

Considering Exposure in Priority Setting

Categorization of the Domestic Substances List under the Canadian Environmental Protection Act (CEPA)

U.S. EPA Exposure Prioritization Community of Practice Teleconference July 8th/08

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Outline

- Background
 - Existing Substances program under the Canadian Environmental Protection Act (CEPA '99)
- Considering Exposure
 - Priority Substances (Assessment)
 - Priority Setting for 23,000 substances (Profiling for Categorization & Screening)
- What we've Learned
- Next Steps

CEPA – Objectives

- To contribute to sustainable development through pollution prevention
- To protect the environment, human life and health from risks associated with pollution
- Encompassing legislation with a broad range of powers
 - information gathering and reporting
 - conduct of research,
 - assessment and management,
 - enforcement and
 - emergency planning
- Administered by Environment and Health Canada
 - Introduced in 1988 (CEPA'88) and renewed in 1999 (CEPA '99)
 - Provision for renewal every 5 years

CEPA Substances

- **Existing Substances**
 - substances in Canadian commerce between 1984-1986 (the Domestic Substances List)
- **New Substances**
 - substances introduced into commerce after promulgation of the New Substances Notification Regulations in 1994
- **Transitional Substances**
 - substances entering Canadian commerce after 1986, but before the promulgation of the New Substances Notification Regulations in 1994

CEPA Assessment of Existing Substances – the Mandate

- Address both exposure and effect to set priorities for risk management
 - Consumer & Environmental Exposure (all media)
 - ***Not occupational***, but provide advice
 - All age groups
- Source characterizations
 - Information gathering
- Publicly accountable – transparent process, peer review, documented outcome
- reverse onus provisions, but responsibility of Government considerable

CEPA Existing Substances

- Under CEPA '88, assessments for specified numbers of Priority Substances (5 yr timeframe)
 - N= 44 on Priority Substances List (PSL) 1
 - N= 25 on PSL 2
 - Risk management now implemented for most considered “toxic” under CEPA
- Included exposure estimates for the general population from all media (often probabilistic based on nationwide monitoring) and consumer products
- Trend from PSL 1 to PSL 2 for increasing focus on consumer (importance of dermal exposure) vs. environmental exposure
 - Role of persistence and bioaccumulation

