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*Votre santé et votre  
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# Contaminated Sites Division Update on Science Activities Risk Symposium June 2, 2011



Canada 

# Health Canada Contaminated Sites Division

- Health Canada is an *Expert Support* Department under the Federal Contaminated Site Action Plan
  - Guidance, training and advice on human health risk assessment
  - Peer review of human health risk assessments
  - Human health-based environmental quality guidelines



# Emerging Issues

Some topical issues that we are currently working on:

- Sediment quality guidelines
- Amortization of short-term exposure
- Guidance for settled dust
- Guidance on application of bioavailability



# Human Health-Based Sediment Guidance?

- CCME sediment guidelines are based on risks to ecological receptors only
- No consistent approach for HHRA of contaminated sediments



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# Why not use soil-based parameters?

- Sediment physico-chemical characteristics differ from soil
- Human exposure duration, exposure pathways and exposure assumptions are different for sediments



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# HC Sediment Working Group Initial Projects

- Scoping project (Golder, 2010):
  - Describe existing approaches for HHRA of sediments
  - Identify existing health-based sediment guidelines
  - Proposed approach for HHRA of contaminated sediments
  -
- Sediment workshop (June 2010)
  - Solicit feedback on proposed approach
  - Identify solutions and next steps for key issues and data gaps
  - Develop a path forward and identify areas for future research



# Sediment Workshop Outcomes

- Key Data Gaps:
  - Sediment ingestion rates and suspended sediment
  - Dermal contact with sediments
  - Approach for fish/shellfish consumption pathway
  - Relevance of the floc and implications for sampling methods
  - Regional variability and availability of background data
- Key Concerns:
  - Eco-based guidelines are not always protective of human health
  - Guidelines must be functional and practical



# Sediment Working Group Current Activities

- Interim guidance on HHRA of contaminated sediments
- Preliminary guidance on evaluation of fish/shellfish consumption pathway as it relates to contaminated sediments
- Development of sediment ingestion rates



**AMORTIZATION  
OF SUBCHRONIC EXPOSURE OVER  
LONGER PERIODS**

**CAN IT BE DONE?  
WHAT NEEDS TO BE CONSIDERED?**



# Amortization – Toxicity Reference Values

- Where applicable:
  - Use short-term TRVs
  - Identify appropriate amortization for each COPC
- No generic default adjustment factor for deriving acute or subchronic TRVs from chronic values

Ratio of <u>Acute</u> to Chronic ATSDR MRLs		Ratio of <u>Subchronic</u> to Chronic ATSDR MRLs	
n = 41	Arith mean = 25 Range = 1 to 200	n= 44	Arith mean = 9 Range = 1 to 100



# Amortization Example - Some Considerations

- Workers exposed to dioxins for 3 days per year
- Chronic TDI is 2.3 pg/kg bw/day
- Question: Could this short term exposure be amortized over a year and compared to the chronic TDI?

## Literature search

- Acute MRL from ATSDR of 200 pg/kg/bw/day
- Short term exposure - chloracne and immunological effects
- Developmental toxicant

