

Science Policy and Cleanup Levels

July 26, 2010

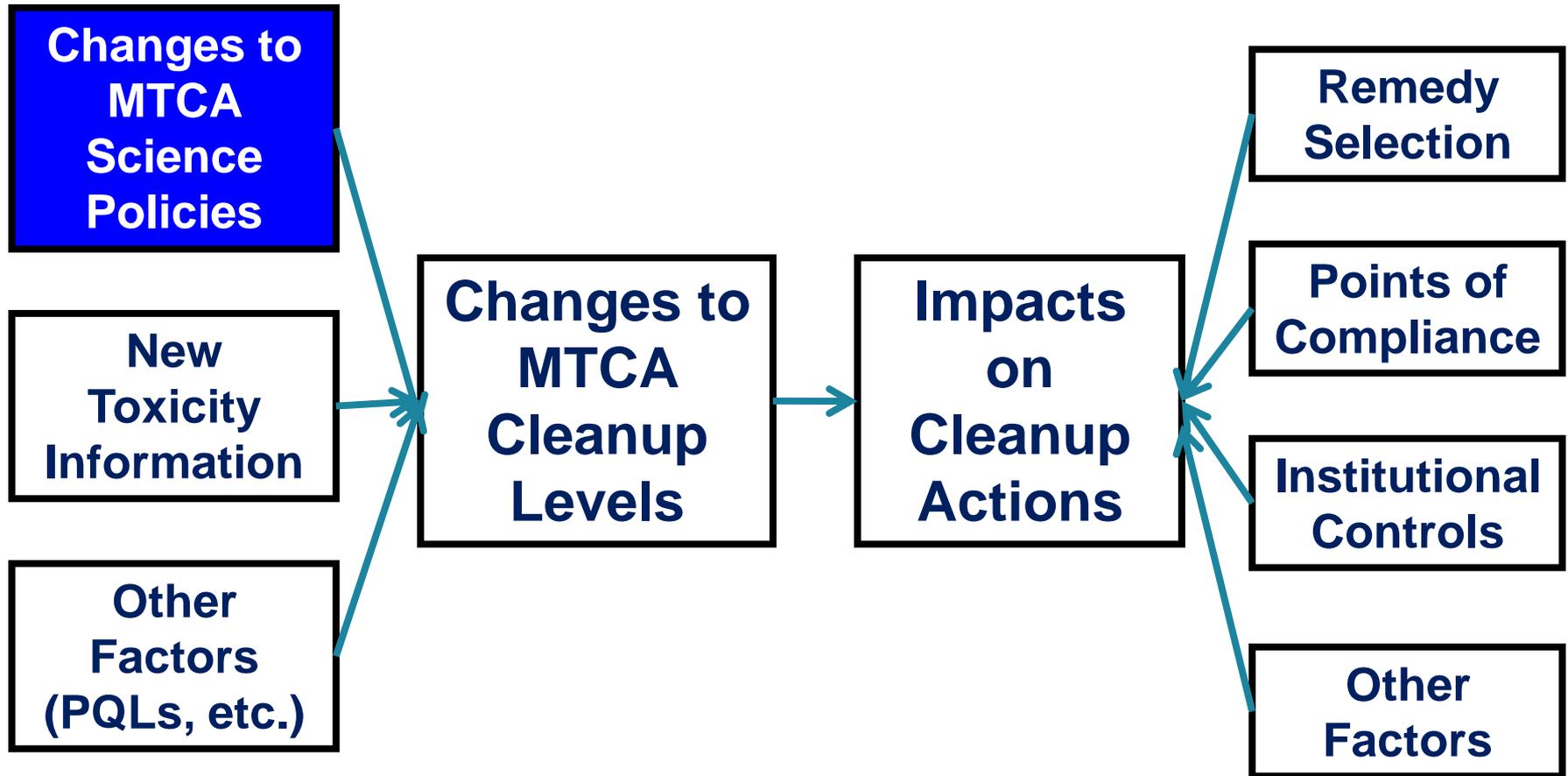
**Toxics Cleanup Program
Department of Ecology**

Topics



- Draft revisions
 - Definition of Carcinogen
 - Toxicity Hierarchy
 - Early Life Exposure Adjustments
 - EPA Inhalation Risk Assessment
 - Concurrent Soil Exposure
- Next Steps

Why Should You Care About Changes to MTCA Science Policies?