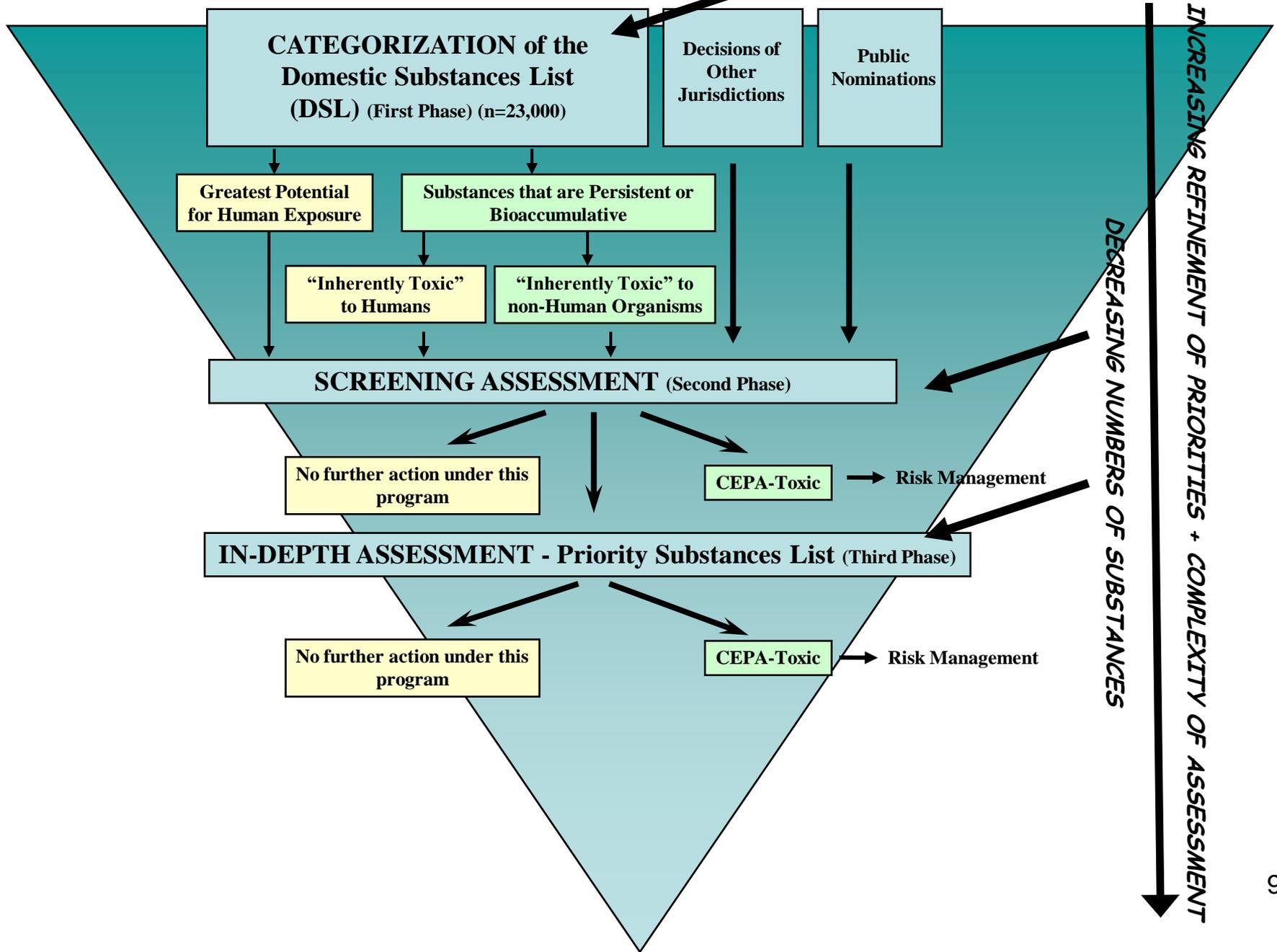
Estimating Dermal Exposure for Priority Substances

- Draft decision tree approach developed and reviewed at peer consultation in Mar '02
- 12 pathways
 - Six “finite dose”
 - E.g., substance in consumer product, soil, household dust
 - Six “infinite dose”
 - E.g., during swimming, bathing, showering, paper or fabric in contact with skin
- Includes “rules of thumb” provided by peer consultation, criteria for evaluating dermal exposure studies
- Hierarchical

From Data Rich to Data Poor

- CEPA '99 extended our mandate to all Existing Substances in Canada (n=23,000)
 - Categorization of the Domestic Substances List (DSL) by September, 2006 (priority setting)*
 - screening,
 - full (Priority Substances) assessment
- ** substances in commerce between 1984 and 1986 not subject to New Substances provisions*

CEPA 1999 Existing Substances Program



Human Health Related Aspects – “Categorization”

Needed to consider:

- “Greatest potential for exposure” (GPE) – all substances
- “Inherently Toxic to humans” (IThuman) – subset of substances
 - Which subset?
 - Those that are P or B [but not inherently toxic to environmental organisms (ITeco)]

Challenge:

- Limited relevance of Persistence (P) or Bioaccumulation(B) to human health
 - Risk = exposure and hazard
 - P or B ≠ exposure or hazard

INTEGRATED FRAMEWORK - HEALTH

DOMESTIC SUBSTANCES LIST

HEALTH CANADA

Application of Simple Tools

DSL
Substances
Identified as
Hazardous to
Human Health

Highest

Lowest

DSL Substances Ranked
According to Potential
For Exposure

Health Draft Maximal List
(n=1896)

Application of Complex Tools

No Further Action
(Not 64c "toxic")