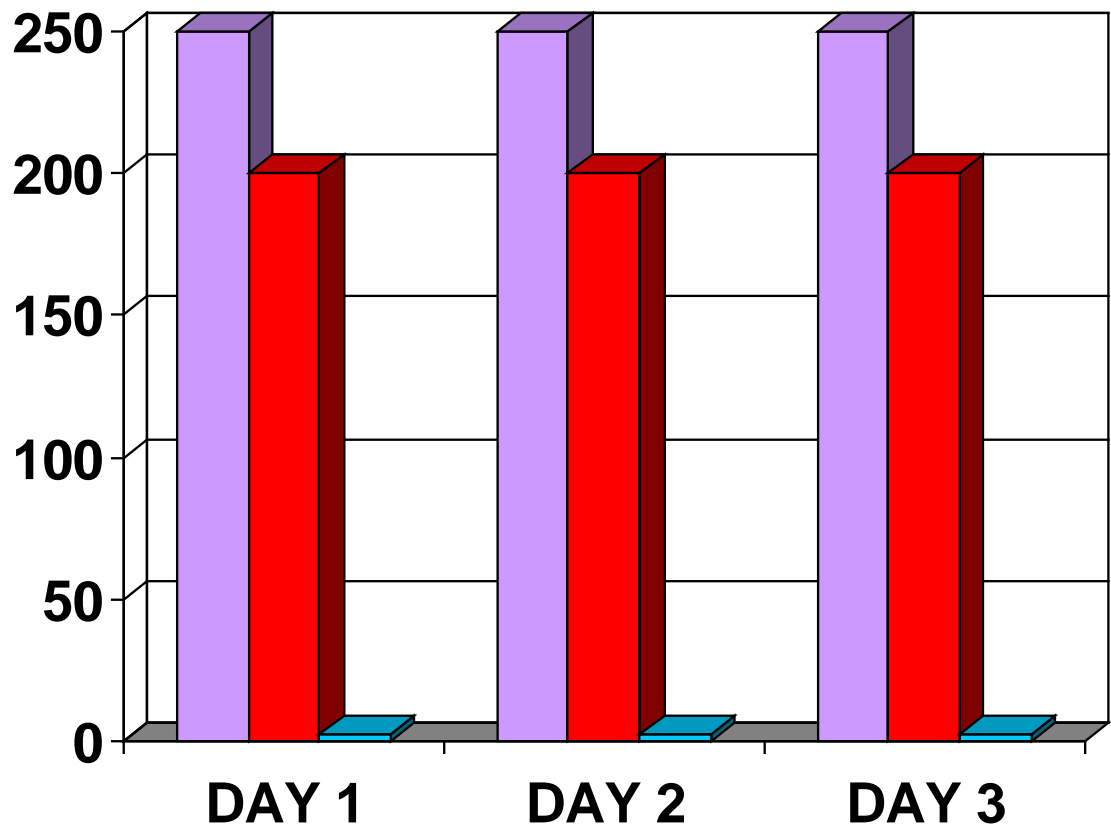


# Example Results

Exposure duration	Calculated exposure	Toxicity reference value
Exposure for each of the 3 days on site	<b>250 pg/kg bw each day for the 3 day exposure duration</b>	Acute MRL is 200 pg/kg/bw/day
What if a report calculated the amortization of exposure over a year?	2.06 pg/kg bw/day over a year if 3 days are amortized over 365 days (does not consider that short term exposure is elevated)	Chronic TRV is 2.3 pg/kg bw/day



# VISUAL OF EXAMPLE RESULTS



- SHORT TERM EXPOSURE
- ACUTE MRL
- CHRONIC TRV

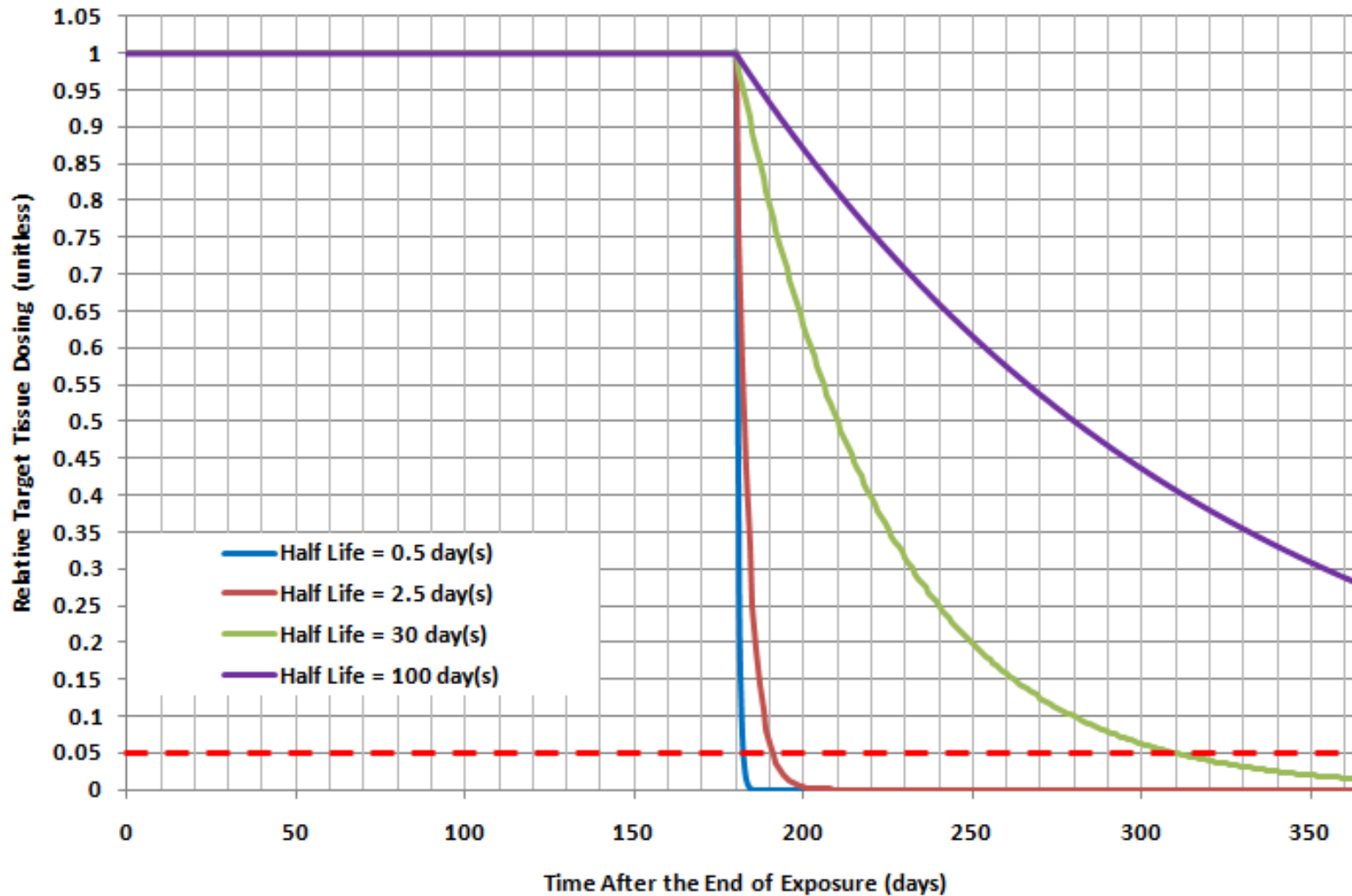


## Example Decision On Amortization

- This example shows it would NOT be justified to amortise a 3 day exposure period over a year for this substance
- For this substance, the TDI is based on a WHO provisional monthly intake of 70 pg/kg bw/day, therefore amortization of the 3 day exposure over 1 month would be consistent with the provisional tolerable monthly intake
- It is critical to assess the short-term toxicity of each substance and the basis for the TRV



