Great Lakes Binational Toxics Strategy Integration Meeting

Existing Substances Program

Environment Canada

June 18th, 2004

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The PSL 1 and PSL 2 Programs

PSL1 Program

- 44 substances were chosen by an Expert Advisory Panel - the Hall Panel - from a list of approximately 300 substances
- Assessments were completed by 1994. 25/44 were found to be CEPA toxic

PSL 2 Program

- 25 substances were recommended by a Expert Advisory Panel to the Minister from a list of almost 700
- 18/25 were found to be CEPA toxic

Update on Second Priority Substances List (PSL2)

- All substances on PSL2 have been assessed or otherwise dealt with within the mandated time frame prescribed under CEPA which expired on December 15th, 2000
- Of the twenty-three substances on PSL2 for which conclusions were reached, eighteen were proposed to be “toxic” and five were proposed not to be “toxic”. The 18 found to be “toxic” included:
  - Nonylphenol and its ethoxylates
  - Ammonia in the aquatic environment
  - Textile mill effluents
  - Chloramines
  - Hexachlorobutadiene
  - Road salts

Update on PSL 2 (continued)

- Acetaldehyde, Acrylonitrile, 1,3-Butadiene, Formaldehyde
- Respirable particulate matter less than or equal to 10 microns
- Ethylene Oxide
- 2-Methoxy ethanol (2-ME), 2-Butoxy ethanol (2-BE)
- N-Nitrosodimethylamine
- Acrolein
- Releases from primary and secondary copper smelters and copper refineries
- Releases from primary and secondary zinc smelters and zinc refineries

- Radionuclides final report still to be released
- Ethylene glycol and Aluminum Salts assessments "suspended" due to lack of conclusive human health data

Update on First Priority Substances List (PSL1)

- Draft reports have been prepared for 13 substances which required Environment Canada or Health Canada follow-up.
  - Chlorinated paraffins (short, medium and long chains) have undergone further assessment and will be published shortly
  - Used Crankcase Oils draft report proposing toxic published in June 2003
  - Styrene, organotin compounds, tetrachloroethane and di-n-octyl phthalate final reports and decisions published November 1, 2003 indicating not toxic
  - Final follow-up reports/decisions on 5 Chlorobenzenes published April 3, 2004
    - Tetra- and Pentachlorobenzes proposed order to add to List of Toxic substances published April 24, 2004 for 60-day public comment period
  - Draft follow-up reports for 3,5-dimethylaniline, bis(2-chloroethyl)ether, and Aniline, indicating Suspect Health toxic published in October 2002

Categorization

What is the Domestic Substances List (DSL)?

- The DSL was created for the purpose of defining a "new substance"
- Originally included 23,000 substances nominated between 1984-1986 as being:
  - in Canadian commerce or used for commercial manufacturing in Canada, or;
  - manufactured or imported in Canada at ≥100kg/year
- These are the substances to be examined under the Categorization and Screening exercise (i.e. not "new substances" added later)