Substances Prioritized & Identified
For Full Screening Health Assessment

ENVIRONMENT CANADA

Substances that are Persistent and/or
Bioaccumulative According to the Regulations

Organic Substances that are
Persistent and/or Bioaccumulative
and Not "Inherently Toxic" to
Non-human Organisms

Substances that are Persistent and/or
Bioaccumulative and "Inherently Toxic"
to Non-human Organisms

EC Substances Identified for
Screening Assessment

Simple and Complex Priority Setting Tools

EXPOSURE

Simple Exposure Tool (SimET) - Relative ranking of all DSL substances based on submitters (S), quantity (Q) and expert ranked use (ERU)

Complex Exposure Tool (ComET) - Quantitative plausible maximum age-specific estimates of environmental and consumer exposure for individuals based on use scenario (sentinel products), phys/chem properties & bioavailability

***Potential for exposure influential in setting priorities
Included simple use profiling for all 23, 000 chemicals, more complex use
profiling for priorities***

HAZARD

Simple Hazard Tool (SimHaz) - Identification of high or low hazard compounds by various agencies based on weight of evidence and expert opinion/consensus

Complex Hazard Tool (ComHaz) - Hierarchical approach for multiple endpoints & data sources (e.g., (Q)SAR) including preliminary weight of evidence framework

The Simple Exposure Tool - SimET

- SimET is a relative ranking tool by which we “binned” and relatively ranked **all 23,000** substances
- Based on three different lines of evidence, derived from the limited information provided for all substances on the DSL:
 - quantity (estimated annual quantity of use, Q),
 - number of submitters (S)
 - ***use (sum of normalized expert ranked use codes, U), reflecting two workshops***
- “Ground-truthed” against more robust and recent data on use
 - Commercial chemical profiles
 - Mandated use surveys
- ***Use*** far more important than ***volume*** as the critical driver

Potential for Exposure (Greatest, Intermediate & Lowest)

	Quantity (kg/year)	Number of Submitters	<i>Sum of Expert Ranked Use Codes</i>
GPE	> 100 000	Top 10%	Top 10%
IPE	> 10 000	n.a.	Top 30%
LPE	All	All	All

Score for each substance = \sum (use x relative ranking for PE)
 – e.g., direct consumer use, dispersive environmental, industrial,
 etc.

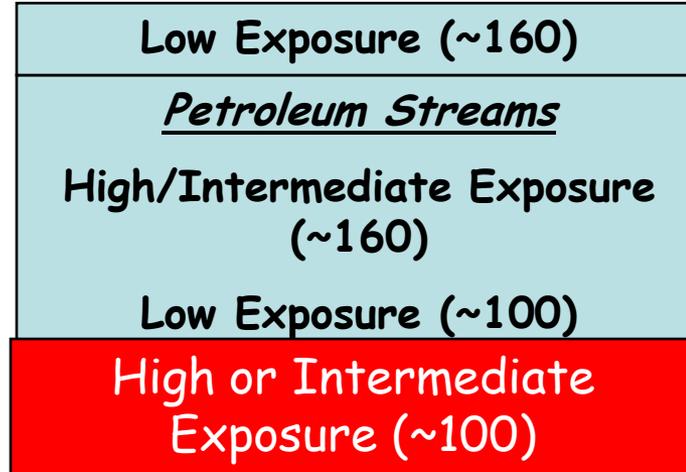
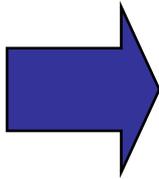
Health DSL Categorization/Prioritization