# 6 Month Exposure then 6 Months Post-Exposure

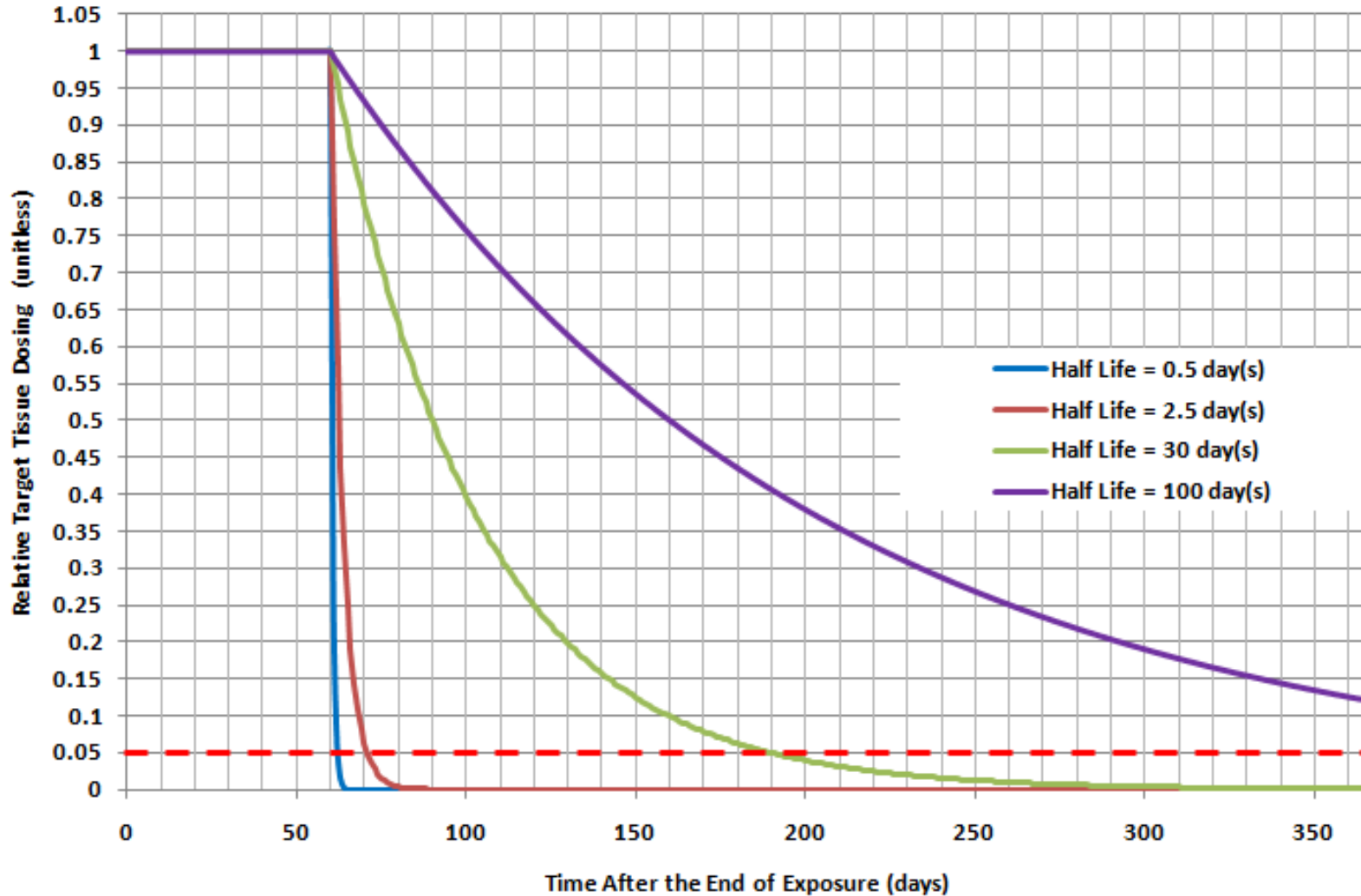


Assuming First Order Clearance Kinetics

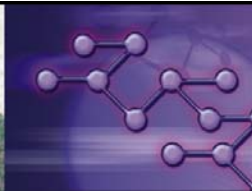


*Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1*

# 2 Month Exposure Then 10 Months Post-Exposure

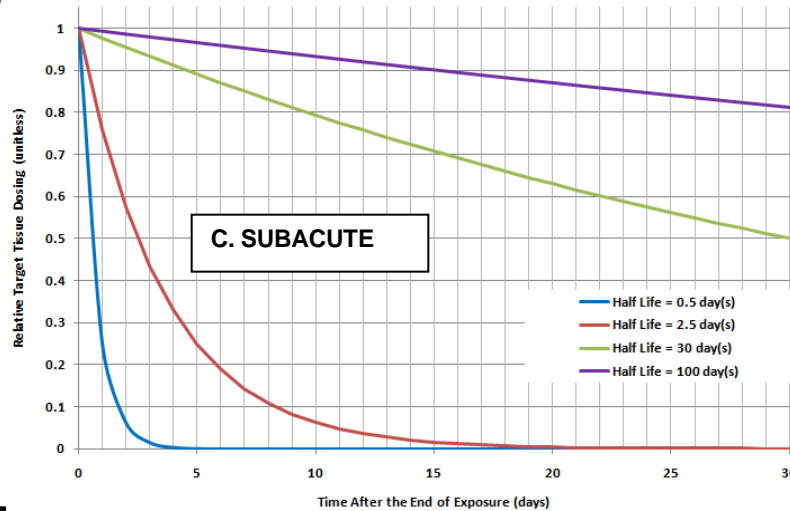
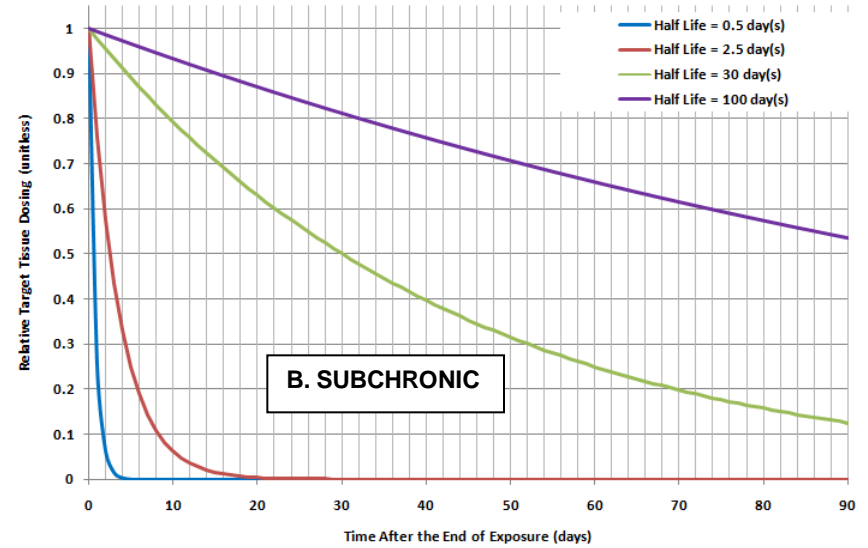
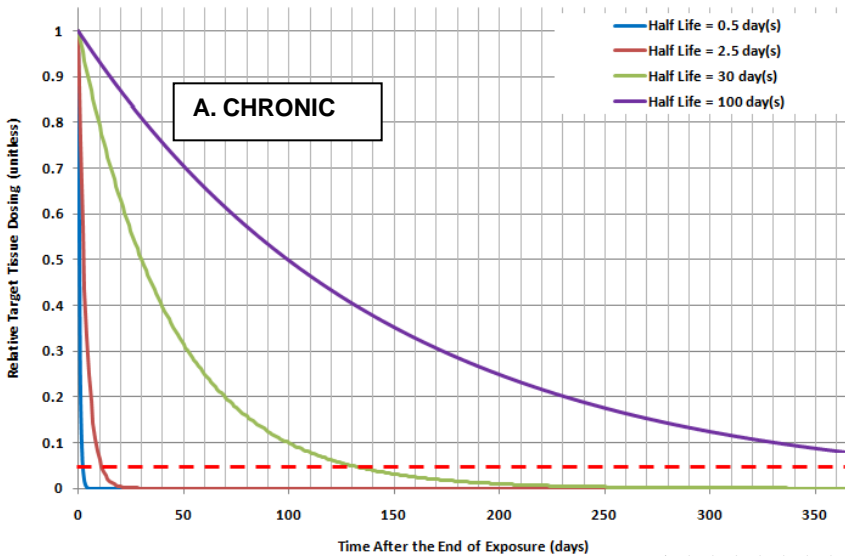