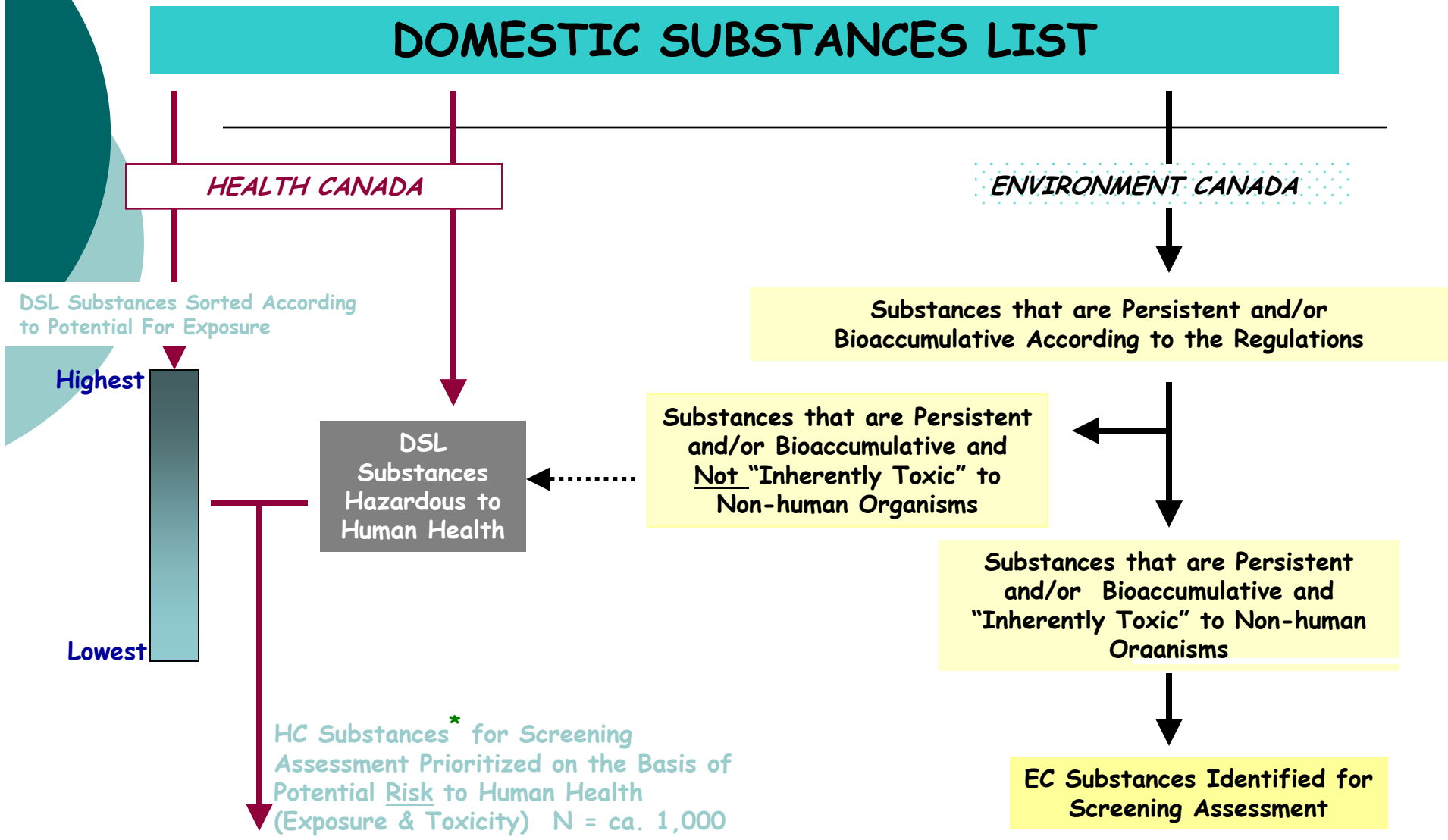
Categorization: Mandate under CEPA 1999, Section 73

- 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). All substances will be categorized to determine if they:
  - May present, to individuals in Canada, the greatest potential for exposure (s.73(1)(a)); or
  - Are persistent or bioaccumulative, in accordance with the P and B regs, and inherently toxic to humans or to non-human organisms, as determined by lab or other studies (s.73 (1)(b))

Categorization

- 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

PROPOSED OVERALL FRAMEWORK FOR DSL CATEGORIZATION



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Approach for technical implementation of ecological approach

- The 23,000 substances were grouped into four groups based on the categorization approach required
  - Organics – amenable to modelling
  - Inorganics – requiring toxicity testing and not amenable to modelling
  - Polymers – amenable to New Substance approaches
  - UVCBs – requiring further grouping to determine which approach is most appropriate
- Once categorization is complete, substances will be grouped differently for assessment purposes

Persistence (P) Criteria

Media	Half-life
air	≥ to 2 days *
water	≥ to 182 days (6 months)
soil	≥ to 182 days (6 months)
sediment	≥ to 365 days (1 year)

*This criteria may be substituted for evidence of atmospheric transport in remote regions of Canada.

