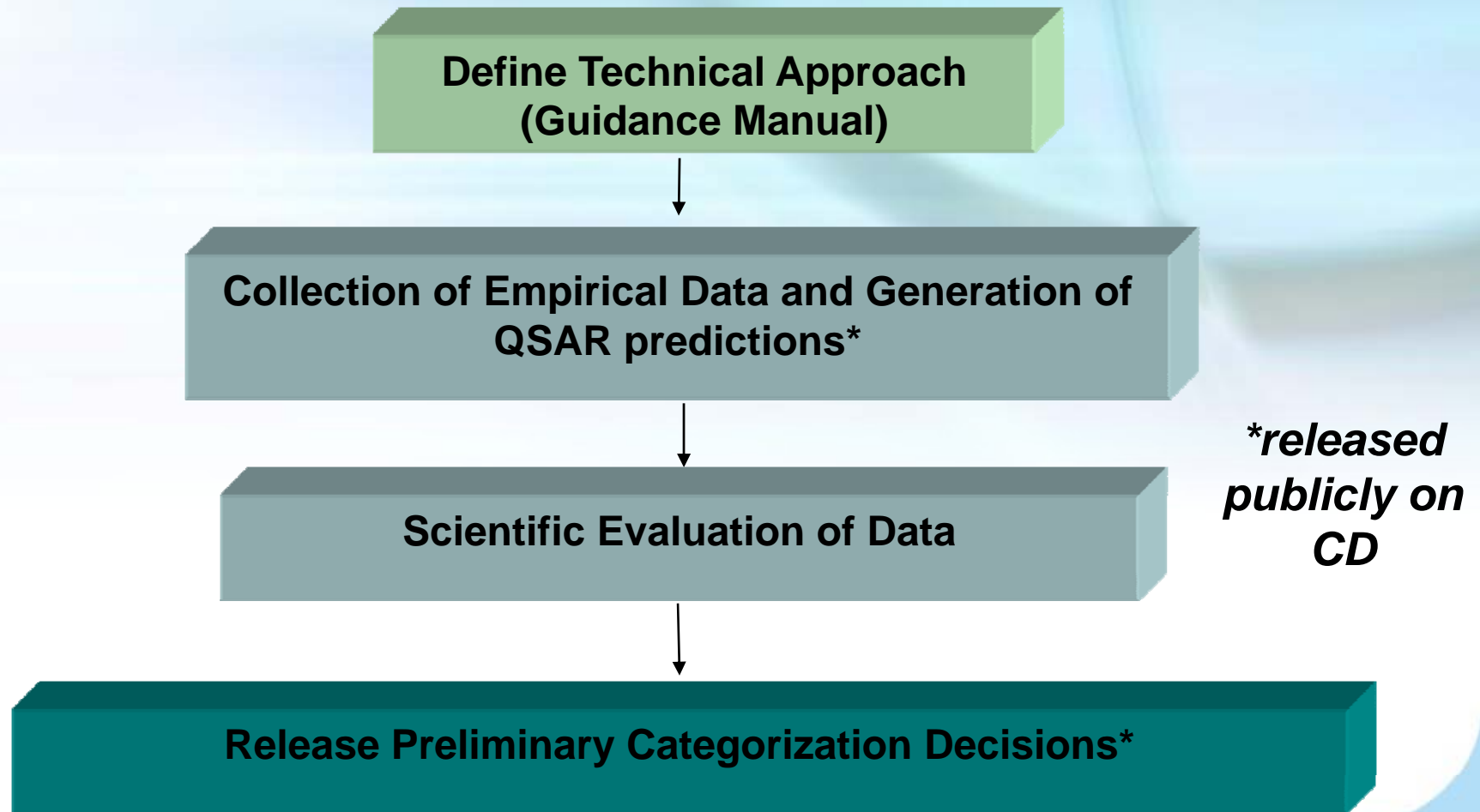
Persistence

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
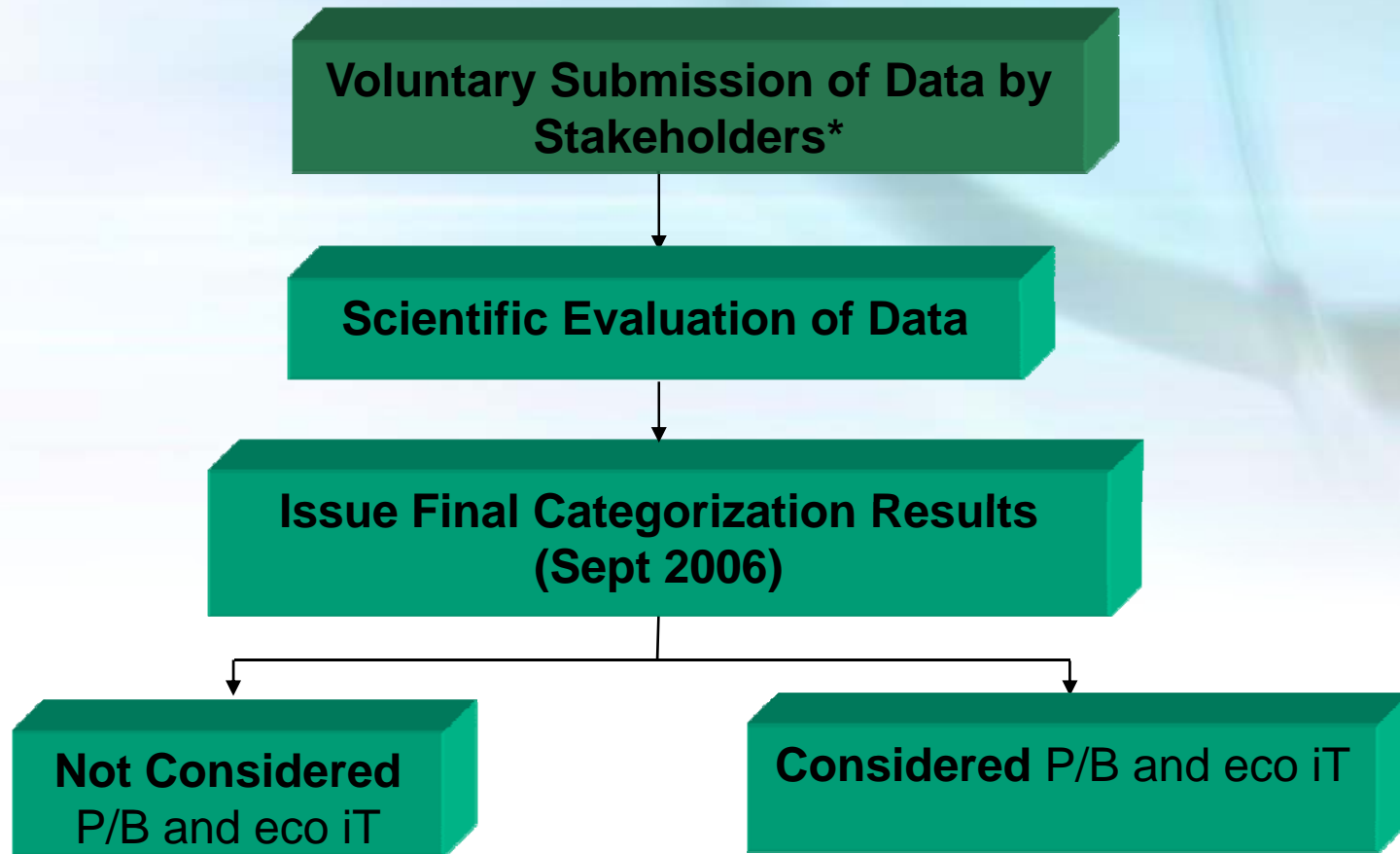
Medium	Half-life
Air	$\geq$ 2 days (or LRT)
Water	$\geq$ 6 months
Sediment	$\geq$ 1 year
Soil	$\geq$ 6 months

Process for Ecological Categorization

Define Technical Approach (Guidance Manual)

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Collection of Empirical Data and Generation of QSAR predictions*

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Scientific Evaluation of Data

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Release Preliminary Categorization Decisions*

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*released publicly on CD

Process for Ecological Categorization (cont'd)

Voluntary Submission of Data by Stakeholders*

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Scientific Evaluation of Data

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Issue Final Categorization Results (Sept 2006)

