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safety... our priority.*

CCME Soil Quality Guidelines and Health Canada Perspectives

Estimated Daily Intakes (EDIs)

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Canada

Estimated Daily Intakes: Why?

- ✓ Canadians are exposed to chemicals through air, water, soil (incl. sediment), food (incl. breast-milk) and consumer products
- ✓ EDIs = **all pertinent exposure sources** (soil, ambient and indoor air, drinking and recreational water, breast milk, etc.) **via all known or suspected pertinent pathways** (inhalation, ingestion, dermal contact)
- ➔ EDIs = **background exposures contributing to the overall exposure of individuals**
- ✓ EDIs have to be taken into account :
 - in the human health risk assessment process (because interest is in risk over background or in excess)
 - in the development and assessment of human health quality guidelines and RTDI (**R**esidual **T**olerable **D**aily Intake) (with $RTDI = TDI - EDI$)



Estimated Daily Intakes: How?

Through a multimedia exposure assessment requiring:

- ✓ large amount of **environmental data** from air, water, soil, food, consumer products, etc. coming from different providers:
 - Federal // Provincial
 - Regional // Municipal
 - Others (e.g. research studies)
- ✓ many **human / exposure parameters**:
 - Rates (inhalation, water consumption, etc.)
 - Human activity patterns (frequencies, durations, etc.)
 - Physiological parameters (body weights, body surface, etc.)
- ✓ many **other things**: methods (level of disturbance (LOD), missing values, outliers, etc.), correlations (between parameters and/or data), etc.



Estimated Daily Intakes in the past...

When available, they are:

deterministic

and

obscure values...

- Very difficult to reproduce and to justify scientifically (methodology, data used, choices, limitations, gaps, etc. = often unknown or lost)



Future Estimated Daily Intakes...

- ✓ **Assessment or re-assessment of EDIs on a regular basis**
 - New sampling methods
 - New analytical methods
 - Temporal window, temporal patterns & spatial
 - Implementation of new methods
- ✓ **Moving from deterministic to probabilistic EDIs (i.e. one dimension Monte-Carlo methods)**
 - Quantitative impact of the different variability sources
 - Statistical distribution of input parameters and results
 - Policy indicator to be chosen
- ✓ **Transparent at all steps**
 - Data and/or key study selection
 - Gaps and limitations
 - EDIs will reflect “potential exposure” not absorbed dose !!



The Health Canada's EDI project

- ✓ 1st attempt: Amec (2005) & Cantox (2006)
- ✓ 2nd attempt started in FY 2008-2009 (2009-2010 = 2nd year)
- ✓ Objective: updating EDIs for the 120 chemicals present in the Contaminated Sites Division's list (CSD)
- ✓ **Reality**:
 - ✓ Development of tools: methodology, quality scoring sheets for environmental and human data/studies
 - ✓ 2008-2009 = work done with 2 consultants (Amec and Senes), with respectively 4 chemicals (Cd, Pb, Hexane, Zn) and 8 chemicals (As, Ba, Be, Cr, Cu, Mn, Ni, Se)
 - ✓ 2009-2010 = full revision for Pb, Ba, Be, Cr VI and total, Ni, Cd and Zn (SQGs) + 1st pass for vinyl chloride



The Health Canada's EDI project: Methodology I

Best available data / key study selection (environmental)

- Data source, Data format (raw data, tables, distribution)
- **Level of representativity** (Canada, Province, Region, Municipality, ...)
- Geographic coordinates, Study type (cross-sectional, continuous), Medium of interest (Outdoor or indoor air, surface water, etc.)
- **Sampling method by medium** (field blanks, replicates, standardized Canadian method, method justification)
- **Lab method by medium** (lab blanks, replicates, lab certification, method accuracy...)
- **Study design** (**hotspot**, selection method description, sample size determination, number of samples)
- **Appropriate statistical treatments** (censored/truncated, outliers treatment and justification)
- **Level of results, Results, Limits identifications**

(see the excel sheets that follow)





ENVIRONMENTAL DATA READING & SCORING SHEET			
Chemical under study			
Other chemicals analyzed			
List of chemicals analyzed (name or chemical symbol)			
Title			
Year			
Exact Reference			
Author(s)			
Affiliation(s)			
		Score detail	Max Score
Data source	Peer reviewed journals		
	Institutional/Governmental Reports		
	Grey literature (e.g., conference poster)		
	Draft/Unpublished		
	Official monitoring network(s)		
Data format (entry)	Raw data		
	Tables		
	Distributions		
Level of representativity	Canada	2.00	2.00
	Province(s)	2.00	
	Region(s)	1.00	
	Municipality(ies)	1.00	
	Other(s) (specify)	1.00	
Georeference(s)	Coordinates		
	Location		
Study type	Continuous		
	Cross-sectionnal		

