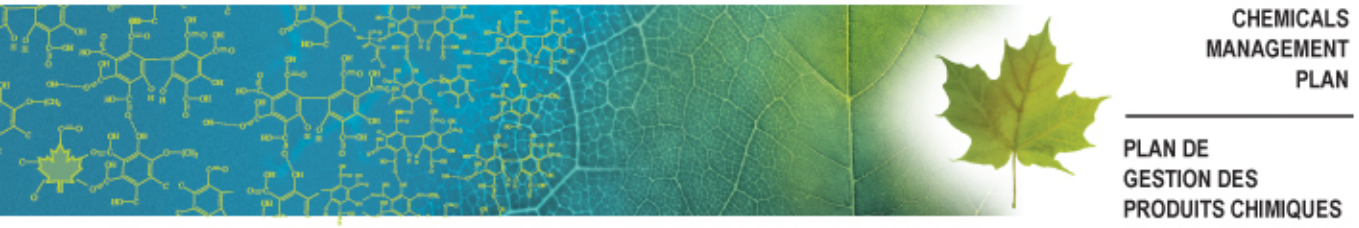
Government of Canada | Gouvernement du Canada

Population Exposure Assessment Approaches and Tools for Health Risk Assessment under CMP

Health Canada – PAHO Workshop

Lima, Peru

November 8-10, 2016



CHEMICALS MANAGEMENT PLAN

PLAN DE GESTION DES PRODUITS CHIMIQUES

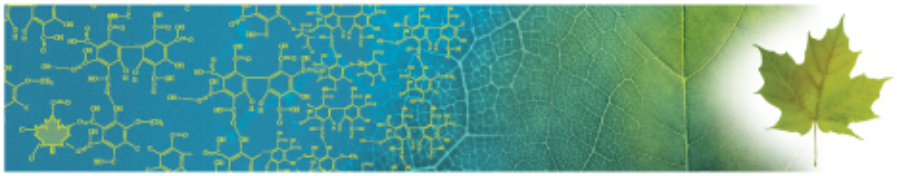
Canada

Outline

- Exposure Assessments for Existing Substances
- Tiered Approach
- Data Gathering
  - Internal Tools
  - Health Canada Partner Engagement
- Exposure Profile
- Exposure Characterization
- Preliminary Scoping of Risk Characterization
- Challenges

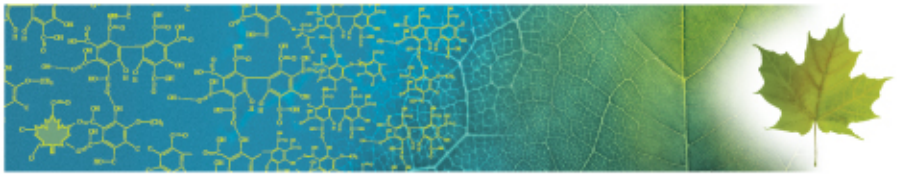
Exposure Assessments for Existing Substances

- Conservative estimates of population exposure (range of age groups considered) from general environment (multimedia) and consumer products (where relevant) derived on basis of measurement data or modelled predictions:
  - Quantitative to extent possible (data dependent)
  - Serves to identify most important sources/routes of exposure
  - Aggregate exposure where appropriate
  - Characterize uncertainties and database confidence