What did we hear about these issues during and after the March 2010 meeting?

1. General agreement that definition of carcinogen needs to be updated based on current EPA guidance
2. General agreement that cleanup levels need to be updated consistent with EPA data hierarchy.
 - Concerns about use of California EPA toxicity values
3. Appears to be support on the use of EPA guidance on early-life stage exposure
 - Wide range of opinions on application to all carcinogens
4. General agreement on updating the rule based on EPA inhalation risk assessment guidance.
5. Range of opinions on modifying soil cleanup level equation to require consideration of soil ingestion and dermal contact.

Fork in the Road

When you come to a fork in the road, take it.
Yogi Berra, New York Yankees



Questions to Keep In Mind During Discussion

...Now I want to hear the next ten words...

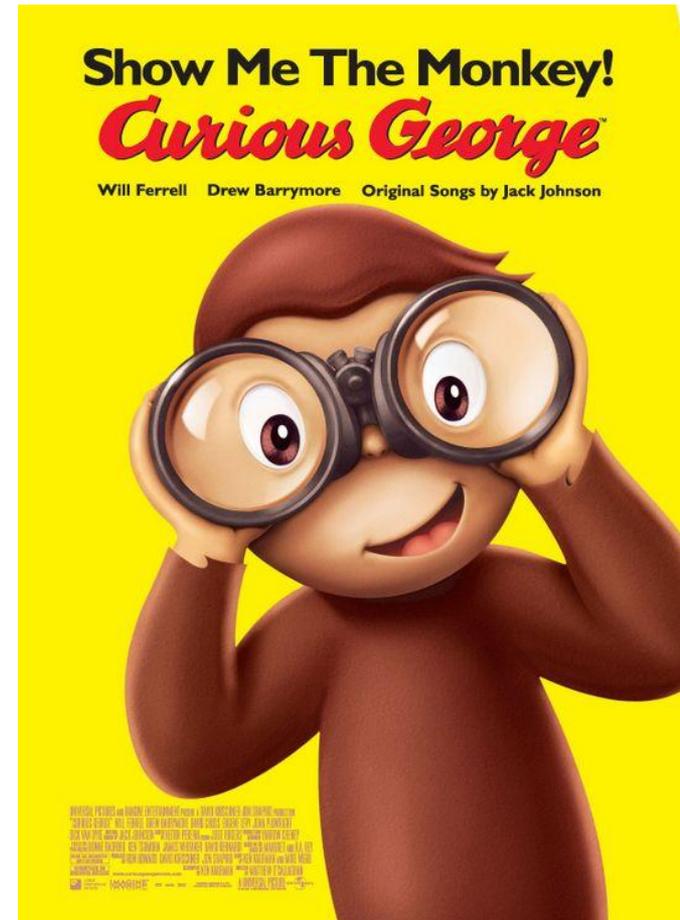
Josiah “Jed” Bartlett

- Does rationale for the draft revision make sense to you?
- If not, why not?
- Are there other options that you think Ecology should consider over the next couple of months?



Questions to Keep In Mind During Today's Discussion

- Do the preliminary evaluations of potential implications of draft revisions make sense?
- Do the preliminary evaluations help you to understand the implications of the draft revisions?
- What additional evaluations would help to understand the practical implications of the draft revisions?