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Medium(s) of interest	Outdoor Air		
	Indoor Air		
	Surface water		
	Tap water		
	Ground water		
	General food		
	Home food		
	Wild food		
	Soils (House, Street, ...)		
Sampling method(s) (by medium)	Name		1.50
	Details		
	Duration		
	Field blank(s)	0.50	
	X-plicat(s)	0.50	
	Conservation/Transportation precaution(s)		
	Does-it compare with CDN std ? Specify		
	Are the method(s) justified ?	0.50	
Lab method(s) (by medium)	Name		2.00
	Details		
	Lab blank(s)	0.50	
	X-plicat(s)	0.50	
	LoD		
	Laboratory certification (iso, commercial vs academic)		
	Method(s) accuracy	0.50	
	Does-it compare with CDN std ? Specify		
	Does-it compare with oth std ? Specify	0.50	

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Study design	Sampling Location		1.00
	Urban		
	Rural		
	Hotspot (source driven)	-100	
	Historical (not necessarily representative of population exposure)		
	Geographical		
	Temporal		
	Industrial		
	Geological formation		
	Other (Specify)		
	Selection method(s) (random, systematic, etc)	0.50	
	Sample size determination (explicit, unknown, etc.)	0.50	
	N		
	Biais/confounding precaution(s)		
	Schedule		
	Duration		
	Physical/Chemical Properties Integrated		
	Based on T1/2		
	Other (Specify)		
	Questionnaire (new, adapted, validated, etc.)		
	New		
	Adapted		
	Validated		
	Other (Specify)		
Appropriate statistical treatments	Censored/Truncated data	0.50	1.00
	Weighting Data		
	Outliers method	0.25	
	Outliers justification	0.25	
	Special Techniques (e.g., Resampling, Kriging)		
	Other (Specify)		

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Level of results <i>Select just 1 category, i.e. the most similar</i>	Detailed raw data	0.50	
	Percentiles data	0.25	
	Single point estimates	0.25	
Results	Min	1.00	2.00
	Lower quartile		
	Median		
	Upper quartile		
	Max		
	Lower cut-off value		
	Upper cut-off value		
	95th percentile		
	StdDev		
	StdDevP		
	95th confidence		
	Arithmetic mean		
	Geometric mean		
	N		
	% missing	0.25	
	% under LOD	0.25	
	Range		
	Distribution fitted		
	Uncertainty analysis		
Identified limits	Author(s)	0.50	0.50
	EDI reviewer(s)		
		Max	2.50
Legend:			
default inclusion criteria	by default, if there is this criteria, the study / data is included		
rejection criteria	by default, if there is this criteria, the study / data is rejected		
item to be scored	Item to consider		



The Health Canada's EDI project: **Methodology II**

- ✓ **Human and other exposure parameters:**
 - Mostly from the Compendium of Canadian Exposure Factors (1997)
- ✓ **Simulation software:**
 - Crystal ball (excel add-in)
- ✓ **Determination of the probabilistic distributions for**
 - The 5 Health Canada age groups (infant, toddler, child, adolescent and adult)
 - All the pertinent pathway of exposure through all the pertinent medium of exposure
- ✓ **Gaps and limitations identification**



The Health Canada's EDI project: Equation examples

✓ Inhalation (ambient air):

$$EDI_{\text{inhalation-out}} = \frac{IR \times C_{\text{air-out}}}{BW} \times \frac{ET_{\text{out}}}{24}$$

Where: EDI in $\mu\text{g/kg.day}$; IR: inhalation rate (m^3/day)

$C_{\text{air-out}}$: concentration of the chemical in outdoor air ($\mu\text{g}/\text{m}^3$)

BW: body weight (kg); ET_{out} : Time spent outdoors (hours/day)

✓ Soil ingestion:

$$EDI_{\text{soil ingestion}} = \frac{SIR \times C_{\text{soil}}}{BW \times 10^3}$$

Where: EDI in $\mu\text{g/kg.day}$; SIR: outdoor soil ingestion rate (mg/day)

C_{soil} : concentration of the chemical in soil ($\mu\text{g}/\text{kg}$)

BW: body weight (kg); 10^3 : conversion factor (mg/g)

And:

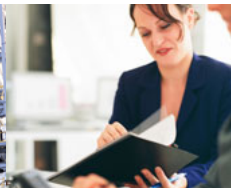
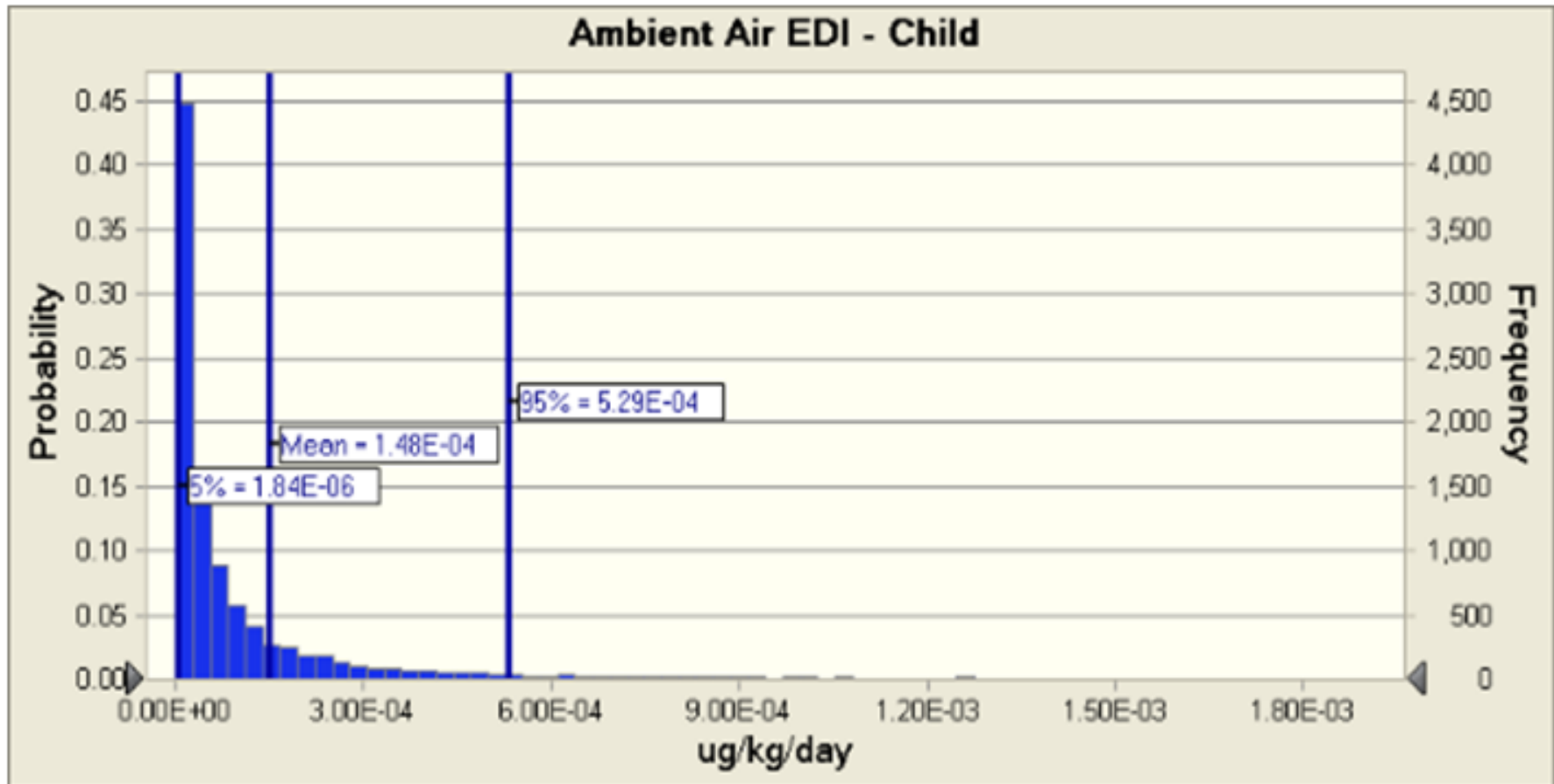
$$SIR = SL_{\text{hands}} \times \frac{SA_{\text{hands}}}{2} \times FSA_{\text{fingers}} \times FQ_{\text{out}} \times SE \times ET_{\text{out}}$$

(2009 – based on WTCWK)