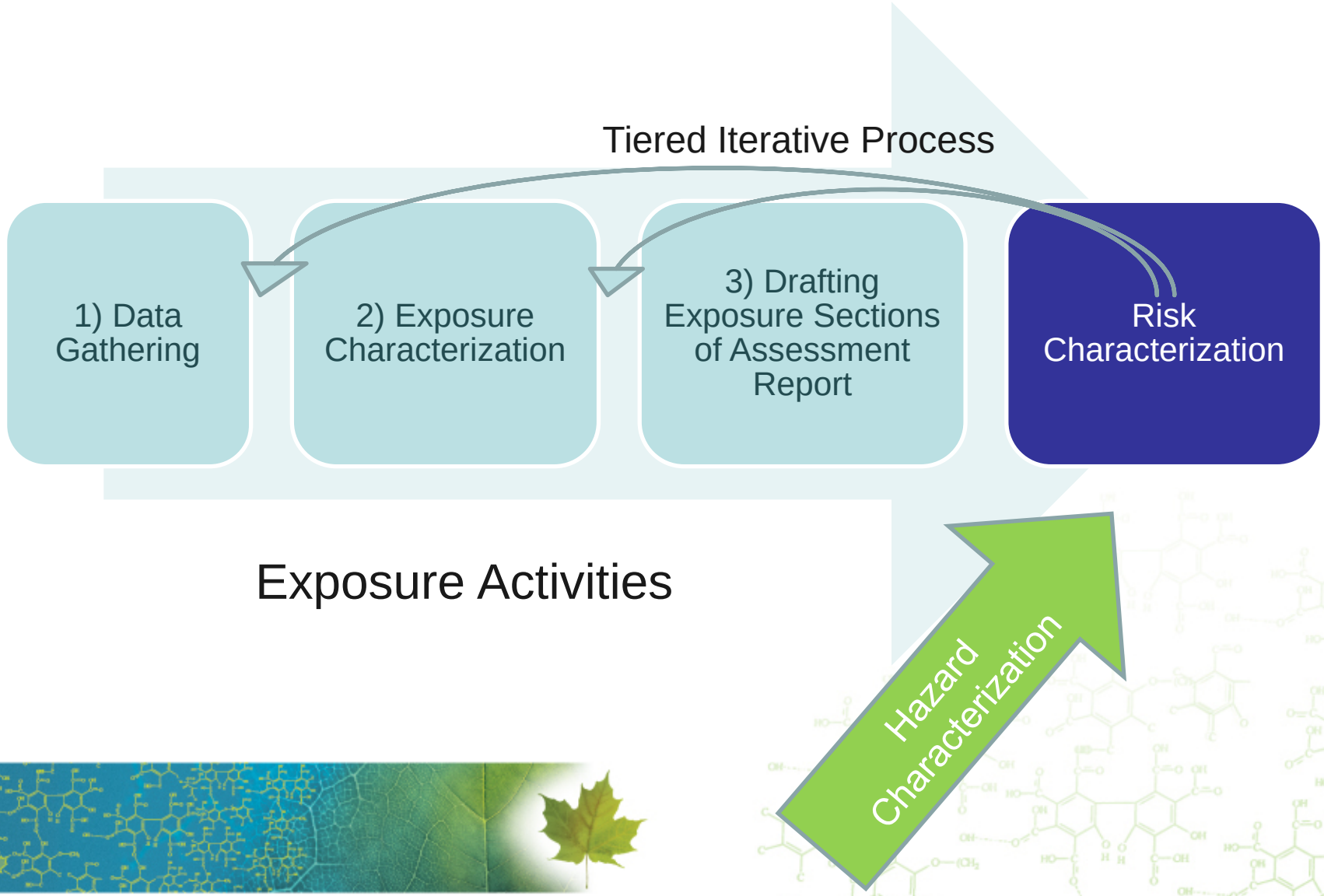


The Nature of Exposure Assessment

- Information sources vary, i.e., not all well defined, standardized studies
- Exposure values are not pre-defined, or outlined for risk assessment
  - In comparison, hazard assessments often rely on studies designed for risk assessment (in identifying critical levels, etc.)
- Exposure varies between jurisdictions and geography
  - Hazard profile of a substance intrinsic to a substance regardless of geography or jurisdiction
- International exposure assessments seldom exist for substances; and when available, considerable scrutiny required for relevance to Canada
- Considerable professional judgement, critical thinking, resourcefulness and creativity are required when assessing exposure
- Degree of resources to invest will also be dependent on the risk situation, and “Type” of assessment within the Risk Assessment Toolbox