Assuming  
First Order  
Clearance  
Kinetics



**Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1**

# Single Exposure Then Post-Exposure



Assuming  
First Order  
Clearance  
Kinetics



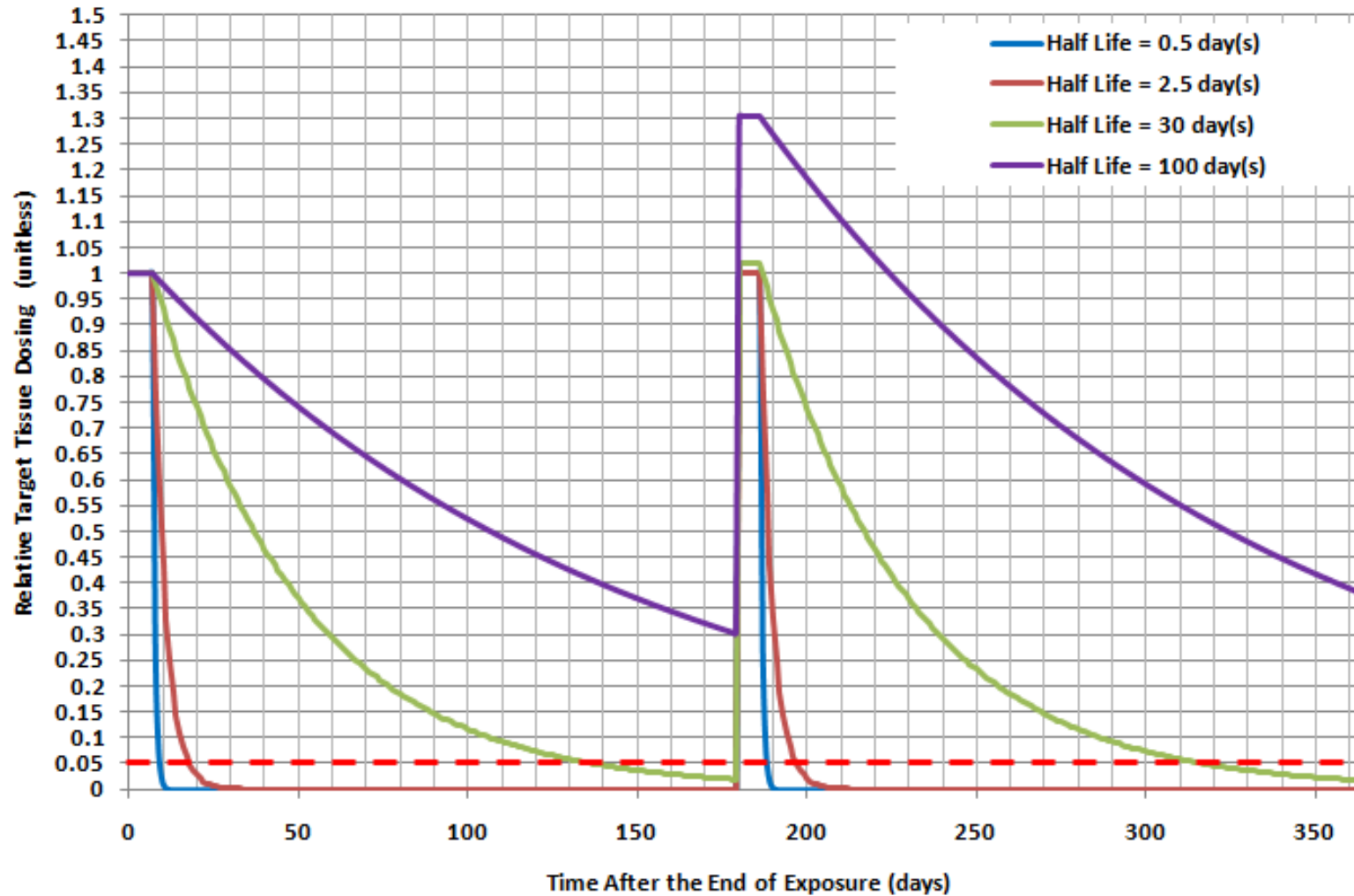
**Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1**

# AMORTIZATION

WHAT ABOUT REPEAT  
SHORT TERM EXPOSURES?