Not Considered P/B and eco iT

Considered P/B and eco iT

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Data Preference for P B iT Profiles

Preference	P	B	iT
Higher	Experimental		
Medium	Analogue / Groupings / Scientific rationale		
Lower	Modelled (QSAR)		

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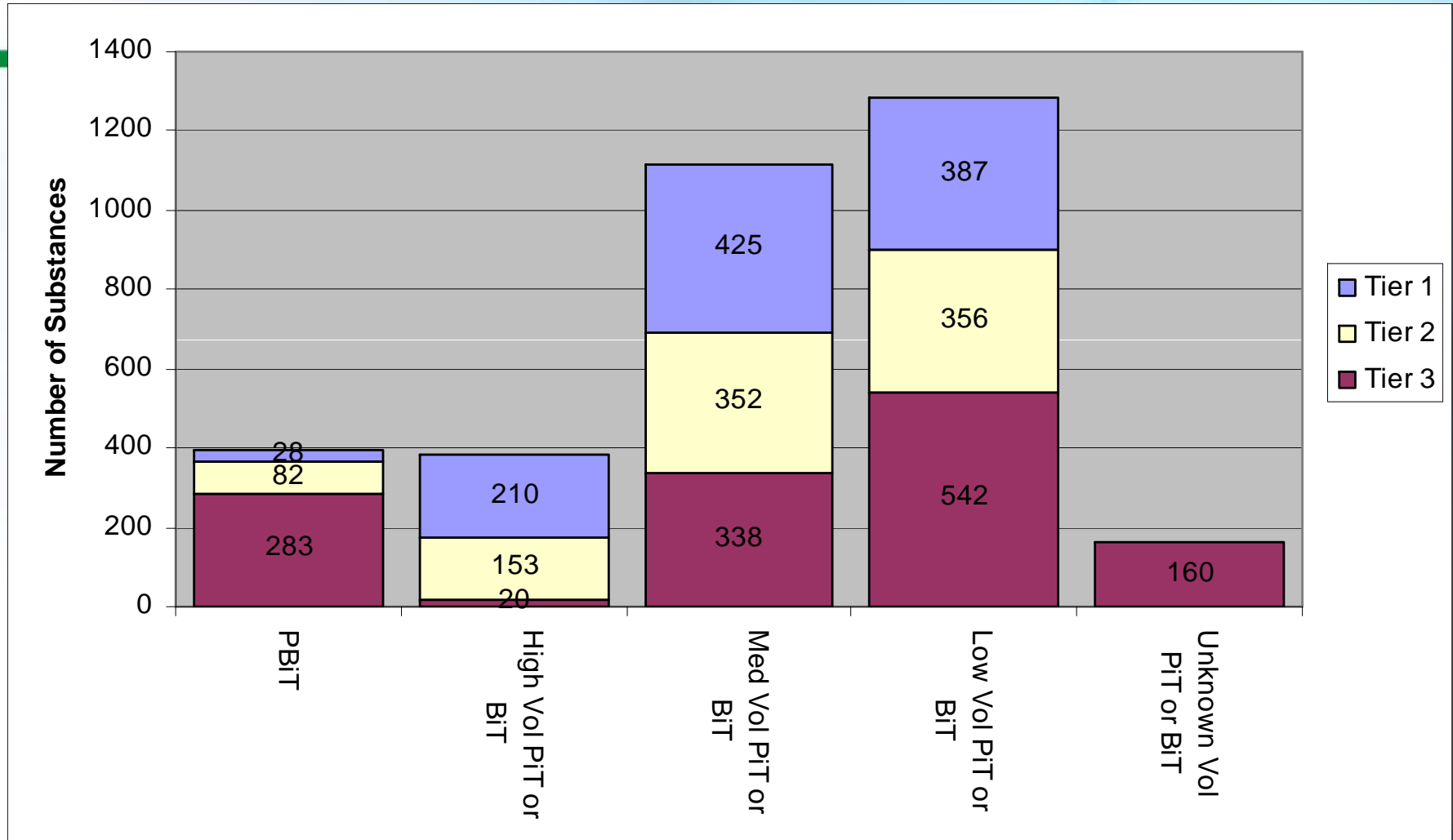
*Low volume <1T; Med volume>=1T and <1000T; High volume >=1000T

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