Bioaccumulation (B) Criteria

	Criteria
Bioaccumulation Factor (BAF)	**≥ to 5000**
Bioconcentration Factor (BCF)	**≥ to 5000**
Log Octanol-Water Partition Co-efficient (log Kow)	**≥ to 5**

- P and B criteria outlined in Regulations

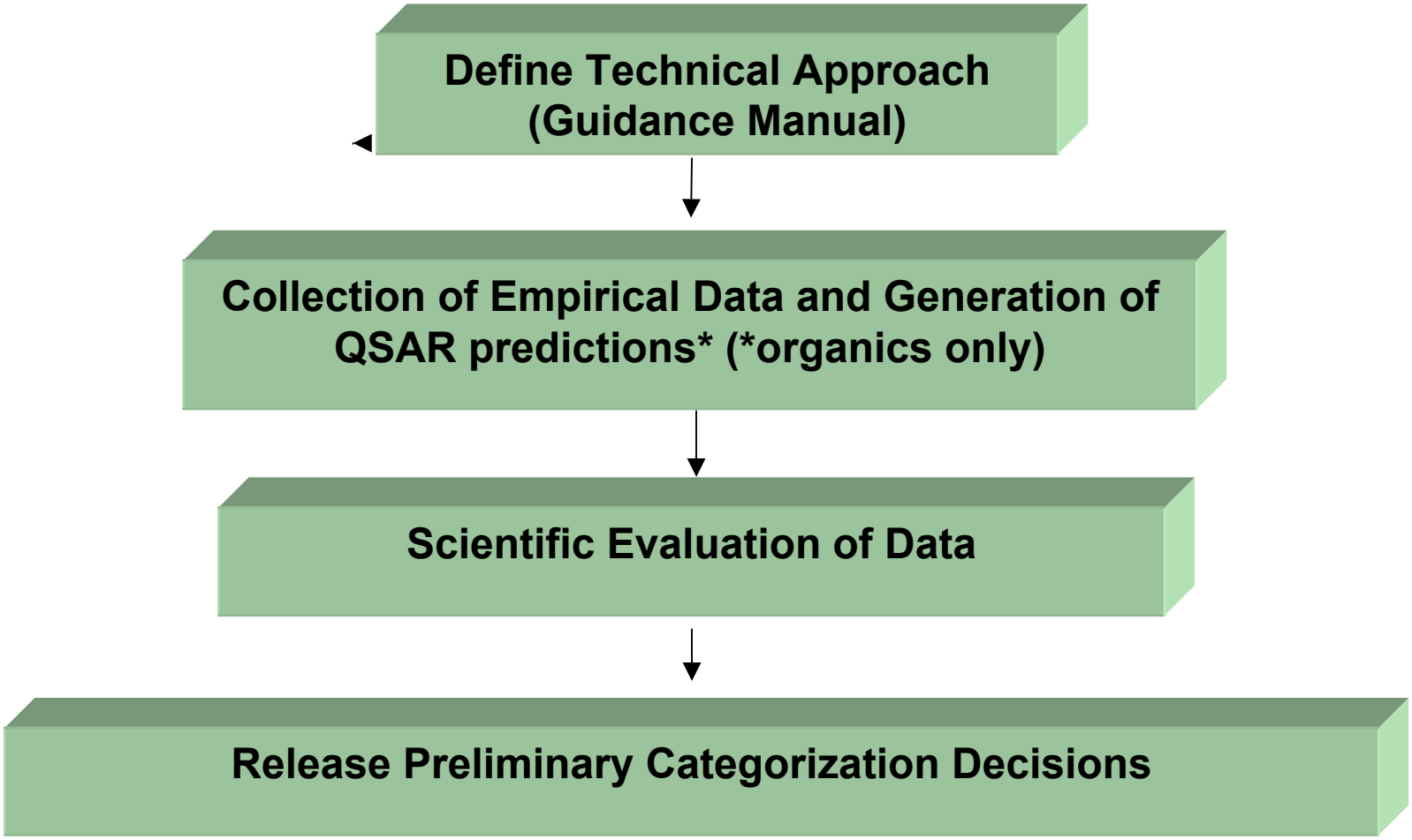
Inherent Toxicity (iT) to Non-human Organisms Criteria

- Focus on aquatic (pelagic) organisms
  - aquatic acute effects:

    LC_{50} (EC_{50}) $\leq$1mg/L
  - aquatic chronic effects:

    NOEC $\leq$ 0.1 mg/L

Process for Ecological Categorization: Organic and Inorganic Substances



Collection/Generation of Categorization Data: Organics

- Very little experimental data available for environmental endpoints. For example for 10,600 discrete organic substances:
  - 935 substances have experimental iT data
  - 141 substances have experimental B data
  - 650 substances have experimental P data
- Quantitative Structure Activity Relationships (QSARs) used to populate database and complement all available experimental data
- Approach to generating and using modelled data published in a Draft Environment Canada Guidance Manual

Ecological Approach for Inorganic Substances

- An expert advisory committee (Inorganic Working Group – IWG) participated in the development of approaches for inorganic substances
- It was agreed that for metal-containing substances
  - all substances are persistent "by default" (P_{DEG})
  - bioaccumulation not be considered
  - inherent toxicity (iT) provides discrimination

Inherent Toxicity (non-humans) for inorganic Substances

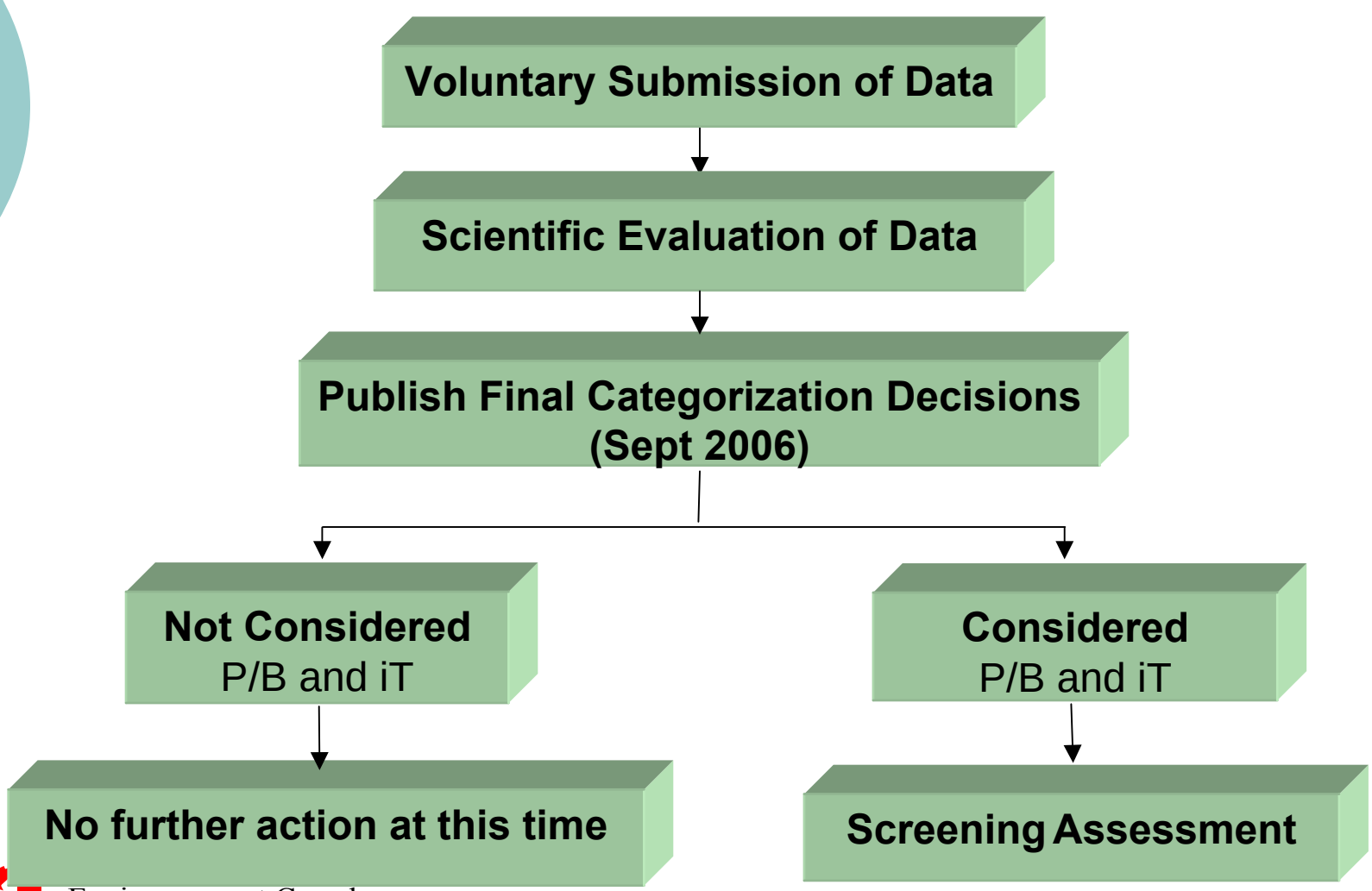
- A metal compound is inherently toxic (iT) if the lowest acceptable LC_{50} of dissolved forms of the metal is less than 1 mg/L, and