# Once per Week, Twice Per Year Exposure

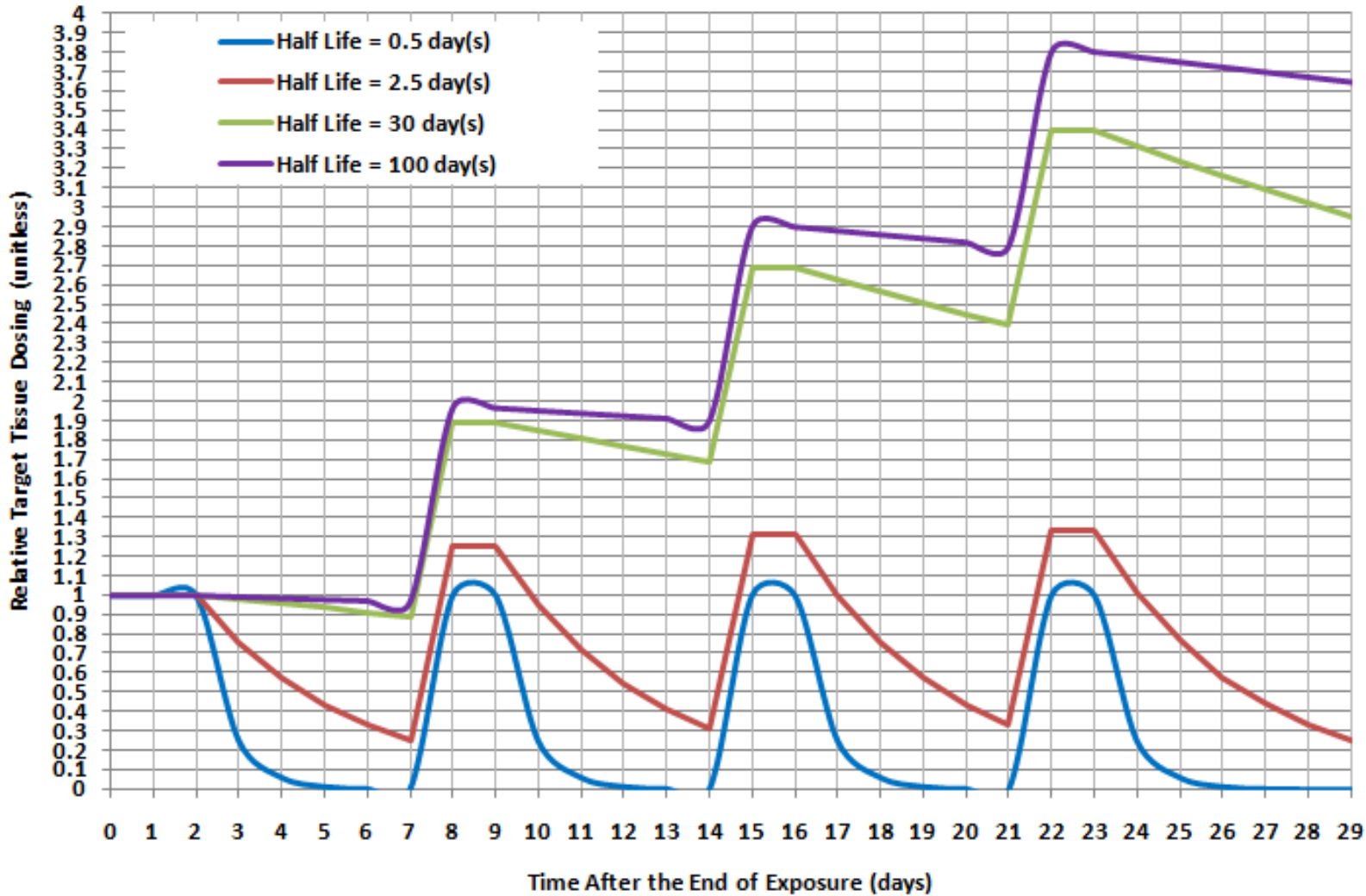


Assuming First Order Clearance Kinetics



*Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1*

# Two Days Per Week For 4 Week Exposure

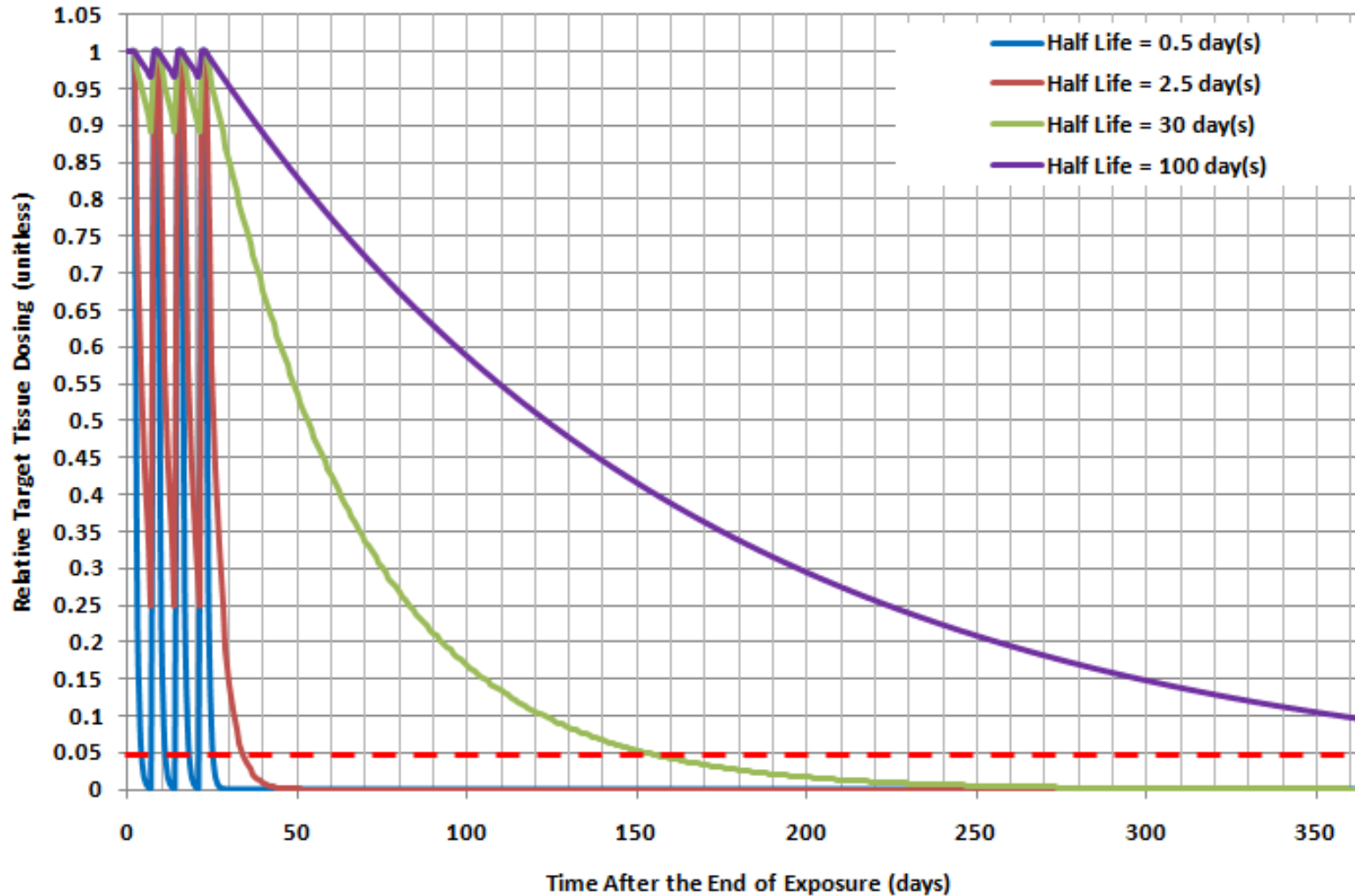


Assuming  
First Order  
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*Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1*