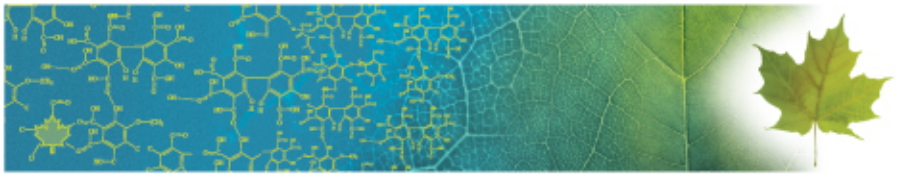


Tiered Exposure Approach and Steps



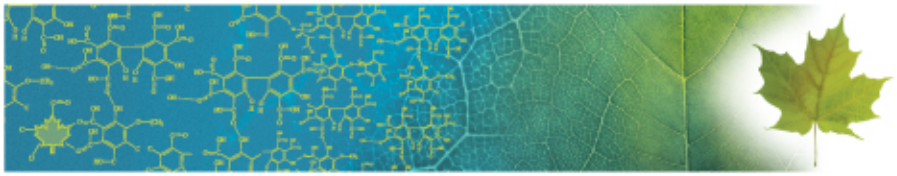
Step-wise Approach to Data Gathering

- Amount of data available/effort to identify each aspect of exposure assessment can vary
  - e.g., concentrations and data on substance in various environmental media compared to information on presence in products
- Amount of information applied to each step may differ, with some steps requiring varying degrees of information gathering
- Focus on exposures of greatest concern or magnitude
- Refine estimates only as much as needed to determine that there is no concern at current levels of exposure
- Strategic and targeted, not exhaustive
- Goal is to compile a reasonable amount of information to support estimate of potential general population exposure in Canada



Data Gathering

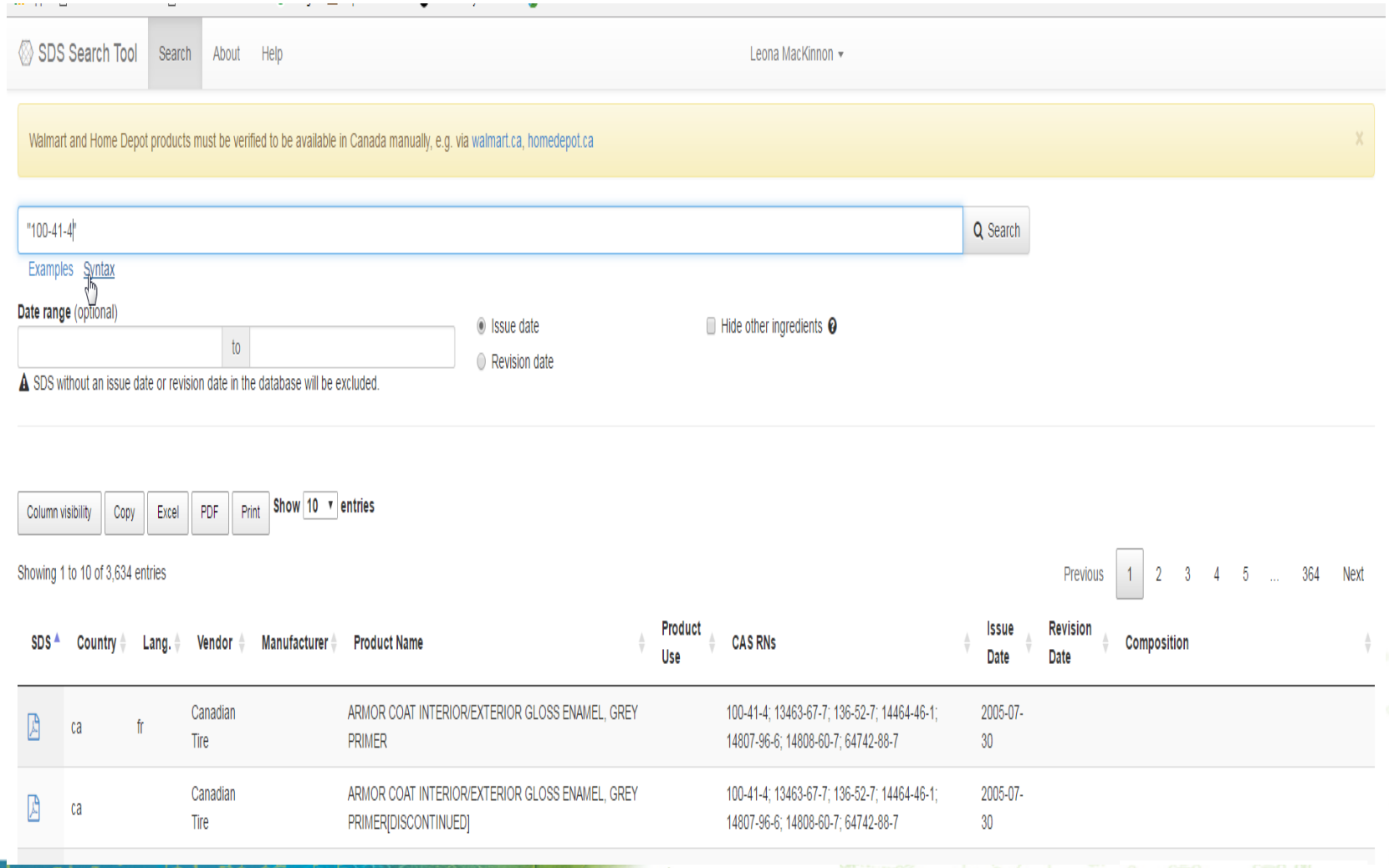
- Types of exposure information:
  - Biomonitoring data
  - Direct Exposure:
    - Consumer products, including mixtures, products or manufactured items
    - Food flavourants/food additives/food packaging
    - Natural health products and drugs (non-medicinal ingredients)
  - Indirect Exposure:
    - Food, breast milk
    - Soil/dust
    - Indoor/outdoor air
    - Drinking water
- Based on past experience, direct exposure to consumer products (including natural health products and drugs) and indirect exposures from food, breast milk, indoor air and dust are often the drivers of human exposures compared to indirect exposures from soil, water, etc.



