

Cleanup Levels & Risk-Related Issues

Easy Entry into Discussion of Difficult Issues

Prepared for
MTCA/SMS Advisory Group
January 11, 2010

Risk-Related Rule Issues

- January 11th Meeting – Toxicity Issues
 - Updates to cleanup levels using new toxicity values (applicable to all environmental media)
 - Adjustments for age-specific differences in exposure and increased child susceptibility to carcinogens (applicable to all environmental media)
 - Revisions to cleanup levels for lead (applicable to all environmental media)
- Other
 - Concurrent exposure for direct contact pathway (soil and sediment)
 - Fish consumption rates for high exposure population groups (surface water and sediments)
 - Methods for evaluating inhalation risks

Risk Based Cleanup Levels

$$\text{Risk} = \int \text{Toxicity} \times \text{Exposure}$$

$$\text{Risk} = \int \text{Toxicity} \times (\text{Concentration} \times \text{Unit Intake})$$

$$\text{Concentration} = \int \frac{\text{Risk}}{\text{Toxicity} \times \text{Unit Intake}}$$

Risk-Based Cleanup Levels Using New Toxicity Values

- New toxicity values available for more than 30 percent of the hazardous substances or groups of hazardous substances included in the MTCA cleanup level tables.
- Use of new toxicity information would result in revisions to some risk-based cleanup levels.
 - Some updated values may be non-controversial (e.g., new IRIS values)
 - Some updated values may be controversial (e.g., trichloroethylene)
- Some revisions will have little practical impacts because cleanup levels also take into account ARARs (e.g. drinking water standards), practical quantitation limits (PQLs) and background concentrations.

Use of New Toxicity Values

Issues and Options

Risk-Based Ground Water Cleanup Levels (Equation 720-2)

Substance	2001 Risk-Based Cleanup Level	2001 Method A Cleanup Level	2009 Risk-Based Cleanup Level	Method A Cleanup Level
Arsenic	0.06	5 (background)	0.06	5 (background)
Benzene	1.5	5 (MCL)	0.8	5 (MCL)
BaP	0.01	0.1 (MCL/Risk)	0.01	0.1 (MCL/Risk)
TCE	4.0	5 (MCL)	3.4	5 (MCL)

Shifting Gears

- Age-Specific Differences in Exposure and Child Susceptibility to Chemical Carcinogens

Early Life Stage Adjustments to Cancer Slope Factors

- Numerous studies over the last 20 years indicate that exposure to carcinogens early in life have a much greater impact on lifetime cancer risks than exposures later in life.
- Most cancer slope factors are based on animal bioassays or epidemiological studies that do not account for exposures during these critical exposure periods.
- EPA and California EPA have developed scientific procedures and policies for adjusting existing cancer slope factors to account for this increased susceptibility.

Cancer Risk Guidance – Early Life Stage Adjustments

- EPA published new guidelines for cancer risk assessment in March 2005:
 - Guidelines for Carcinogen Risk Assessment.
 - Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens
- California EPA conducted an independent review and updated their cancer guidelines in 2009.

Regulatory Guidance

- EPA regulatory guidance on early life stage exposure applies to carcinogens that operate via a mutagenic mode of action.
 - EPA guidance lists 12 chemicals (including vinyl chloride and benzo[a]pyrene)
- EPA recommends that cancer slope factors for these types of carcinogens be adjusted by a factor of 1 to 10 (factor depends on age interval)
- California EPA guidance document recommends that similar adjustments be made for all carcinogens (independent of mode of action)

Trichloroethylene – Ground Water Issues and Options

Options	Trichloroethylene	Implications for Cleanup Levels (Drinking Water)
Current Rule	4.0	Cleanup level based on MCL (5 ug/L)
Current Rule + EPA Region III Cancer Slope Factor	3.4	Cleanup level based on MCL (5 ug/L)
U.S. EPA Guidance on Early Life Stage	2.7 (exposure adjustment only)	Cleanup level based on MCL (5 ug/L)
Calif. EPA Guidance on Early Life Stage	1.1	Cleanup level based on MCL (5 ug/L)

Benzo[a]pyrene – Soil Issues and Options

Options	Benzo[a]pyrene (mutagenic mode of action)
Risk –Based Current Rule	0.1 mg/kg
Risk-Based U.S. EPA Guidance	0.02 mg/kg
Risk-Based California EPA Guidance	0.02 mg/kg
Mean Background Levels California Background Study (UTL – 95% coverage/95% range)	0.16 – 0.18 (@ 0.9 – 1.5)

Shifting Gears

- Cleanup Levels for Lead-Contaminated Soils (and other media)

Current MTCA Lead Cleanup Level

- Cleanup level (250 mg/kg) developed in 1991
 - Young children = sensitive population group
 - Neurological development = critical effect
 - Acceptable blood lead level = 15 ug/dL
 - Slope factor model used to estimate soil level that would prevent blood lead levels > 15 ug/dL in 99% of children