  ① the solubility of the metal compound is greater than 1 mg/L.
  - IWG (2001) recommendation; applied when solubility data are semiquantitive

  or

  ② the solubility of the metal compound is greater than the LC_{50} of the metal.
  - Alternative, applied when solubility data are quantitative

Process for Ecological Categorization: Organic and Inorganic Substances (cont'd)



Voluntary Submission of Ecological Data – Organics

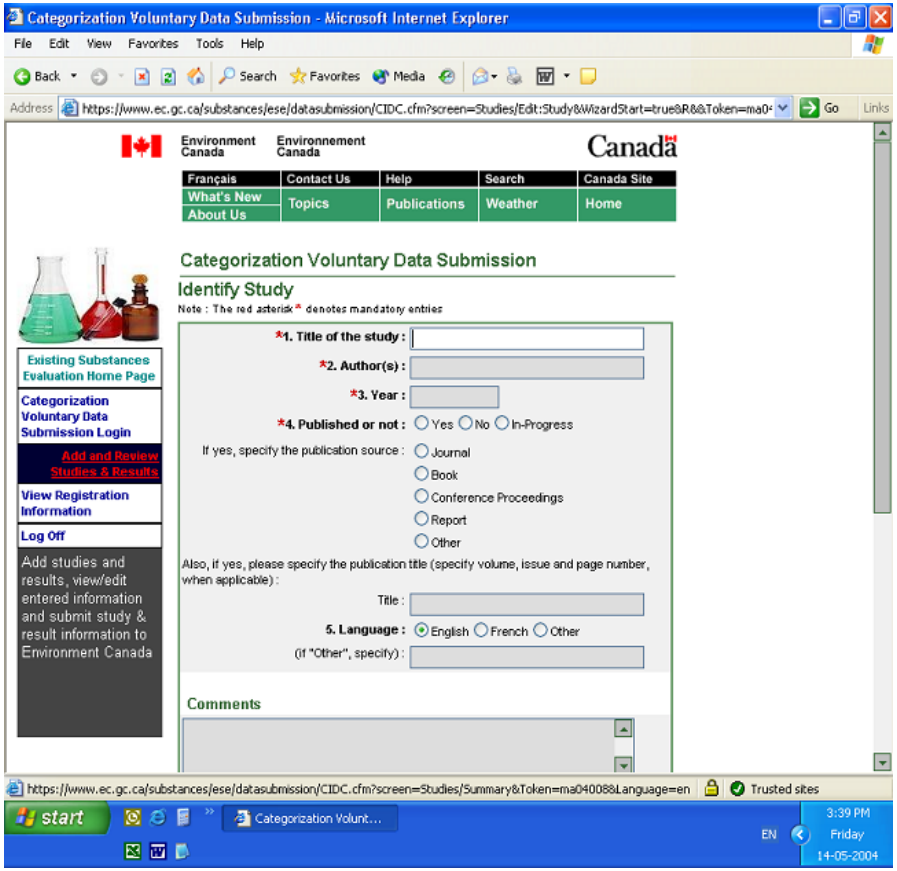
- We are now inviting interested parties to voluntarily submit experimental data on P, B and aquatic toxicity to help improve or refine our preliminary categorization decisions for the organics
- Not all the substances require the same amount of data. Those with a lower weight of evidence would benefit from data submission.
- Organics and inorganics have been organized into different groups to communicate priorities for voluntary submission of data from stakeholders

Categorization Voluntary Data Submission

- Visit the Existing Substances Web Site at: www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_organics.cfm and select "Voluntary Submission of Data"
- Instructions for registering your organization with the site and submitting data are provided on the main page
- Organizations are asked to register online and will be provided a secure login