Internal Data Gathering Tools

- **ePROBLEM FORMULATION DATABASE (ePFDB):**
  - Gives an early indication of which key sources of exposure might drive assessment and helps focus further data gathering
- Safety Data Sheet Search Tool
  - Web-based (few major retailers in Canada)
  - Export directly to Excel or PDF
- Internal Exposure Data Gathering Strategy (EDGS)
  - Web-based
  - Compilation of information sources both automated and manual
  - Automated search includes ChemIDplus, OECD eChemPortal, Health Canada Natural Health Products Ingredients Database and Drug Product Database, etc.
  - Also manual searching options

SDS Search Tool



EDGS Search Tool

EDGS | Guidance | Manual Search | Automated Search | About | Help | Leona MacKinnon

Your query: 100-41-4
Searching for: 100-41-4, 1678-91-7, 25837-05-2, 27536-89-6, 68908-88-3, 70955-17-8

Identity | Biomonitoring | Phys-chem | Products and Food | Environmental Media | International Assessments and Activity | Other Information | Synonyms

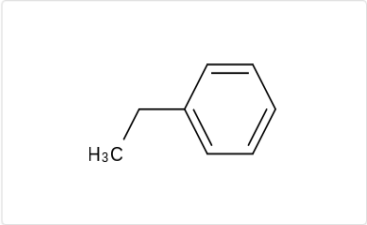
Identity

Source	Status	Result

Canada DSL ✔

Identifier	Chemical Name	Substance Category	Overall CMP Status
100414	Benzene, ethyl-	1	CMP2
27536896	Benzene, ethyl-, homopolymer	10	Not a CMP Priority
68908883	Benzene, ethyl-, benzylated	6	CMP2
70955178	Aromatic hydrocarbons, C12-20	6	Not a CMP Priority

PubChem ✔

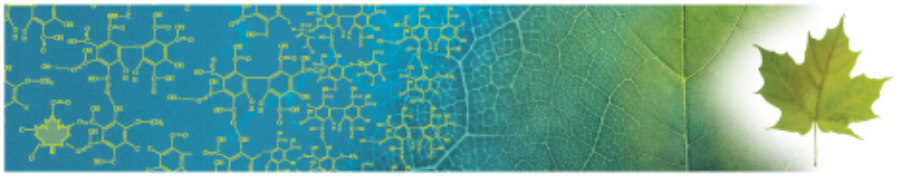


View on PubChem

CAS RN	100-41-4, 1678-91-7, 25837-05-2, 27536-89-6, 68908-88-3, 70955-17-8
IUPAC Name	ethylbenzene
Formula	C8H10
Molar Mass	106.168
SMILES	CCC1=CC=CC=C1
InChI Key	YNQLUTRBYVCPMQ-UHFFFAOYSA-N
Synonyms	ETHYLBENZENE, Phenylethane, Benzene, ethyl-, ... more