New Scientific and Regulatory Information Since 2001

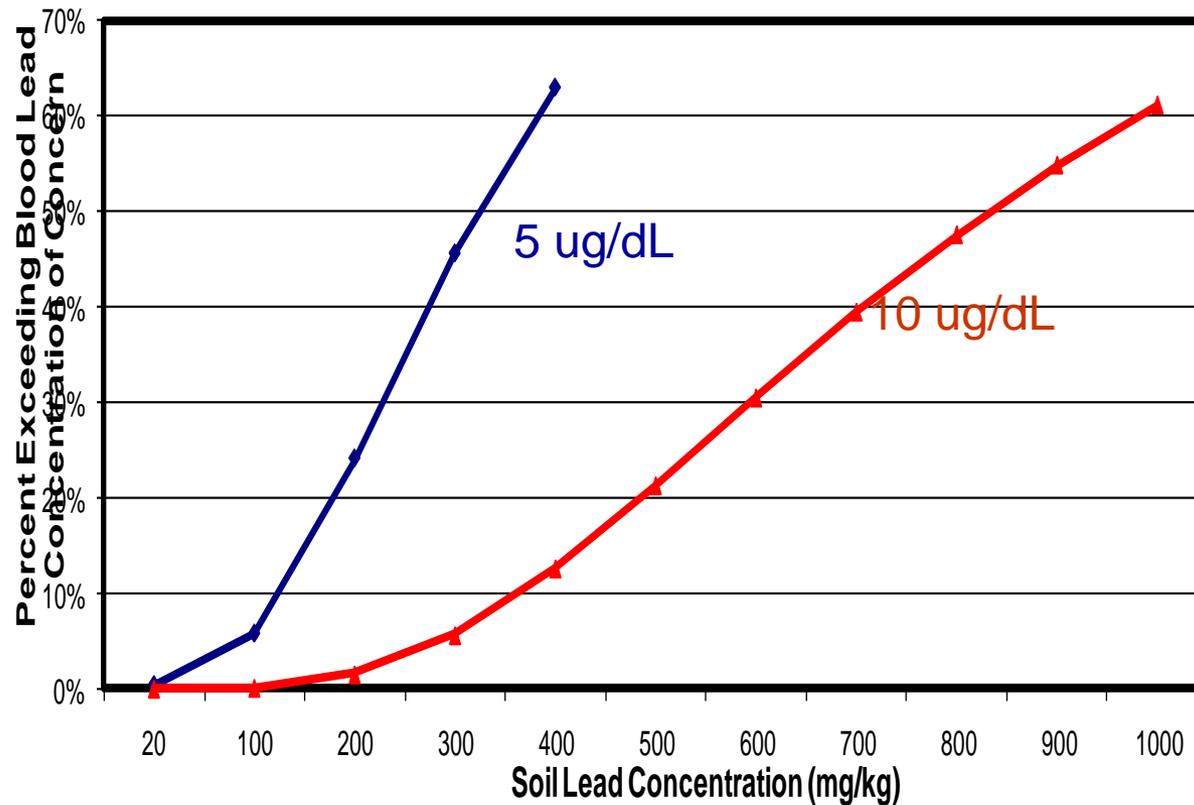
- Numerous new studies have been completed since 2001.
 - Health risk below 10 ug/dL
 - Non-linear dose/response/No identifiable threshold
 - Additional health endpoints
- Several expert review have reach conclusions on new information.
- Several regulatory actions:
 - EPA Air Quality Program (2 ug/dL = acceptable incremental blood lead concentration)
 - California EPA (Revised drinking water standards and soil cleanup levels using 1 ug/dL increment) – Soil cleanup levels = 90-120 mg/kg
 - DOH Advisory Committee – Consider use of 5 ug/dL for blood lead screening guideline

MTCA Science Advisory Board

(2004-2008 Discussions)

- Agreed there is a credible scientific basis for revising the MTCA cleanup level
- There is a credible scientific basis for continuing to base the lead cleanup level on:
 - Protection of infants and young children
 - Prevention of adverse neurological and neurobehavioral health impacts.
 - Evaluations that use blood lead concentrations to characterize lead exposure.

Soil-Blood Lead Relationships (12 - 36 month age interval)



Soil Cleanup Levels for Lead

Options and Issues

Model	Key Assumptions/Choices	Risk-Based Level
IEUBK	<ul style="list-style-type: none"> Target Blood Lead Level = 10 ug/dL Age Group = 12-36 months Standard assumptions (5% probability) 	250 mg/kg (current CUL)
IEUBK	<ul style="list-style-type: none"> Target Blood Lead Level = 5 ug/dL Age Group = 0-84 months Standard assumptions (5% probability) 	120 - 200 mg/kg
IEUBK	<ul style="list-style-type: none"> Target Incremental Blood Lead Level = 2 ug/dL Age Group = 12-36 months Standard Assumptions (5% probability) 	70-200 mg/kg
Other	<ul style="list-style-type: none"> Use of EPA All Ages Model Use of California LeadSpread Model Slope Factor Approach 	

Broad Risk Issues - Next Steps

- Finish Internal Evaluations (January-February):
 - Summarize the technical bases for new toxicity values that form the bases for risk-based cleanup levels
 - Review EPA proposals for TCE toxicity values/dioxins
 - Review EPA Region III recommendations for toxicity values for chemicals with no values in the IRIS database
 - Sensitivity analyses for lead calculations (per SAB advice)
 - Explore other lead exposure models
- External Feedback on issues and options (Winter/Spring)
 - Work Group Meetings
 - MTCA Science Panel Review
- Internal Evaluations and Recommendations (Spring)