# 2 Days Per Week for 4 Weeks Then Post-Exposure

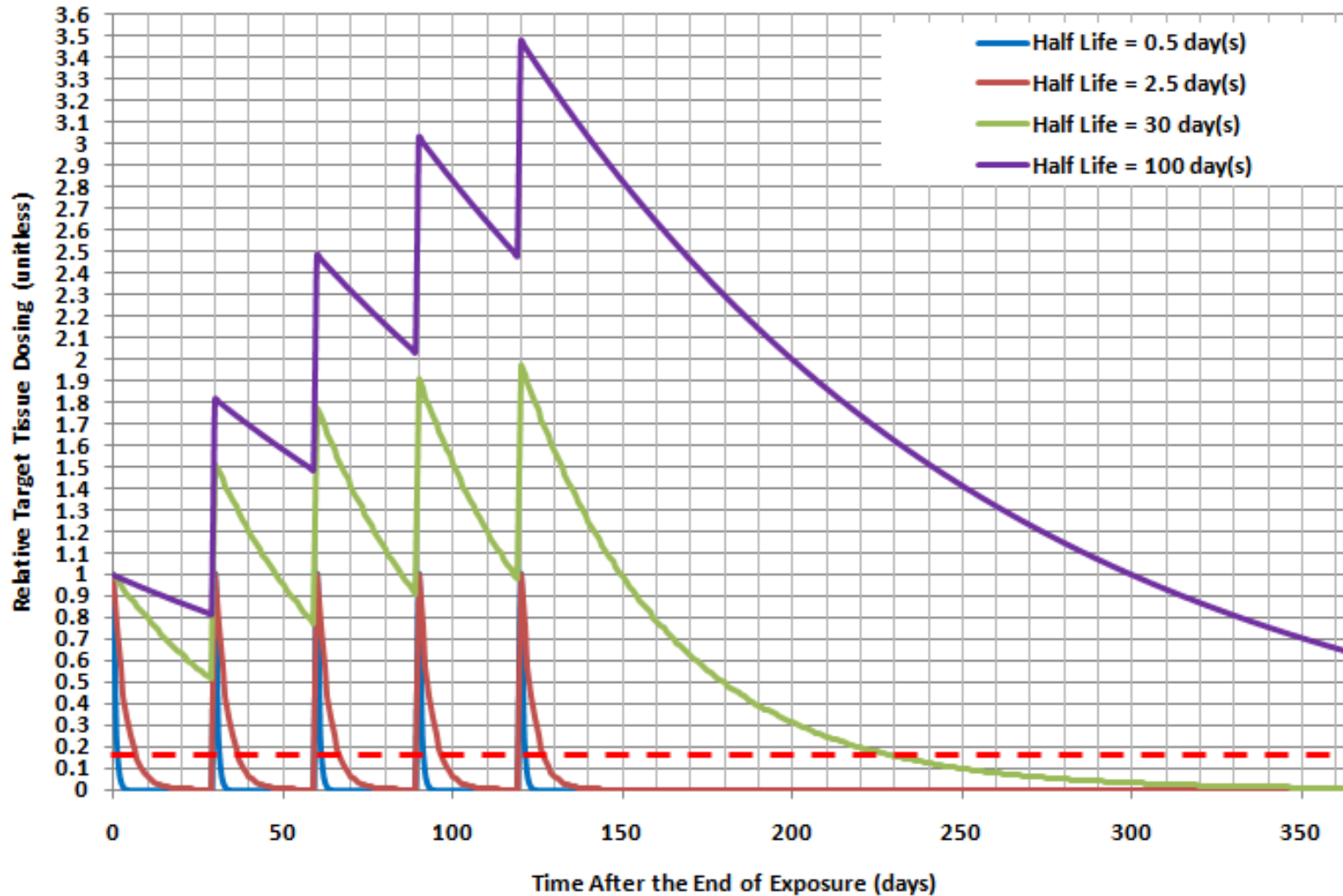


Assuming First Order Clearance Kinetics



*Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1*

# Once per Month for 4 Months Exposure

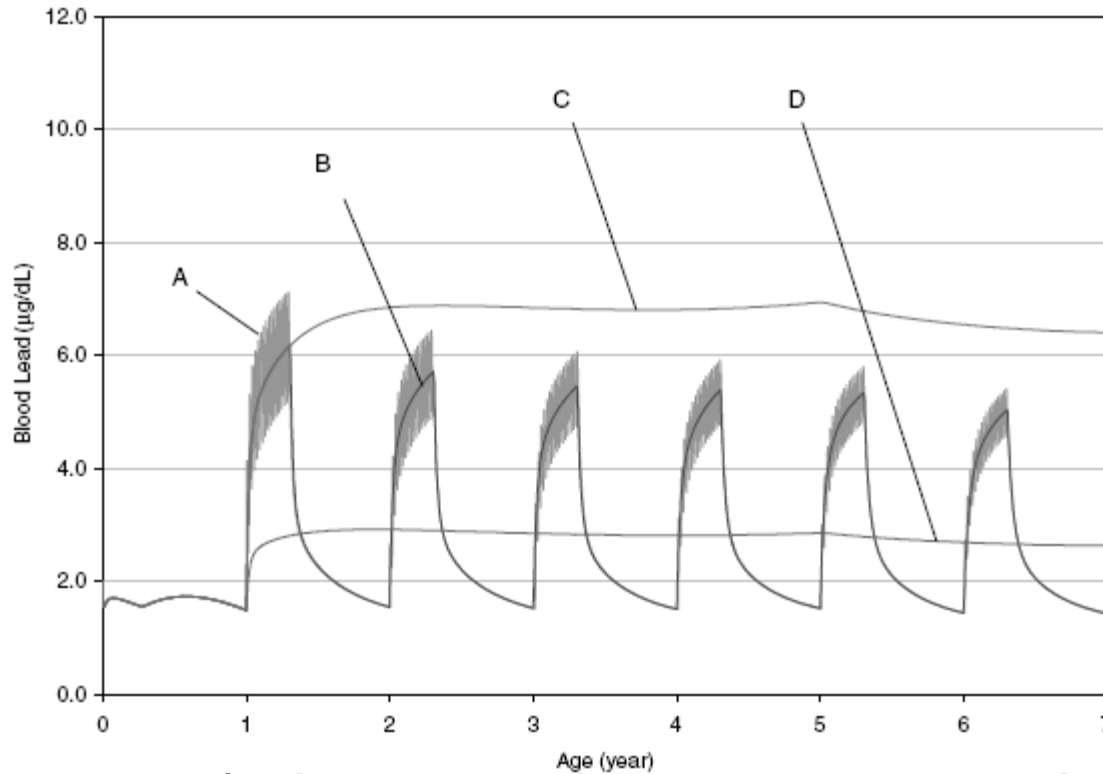


Assuming First Order Clearance Kinetics



**Note: relative target tissue dosing is idealized as it is unlikely that steady state will be reached on day 1**

# Repeat Short Term Exposure - Lead



From ([Lorenzana et al., 2005](#)). Time course of blood lead concentrations predicted by the Leggett model associated with increased lead exposure for 2 days a week, 16 weeks per year. A indicates the blood lead profile if exposures are modeled on a daily basis; B indicates the blood lead profile if the daily lead exposure is averaged over a week; and D indicates the blood lead profile if the daily lead exposure is averaged over a year.



# Guidance On Amortization

- Identify short term toxicity values and whether there are developmental effects
- Consider pharmacokinetics if there is repeat exposure
- Do not amortize without scientific rationale with regard to potential adverse short-term health effects
- Rationale needs to be consistent with the toxicity (dose-response) data and protective of sensitive health effects for each COPC
- See DQRA for additional guidance

**\*\*PQRA short-term amortization is for ranking only – not for DQRAs or SSTLs\*\***



**GUIDANCE ON SETTLED DUST AND  
DUST SCREENING CONCENTRATIONS  
AT CONTAMINATED SITES**



# Guidance on Settled Dust in HHRA

- Currently there is no federal Canadian guidance available for evaluating substances in indoor dust
- Approach for developing human health-based indoor dust screening concentrations ( $DSC_{HH}$ ) is being developed