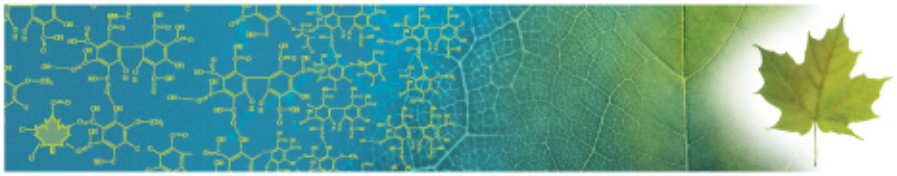
ECHA Inventory ✔

EC RN	CAS RN	EC Name	Formula	Description
202-849-4	100-41-4	ethylbenzene	C8H10	
216-835-0	1678-91-7	ethylcyclohexane	C8H16	
247-292-8	25837-05-2	(2H10)ethylbenzene	C8D10	
272-685-6	68908-88-3	Benzene, ethyl-, benzylated		
275-055-9	70955-17-8	Aromatic hydrocarbons, C12-20		A complex combination of hydrocarbons obtained from the distillation of biphenyl and naphthalene feedstocks. It consists predominantly of hydrocarbons having carbon numbers predominantly in the range of C12 through C20, such as alkylbenzenes, alkylnaphthalenes, indans, fluorenes, acenaphthalenes, phenanthrenes and anthracenes, and boiling in the range of approximately 282°C to 427°C (540°F to 800°F).



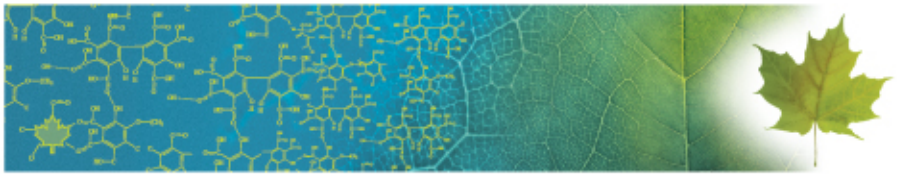
Health Canada Partner Engagement

- Consultation and request for information from others within Health Canada is a very important aspect of exposure data gathering
  - Consumer Product Safety Directorate
    - Information on substances in cosmetics and personal care products in Canada, consumer product testing, migration studies
  - Health Products and Food Branch
    - Food/dietary surveys, food packaging, food flavourants/additives, natural health products, drugs
  - Pest Management and Regulatory Agency
    - Pesticide data, inert ingredients
  - Risk Management Bureau
    - Industry engagement, S71 survey data follow-up
  - Environment and Health Science Research Bureau
    - Monitoring studies (biomonitoring, dust, consumer products, migration/emissions)
  - Chemicals Surveillance Bureau
    - Human biomonitoring data, initiatives
  - New Substances Assessment and Control Bureau
    - Database read-across, previous assessments, common assessment priorities
- Common coordinated approach for contacting HC partners



Exposure Profile

- Used to compile/summarize relevant exposure information
  - Excel spreadsheet
- Provides an overall picture of:
  - How the substance is used (consumer products/applications)
  - Where the substance is found (environmental media and biomonitoring)
  - Any other information relevant to the assessment
- Includes information on:
  - Physical-chemical properties
  - Uses (focus on consumer uses)
  - Reported volumes in Canada (from industry submissions)
  - Presence in environmental media (air, water, soil, dust), food and breast milk



Example of Exposure Profile

Strategy for Gathering Phys-Chem Properties:

- Include only a few references to each of the following phys–chem properties
- These are important to understanding exposure potential
- Consult with EC counterparts

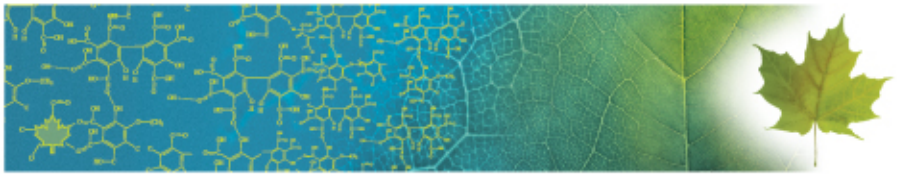
	CAS RN	Reference	Value	Units	Empirical or Modelled	Year
Molecular Weight						
Physical State						
Melting Point						
Vapour Pressure						
Henry's law constant						
Water Solubility						
Log Kow						
Log Koc						
pKa						