Sept 2006

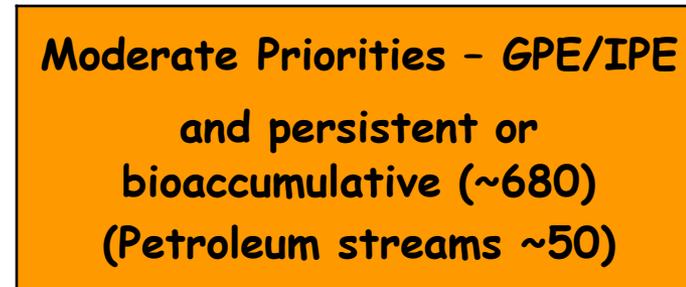
Health Priority Setting

Oct. 2004

Health
Draft
Maximal
List



*High Health
Priorities
for Action - High
Hazard Substances*



*Moderate Health
Priorities for
Action - Hazard
Unknown*



Post Categorization Refinement of Exposure for the Moderate Group

Objective:

- Multi-tiered approach for consumer and environmental exposure
 - generic scenarios, defaults and most common use/product categories in early stages
 - E.g., sentinel products - consumer product that yields the highest exposure for one of its component substances
 - Increasing refinement in subsequent stages
 - Efficiency

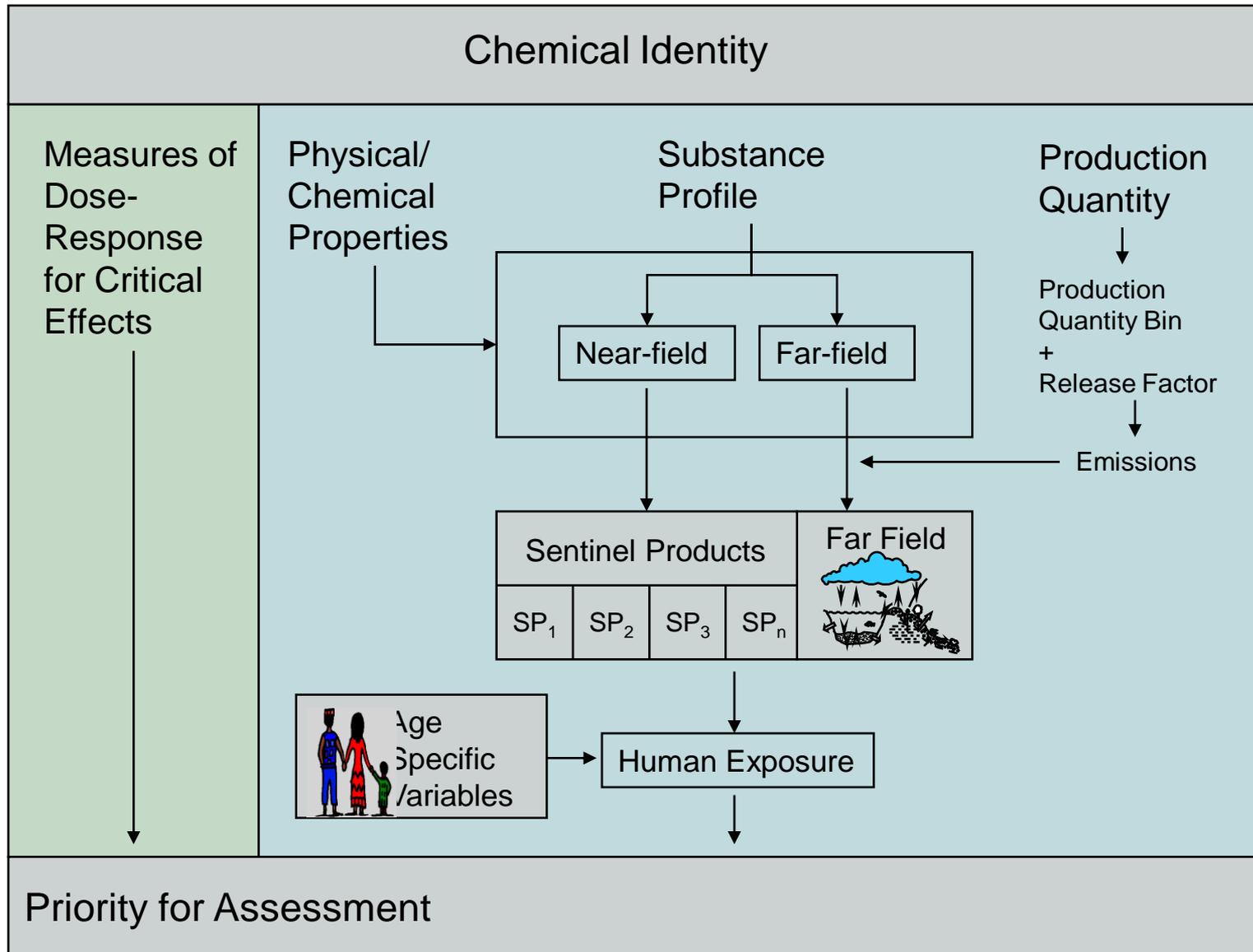
Approach:

- Considering algorithms and default values in consumer exposure tools based on
 - Transparency, Defensibility
 - “Validation”/Acceptance and Use
 - Scope
 - Relevance
 - Complexity for various iterations

Post Categorization Refinement of Exposure for the Moderate Group

- Methodology:
 - Comparison of algorithms and default values in consumer exposure tools as basis for iterative approach
 - Including those developed for the program
 - Lifeline/peer input meeting – Nov/04
 - Development of use profiles for hundreds of chemicals based on robust search strategies
 - 8 models/algorithms (listed in A 1)
 - Sources of default values listed in A2

Overview of Early Tier



Selecting Sentinel Products* from Use Profiles (Very Early Tier)

Substance

Use search

- Uses in products, functions, generic maximum concentration in formulations, etc.
- Physical chemical properties, etc

Selection of Sentinel Product

Using the search information consider potential Sentinel Product Functions and Sentinel Products applying the guiding principles and matrix

Exposure Characteristics	Age Classes					
	0-6 months	0.5-4 yrs	5-11 yrs	12-19 yrs	20-59 yrs	60+ yrs
Magnitude of Exposure						
Duration and/or Frequency of Exposure						
Route of Exposure						

Near field exposures estimated by age class, route, and duration

*A sentinel product is a specific type of consumer product with a defined composition and use that yields the highest exposure to an individual for one of its component substances as compared to other consumer products containing that substance.

Tier 1 Model Comparison – Most Common Product Categories

Product Category	Route of Exposure	ComET	ConsExpo	ECETOC	CEM	SDA
Personal Care and Over-the-Counter Products						
<i>Mucous membrane contact products</i>	Inhalation					
(lipstick, toothpaste/mouthwash, eye makeup, contact cleaner)	Dermal	X	X			X
	Oral		X			X
<i>Leave-on Products</i>	Inhalation	X	X			X
(creams, deodorant, hair preparations, face make-up, powder)	Dermal	X	X			X
	Oral					
<i>Rinse-off Products</i>	Inhalation					
(soaps, shampoo/conditioner, cleansers)	Dermal	X	X		X	X
	Oral					
<i>Over-the-Counter Products</i>	Inhalation					
(wipes, shaving aids, oral dosing, topical dosing, lubricants)	Dermal	X	X			X
	Oral	X				X

Tier 1 Model Comparison – Most Common Product Categories (cont'd)

Product Category	Route of Exposure	ComET	ConsExpo	ECETOC	CEM	SDA
Household Cleaners and Detergents	Inhalation	X	X	X	X	X
(aerosol foam cleaner, spray window cleaner, solvent-based cleaners, carpet cleaning, air freshner, outdoor cleaner, laundry)	Dermal	X	X	X	X	X
	Oral			X		
Fabric, Textile and Leather Products	Inhalation					
(clothing residuals, upholstery/bedding residuals, cloth/leather treatment)	Dermal	X	X	X		X
	Oral	X	X	X		
Paints, Varnishes and Coatings	Inhalation	X	X	X	X	X
(latex and oil based paints, acrylic paints, varnishes, coatings, paint removers/strippers)	Dermal	X	X	X	X	
	Oral		X			
Building Materials/Wood Products	Inhalation			X		
(lumber, flooring and panel products, wood and wood furniture, wood polishing, insulation products, adhesives, fillers/sealants, refinishing/sanding)	Dermal			X		
	Oral			X		