Categorization Voluntary Data Submission

Entering the study



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Screening Assessment

Screening Assessments

- Ministers of Environment and Health are required under S.74, CEPA 1999:
  - to conduct screening assessments (SA), on substances meeting the categorization criteria, to determine whether the substance is “toxic” or capable of becoming “toxic” as defined in CEPA 1999.
- No defined timelines for conducting SA

“Toxic” under CEPA 1999, Section 64

A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity (EC)

(b) constitute or may constitute a danger to the environment on which life depends (EC)

(c) constitute or may constitute a danger in Canada to human life or health (HC)

Outcome of Screening Assessments

SCREENING ASSESSMENT

No further action under this program

Add to Priority Substances List for further assessment

Recommend adding to Schedule 1 Toxic List

Current Screening Assessments

- Concurrent with categorization, high priority substances have been undergoing assessment
- These substances have/are being assessed using a screening assessment (SA) approach
  - PBDEs – part of pilot
  - PFOS, its salts, and its precursors
  - PFOA and PFCS
  - Organotins – transitional substances
  - Organoperoxys – transitional substances

Polybrominated Diphenyl Ethers (PBDEs)

- SA addressed seven PBDE homologues: tetra to deca
- Based on environmental considerations, it is proposed that PBDEs be considered "toxic" as defined in Section 64 of CEPA 1999
- The tetra-, penta- and hexa- PBDEs satisfy the criteria for virtual elimination in CEPA 1999 and should be considered for addition to the Virtual Elimination List
- The hepta- to deca- PBDEs can be transformed to the bioaccumulative forms in the environment, and therefore would be considered as candidates for virtual elimination under the federal Toxic Substances Management Policy (TSMP)

PBDEs for Public Comment

- First screening assessment published May 8, 2004 for 60-day public comment period
- The draft Canada Gazette Notice and the Environmental Screening Assessment may be viewed from the following website:
  - http://www.ec.gc.ca/CEPARegistry/subs_list/assessments.cfm
- The Human Health PBDEs SA may also be accessed from this website

Perfluorooctane sulphonate (PFOs)

- PFOS, its salts and its precursor
- Ecological and human health screening assessments to be released for 60-day public comment period this summer
- Look for update on our What's new home page: http://www.ec.gc.ca/substances/ese/eng/esehome.cfm

The Pilot Project – SA experience

- The new screening assessment (SA) approach is being tested on the 123 substances in the pilot project
- 15 substances underwent SA last year
- Experience gained will allow recommendations to be made to modify processes or technical considerations as needed
- The results of these assessments will be available by 2006

Ecological Screening Assessments: Problem Formulation

- The first step in the ecological screening assessment, usually consisting of:
  - reviewing data initially collected
  - identifying critical data gaps, and
  - proposing an assessment approach
- This step will be important in order to set priorities among all the substances categorized "in"

Conclusion

- The PSL 1 follow-up reports as well as current assessments and the pilot study will identify new candidates for action in the next 3 years.
- The Screening Assessment Program will not be fully implemented until 2006 when categorization is complete
- In 2004 and 2005 stakeholders are invited to voluntarily submit data to support categorization.

Fact Sheets

- Overview of Existing Substance Program in Environment Canada: http://www.ec.gc.ca/substances/ese/eng/overview.cfm
- · Background on Ecological Categorization of Substances on the Domestic Substances List: http://www.ec.gc.ca/substances/ese/eng/dsl/cat_background.cfm
- · Ecological Categorization Criteria: http://www.ec.gc.ca/substances/ese/eng/dsl/cat_criteria.cfm
- · Progress on Organic Substances - Preliminary Ecological Categorization Decisions and Opportunity for Input from Stakeholders: http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_organics.cfm
- · Progress on the Ecological Categorization of Inorganic Substances and Opportunity for Input from Stakeholders - http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_inorganics.cfm
- · Progress on Ecological Categorization of Organic Metal Salts: Preliminary Ecological Categorization Decisions and Opportunity for Input from Stakeholders - http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_oms.cfm
- · Progress on the Ecological Categorization of Organometallics - http://www.ec.gc.ca/substances/ese/eng/dsl/cat_progress_om.cfm

For further information

- **Existing Substances Branch website:**
  http://www.ec.gc.ca/substances/ese/

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