Example of Exposure Profile

	A	B	C	D	E	F	G	H	I	J	K
1	Consumer Products for				Group Name						
2	CAS RN	Reference	Category	Product Type	Product Description	Brand Name	Location; year	Concentration	Detection Frequency	Notes	Likely applicable to Canada?
3	Cosmetics										
4											
5	Cleaning Products										
6											
7	Paints and Coatings										
8											
9	Clothing and apparel										
10											
11	Textiles for furniture										
12											
13	Other furnishings										
14											
15	Electronics and Electrical equiment										
16											
17	Automotive Industry										
18											
19	Misc. Consumer Products										
20											
21	HC regulated uses (HC Partners)										
22											

Example of Exposure Profile

	A	B	C	D	E	F	G	H	I	J	K	L	M	N
1	Indoor Air Monitoring for			Group Name										
2	CAS RN	Reference	Media/ Material	Microenvironment	City	Country	Sampling Year	Sample Size	Concentration	Units	DL or LOQ	Detection Frrequency	Sample Description	Notes
3	Canada													
4														
5	USA													
6														
7	Europe													
8														
9	Other													
10														
11														



Sources

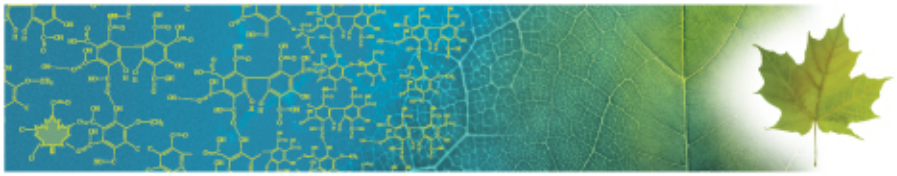
- Includes “where” and “how much” of the substance(s)
- Do they occur naturally in the environment?
  - If yes, how or where?
  - Or, are they anthropogenic?
- Volumes in Canada (import, manufacture, use, export)
  - Typically from industry surveys (be aware of CBI)
  - Include the year reported
- Volumes globally (when available)
  - US EPA Inventory Update Reporting volumes
  - Volumes reported by European Union’s REACH Initiative
  - High production volume chemical in another jurisdiction (US, Europe, etc.)?
    - *Anything that may inform its possible presence in Canada*

Uses

- Where is it used?
- What is its function in products? (i.e., plasticizer to make plastics soft, solvent, intermediate).
- Known Canadian uses/applications
- Global uses/applications
  - Anything that may inform its possible use in Canada
- Using the Exposure Profile
    - Combining and consolidating in text format
    - Be aware of CBI

Exposure Characterization

- Key drivers are considered
- Compiled into an Excel spreadsheet (Exposure Characterization Table), especially for data-rich substances or group assessments
- Ensures all relevant scenarios have been considered
  - Comparison of all potential sources of exposure and ranking scenarios based on anticipated exposure estimates
- Includes a rationale to address:
  - Use of representative scenarios (“sentinel”)
  - Qualitative vs. quantitative scenario
  - Exclusion of scenarios (e.g., very low exposure or not relevant to Canada)
- Tiered approach and precaution applied



Environmental Media and Food

Rank relevant information for general population exposure:

- Geographic: Canada > US > Elsewhere
- Temporal : Recent (< 5 years) > Older

Modelling:

– Several models are available free online to model environmental media exposure in the absence of data:

- Screen 3 (air dispersion model), ChemCan (fugacity model for environmental distribution), US EPA's E-FAST (e.g., point source, down the drain)
- Additional tools always being developed for consideration

Environmental Media and Food

Multimedia intake table

- Spreadsheet that automatically calculates intakes for environmental media for all age groups
- Input values for each source into table to calculate daily exposure
- Identifies populations with highest exposures and principle sources

Standard Values and Intake Table

Route of exposure	Estimated intake (µg/kg-bw per day) of (substance name) by various age groups							
	0-6 months			0.5-4 years	5-11 years	12-19 years	20-59 years	60+ years
	breast fed	formula fed	not formula fed					
Ambient air		0.00		0.00	0.00	0.00	0.00	**0.00**
Indoor air		0.00		0.00	0.00	0.00	0.00	**0.00**
Drinking water	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**
Food and beverages	0.00	0.00	0.00	0.00	0.00	0.00	0.00	**0.00**
Soil		0.00		0.00	0.00	NA	NA	**NA**
Total intake	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**	**0.00**