Detailed Use Profiling

- Developed for hundreds of chemicals as a basis for additional prioritization based on exposure
 - Identifies all possible uses of a substance, based on structured and iterative search strategy
 - Different Search Strategies for various groups of substances
 - Range, 40 to 60 sources for organics, polymers, substances of unknown composition (UVCBs)
- Much information on use patterns is publically available though resource-intensive to access
- Efficiency & effectiveness in accessing relevant information a function of increasing experience

Detailed Use Profiling (Cont'd)

- High confidence in information on data-rich substances
 - Generally sufficient for selection of sentinel products and quantitative exposure prediction
- Less confidence in outcome for data-poor substances (e.g consistency for UVCBs, polymers)
 - Requires greater iterations of more extensive searching
 - Confidence less owing to more limited number of sources and as a result, limited opportunity for consistency

What Have We Learned?

- Simple use profiling for all Existing Substances changes how we do business, in terms of designating our true priorities
- Importance of consumer vs. environmental exposure
 - Persistence/bioaccumulation \neq exposure
- Volume \neq exposure; use profiling more influential
 - implications for selection criteria for current testing programs
- Importance of early and iterative use profiling
 - Much of the information is publically available

Next Steps

- Tiered approach to predicting consumer exposure drawing on defensible algorithms and default values
- The detailed exposure estimates for the 69 Priority Substances (or groups of substances) offer potential for developing “quantitative anchors” for the relative rankings for “potential for exposure” for all 23, 000 substances
 - E.g., based on comparative (simple and more complex) use profiles, physical-chemical properties and quantitative estimates of exposure

IPCS Framework for Combined Exposure to Multiple Chemicals

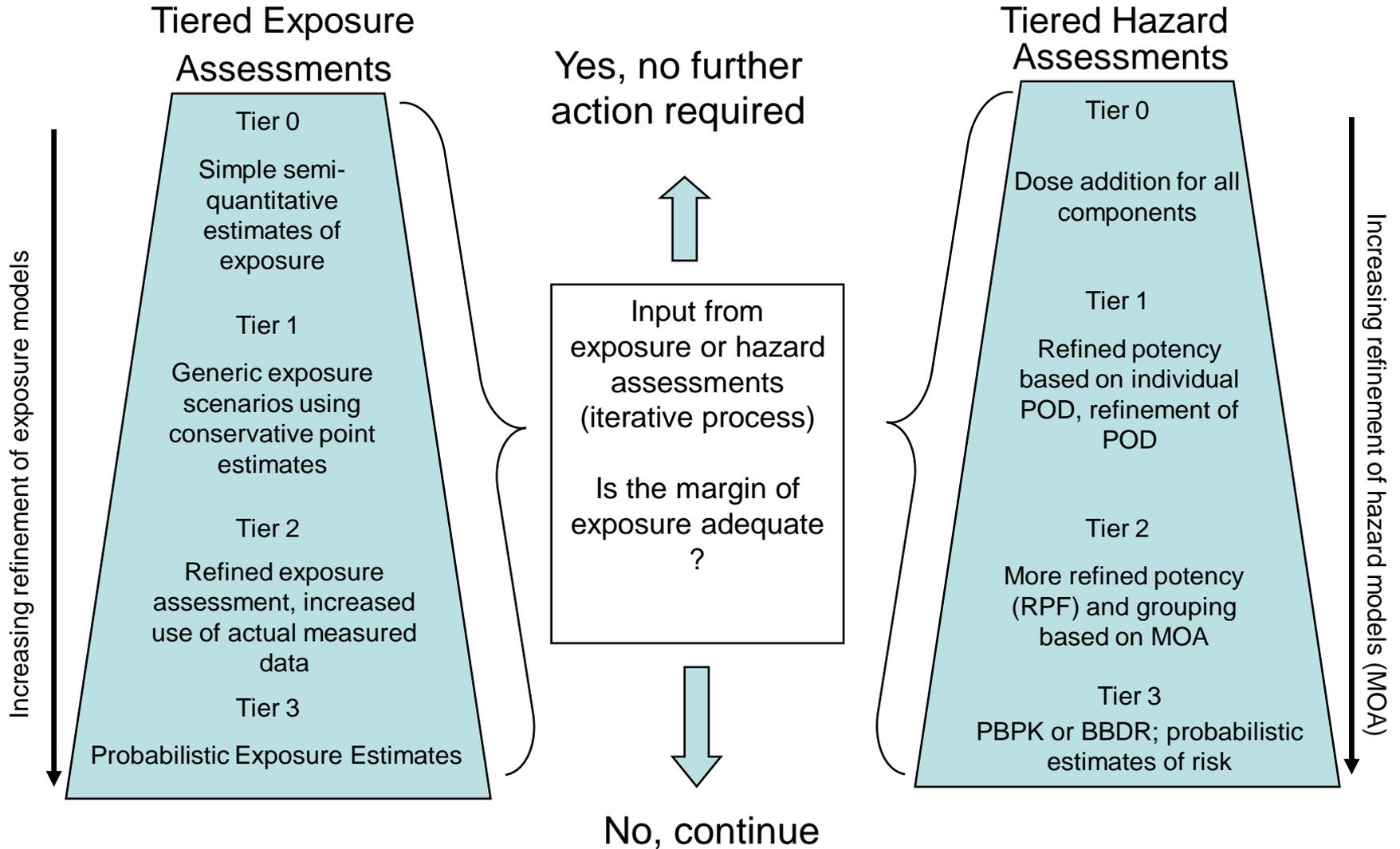
Early and Continuing Consideration of Exposure