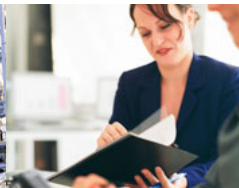
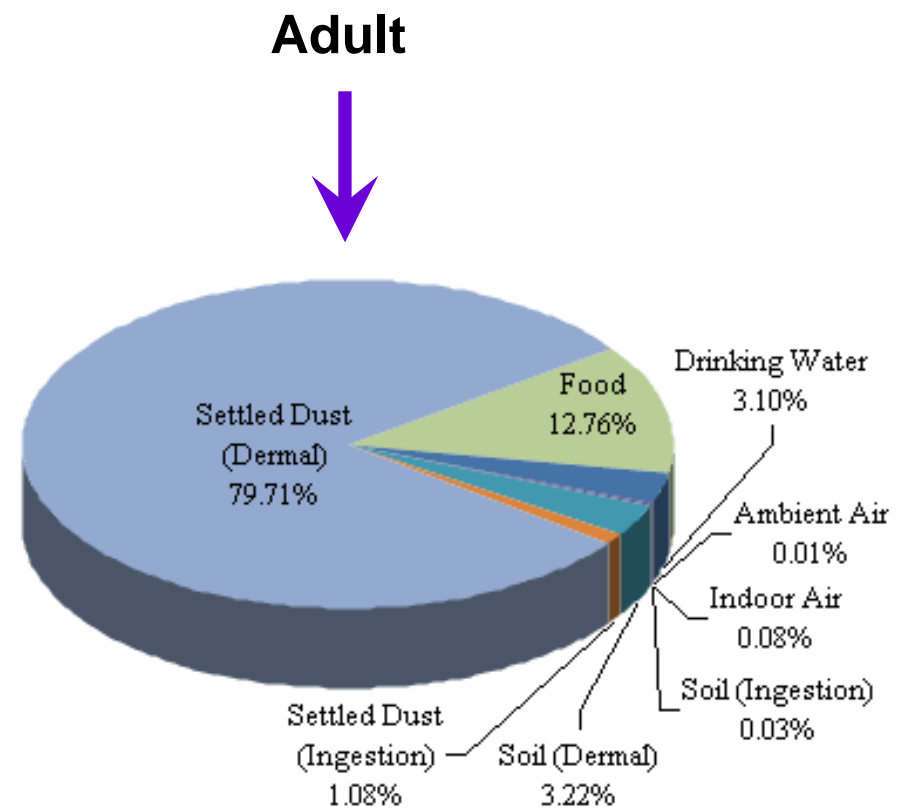
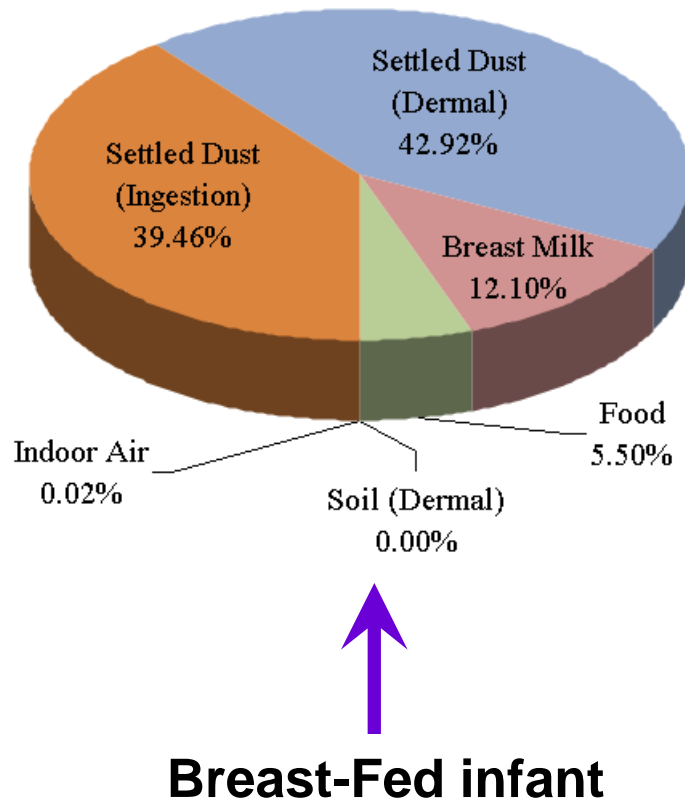
The Health Canada's EDI project: Result examples I

✓ Ambient air EDI for Child (lead example):



The Health Canada's EDI project: Result examples II

✓ Source apportionment (lead example):



The Health Canada's EDI project: Result examples III

✓ Data gaps (interim report):

Table 1. Summary of Data Available from Databases

Chemical	Water			Soil		Ambient Air	Indoor Air	Indoor Dust	Food
	Ontario DWSP	NFLD	SASK	Rencz 2006	GSC database	NAPS	NHEXAS	NHEXAS	HC TDS
Ba	Y	Y	Y	N	Y	Y	N*	N*	Y
Be	Y	N	Y	N	Y	Y	N	N	Y
Cd	Y	Y	Y	N	Y	Y	Y	Y	Y
Cr(VI)	N	N	N	N	N	N	N	N	N
Cr(total)	Y	Y	Y	Y	Y	Y	Y	Y	N
Ni	Y	Y	Y	Y	Y	Y	N*	N*	Y
Zn	Y	Y	Y	Y	Y	Y	N*	N*	Y
Vinyl chloride	Y	N	Y	N	N	Y	N	N	N

* Data are available for Arizona only, and all of the data are below the MDLs. As such, this data cannot be used. No database exists for concentrations of chemicals in breast milk; data from literature sources are required for all eight chemicals



Thanks for your attention