Exposure Factor	Age Groups							Reference
	0-6 mths		6 mths - 4 years	5-11 years	12-19 years	20-59 years	60+ years	
Body Weight (kg)	7.5		15.5	31.0	59.4	70.9	72.0	Health Canada 1998
Inhalation Rate (m^3/day)	2.1		9.3	14.5	15.8	16.2	14.3	Health Canada 1998
Drinking Water Intake (L/day)	Breast Fed	0	0.7	1.1	1.2	1.5	1.6	
	Formula Fed	0.3 or 0.8						
	Not Formula Fed	0.8						
Soil Ingestion Rate (mg/day)	**30**		**100**	**65**	**30**	**30**	**30**	

Exposure Scenarios - Products

- Use Exposure Characterization Table and determine:
  - Key drivers of exposure
  - Representative scenarios (products used by consumers)
  - Which scenarios to address qualitatively and quantitatively

- Build an exposure scenario for each quantitative scenario identified
  - Using models or equations
  - Consult guidance materials and previous assessments
    - Keep a record, including rough calculations for lesser scenarios, to ensure they result in lower expected exposure than the chosen representative scenarios.
  - Refine scenario inputs, if necessary (i.e., if determined to be too unrealistic).

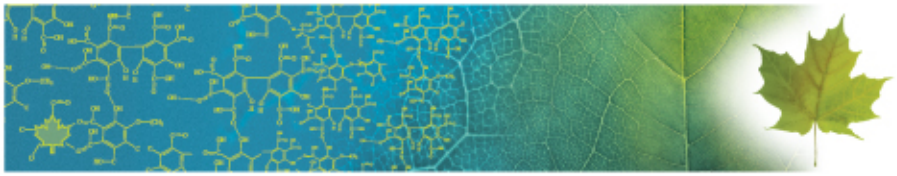
Modelling Consumer Product Exposure

- Models are used to estimate exposure via consumer products
  - ConsExpo (RIVM) [available free online] used to estimate consumer product exposure
  - Internal database CIN-E^2 (estimates exposures to group of substances at same time, simple algorithms, dermal and oral exposures)
  - Wall paint exposure model (WPEM) developed by US EPA for assessing exposure to paint products

- Internal guidance documents developed for scenarios
  - Mouthing Database (various equations and defaults)
  - Dermal absorption guidance
  - Defaults for personal care products
  - Defaults and equations for household cleaning products
  - Ink scenario

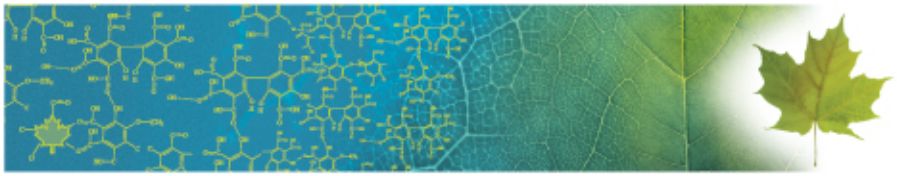
Exposure Characterization Table

	A	B	C	D	E	F	G	H	I	J	K
1	**Consumer Product Summary for**		[Insert Substance or Grouping Name Here]								
2		*CBI data is in red									
3											
4	CAS RN	Category	Product	Canadian Data?	Int'l Data?	Conc. and units	References	Route of Exposure (O/I/D)	*Evaluate Exposure Scenario? (Y/N)*	*Rationale*	
5		Adhesives									
6		Agricultural and Fertilizer									
7		Automotive, Aircraft and Transportation									
8		Chemical Manufacturing									
9		Cleaning Products									
10		Combustion and Fuel									
11		Cosmetics and Personal Care									
12		DIY Products									
13		Dyes and Pigments									
14		Electronics & Electrical Equipment									
15		Explosive and Military									
16		Food Packaging									
17		Industrial or Commercial Use									
18		Medical, Health Products and Veterinary									
19		Metals, Metallurgical, Metal Plating, Mining and Mineral Products									
20		Paints and Coatings									
21		Pest Control Products									
22		Petroleum, Oil Well Drilling and Treatment									
23		Pharmaceuticals									
24		Plastics and Plasticizers									
25		Printing and Writing Products and Printing Inks									
26		Pulp and Paper and Wood Products									
27		Research and Development and Analytical Reagents									
28		Rubber									
29		Textile, Leather and Tanning									
30		Tobacco									
31		Toys and Children's Products									
32		Waste Management									
33		Water and Wastewater									
34											