Criteria for Considering an Assessment Group

- What is the nature of exposure and are the components known?
- Is exposure unlikely or very low taking into account the context? Is there a likelihood of co-exposure within a relevant time frame ?
- What is the reason to believe that components act similarly or interact?
 - Information on chemical structure
 - Hazard or other biological data (**tox or efficacy**)

Sample Tiered Exposure and Hazard Considerations

Mixture or Component Based



See text for details

More Information?

- Existing Substances Division Website – <http://www.hc-sc.gc.ca/exsd-dse>
- Health Canada Existing Substances Mailing List – <http://www.hc-sc.gc.ca/hecs-sesc/exsd/listserv.htm>
- Additional Inquiries – ExSD@hc-sc.gc.ca
- IPCS Harmonization Website <http://www.who.int/ipcs/methods/harmonization/index.html>

A.1 Models and Sources of Algorithms Considered

- ComET (developed by Health Canada and The LifeLine Group)
- ConsExpo v. 4.0
- ECETOC (from Targeted Risk Assessment 2004 Technical Report No. 93)
- Soap and Detergent Association 2005
- EAU – Cosmetic Workbooks (Health Canada’s Environmental Assessment Unit)
- CEM v. 1.2 (from US EPA E-FAST)
- U.S. EPA 1997 (Exposure Factors Handbook Volume I)
- Health Canada 1995 (Handbook for Exposure Calculations)

A.2 Default Values Considered

- Versar Inc., 1986. Standard Scenarios for Estimating Exposure to Chemical Substances During Use of Consumer Products, Volume I and II
- ConsExpo v 4.0 (and RIVM Factsheets)
- SDA (Soap and Detergent Association) 2005. Exposure and Risk Screening Methods for Consumer Product Ingredients
- ECETOC 2004. Targeted Risk Assessment, Technical Report No. 93
- ComET (Health Canada/LifeLine)
- US EPA 1997. Exposure Factors Handbook Volume III – General Factors
- EAU (Environmental Assessment Unit – Health Canada) 2005. The Cosmetics Exposure Workbook
- Various books on product formulations to obtain weight fractions