- This will permit the interpretation of the significance of measured indoor settled dust levels of COPCs within contaminated site risk assessments



# Evaluating Settled Dust in HHRA

- DSCs are meant as “screening” concentrations
  - an exceedance does not necessarily indicate a risk, but suggests the need for additional site-specific human health risk assessment
- The most important difference from the CCME approach for the derivation of  $SQG_{HH}$  and the options for the derivation of  $DSC_{HH}$  is the need to express dust screening concentrations in units of both “ $\mu\text{g}/\text{m}^2$ ” and “ $\mu\text{g}/\text{g}$ ”



## Update on Activities Re: Settled Dust Guidance

- Health Canada is preparing a guidance document on evaluation of settled dust in contaminated site risk assessments
- Webinar was held - the consultation was designed to obtain feedback on various options identified
- Consultant report and webinar information is available upon request





**GUIDANCE ON USE OF  
BIOAVAILABILITY  
WITHIN RISK ASSESSMENT**

# Bioavailability in Risk Assessment

- Health Canada is preparing a guidance document on incorporation of oral bioavailability of COPCs in soil
- Considerations:
  - Is the rationale for use of a RBA provided and adequately supported?
  - Is the bioavailability study protocol acceptable?
  - Are the qualifications of the investigators and laboratory adequate?
  - Are study results properly presented? e.g., how do results compare with similar studies reported in the literature?



# Current Status With Regard to These Issues

- Contractor reports are available ([cs-sc@hc-sc.gc.ca](mailto:cs-sc@hc-sc.gc.ca))
- No formal guidance is currently available on the issues presented herein
- Health Canada is available to provide advice