Exposure Characterization Table

	A	B	C	D	E	F	G	H	I
1	Environmental Media and Food Summary for					[Insert Substance or Grouping Name Here]			
2		*CBI data is in red							
3									
4	CAS RN	Media	Description	Canadian Data?	Int'l Data?	Conc. and units	Reference (s)	Use to calculate Daily Intake (Y/N)	Rationale
5		Ambient Air							
6		Indoor Air							
7		Drinking Water							
8		Soil							
9		Dust							
10		Breast milk							
11									

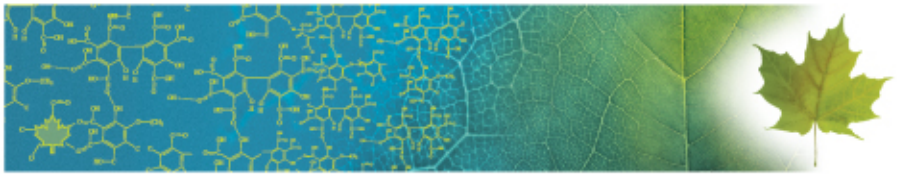


Preliminary Scoping for Risk Characterization

Exposure ⇆Hazard

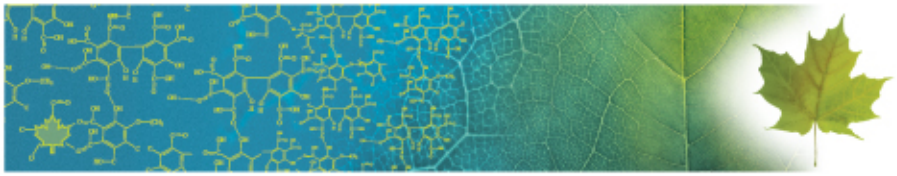
- Important to consider hazard characterization simultaneously
  - What are the likely exposure routes?
  - What are the most likely exposure sources?
  - What is the expected duration of exposure?

- Helps focus hazard characterization on the key routes of exposure and corresponding hazard studies.



Challenges

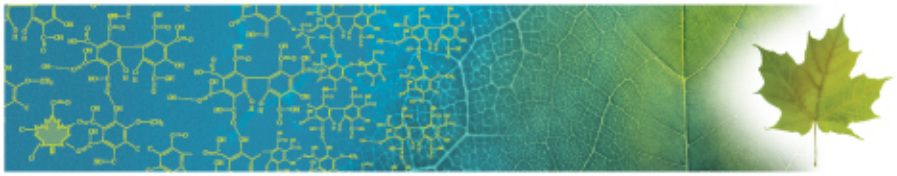
- Limited information on Canadian specific uses and releases for data-poor substances (e.g., UVCBs, polymers)
- Limited public information available about the concentration of a specific substance in consumer products, but generic information available
- Information about use of a chemical may be outdated
- Information needs to be validated (sometimes original reference is not available, lack of cited sources)
- Discrepancy among difference sources of information
- Use of trade names can be misleading
- Validity of MSDS information
- Lack of public data on consumer habits and practices, market research



Useful Links - Models

- Environmental Exposure Models
  - CEMC's ChemCan Fugacity Model: http://www.trentu.ca/academic/aminss/envmodel/models/CC600.html
  - U.S. EPA's Screen 3 (air dispersion model) includes links to other air models: https://www3.epa.gov/ttn/scram/dispersion_screening.htm#screen3
  - U.S. EPA's E-FAST: https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014

- Consumer Product Exposure Models
  - RIVM's ConsExpo model version 4.1 (new web version launched in October 2016): http://www.rivm.nl/en/Topics/C/ConsExpo
  - U.S. EPA's Consumer Exposure Model (CEM) (old version is part of E-FAST): https://www.epa.gov/tsca-screening-tools/cem-consumer-exposure-model-download-and-install-instructions
  - U.S. EPA's Wall Paint Exposure Model (WPEM): https://www.epa.gov/tsca-screening-tools/wall-paint-exposure-assessment-model-wpem



Useful Links

- Chemical Substances Website: http://www.chemicalsubstanceschimiques.gc.ca/index-eng.php?utm_source=VanityURL&utm_medium=URL&utm_campaign=chemicalsubstances.gc.ca
- Existing Substances Risk Assessment Bureau: http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/index-eng.php

- Canadian Health Measures Survey: http://www.hc-sc.gc.ca/ewh-semt/contaminants/human-humaine/chms-ecms-eng.php