Definition of Carcinogen

- Reason for the revision:
 - EPA updated their cancer risk assessment guidelines in 2005
- Draft revision:
 - Incorporate reference to EPA 2005 guidelines (“carcinogenic to humans” and “likely to be carcinogenic to humans”)
 - Deleted the phrase “...any substance that causes a significant increased incidence of benign or malignant tumors in a single well conducted study...”
- Rationale
 - Consistent with current scientific information
 - Consistent with current MTCA definition and EPA guidance
 - Falls within range of definitions used by other Ecology programs and other state cleanup programs
 - Feedback from MTCA/SMS Advisory Group and Vapor Workgroup

Definition of Carcinogen

Definition of “Carcinogen” (WAC 173-340-200) DRAFT

"Carcinogen" means any hazardous substance ~~or agent~~ that produces or tends to produce cancer in hu-mans. For implementation of this chapter, the term carcinogen applies to substances on the United States Environmental Protection Agency lists of A (known human) and B (probable human) carcinogens, ~~and any substance that causes a significant increased incidence of benign or malignant tumors in a single, well conducted animal bioassay, consistent with the weight of evidence approach specified in the United States Environmental Protection Agency's Guidelines for Carcinogen Risk Assessment as set forth in 51 FR 33992 et seq. and substances that meet the criteria for classification as "carcinogenic to humans" or "likely to be carcinogenic to humans" consistent with the USEPA's "Guidelines for Carcinogen Risk Assessment" EPA/630/P-03/001F, USEPA, March 2005.~~

Definition of Carcinogen

Preliminary Evaluation of Implications

Estimated Number of Carcinogens Meeting Current and Draft MTCA Definition		
Number of Hazardous Substances on the 2007 CERCLA Priority List of Hazardous Substances	81 Substances in top 100 with separate toxicity values	
	Current Rule	Draft Revision
Estimated Number of Hazardous Substances Classified as Carcinogens under MTCA	50	50
Category A (Known Human) Carcinogens	6	6
Category B (Probable Human) Carcinogens	31	31
Substances Causing Significant Tumor Increase	13	
Classified by EPA Using 1996 or 1999 Draft Guidelines (EDB and chloroform)		2
Meets EPA 2005 Cancer Guidelines		11

Toxicity Hierarchy

- Reason for the revision:
 - EPA published guidance in 2003 (OSWER Directive 9285.7-53)
 - Implementation issues over last 10 years
- Draft revision:
 - Add reference to OSWER Directive 9285.7-53 (EPA data hierarchy)
 - Delete reference to HEAST values
 - Create framework for regular updates to CLARC database
- Rationale
 - Consistent with current EPA guidance
 - Workable approach for incorporating new scientific information
 - Consistent with other state cleanup programs
 - Appears to be consistent with feedback from MTCA/SMS Advisory Group and Vapor Workgroup (**Concerns with California EPA values**)

Toxicity Hierarchy

Draft Rule Provisions on Cancer Slope Factor Hierarchy (WAC 173-340-708(8))

(8) Cancer slope factor and inhalation unit risk factors.

(a) Cancer slope factors and inhalation unit risk factors available through the integrated risk information systems (IRIS) data base shall be used to establish cleanup levels and remediation levels. If such values are not available through the IRIS database, cancer slope factors and inhalation unit risk factors available from the National Center for Environmental Assessment shall be used. These values shall be used unless the department determines that there is clear and convincing scientific data which demonstrates that the use of a particular value is inappropriate.

(b) Cancer slope factors and inhalation unit risk factors from other sources may be used to establish cleanup levels and remediation levels when values are not available in the IRIS database. The department will use the criteria in OSWER Directive 9285.7-53 when evaluating whether particular values can be used to support decisions on cleanup levels or remediation levels.

(c) The department shall publish and periodically update a list of cancer slope factors and inhalation unit risk factors. The department shall provide an opportunity for public review and comment before publishing a final list and/or updated list.

Toxicity Hierarchy

What toxicity values are likely to be used under MTCA?

Toxicity Values Used to Develop Regional Screening Concentrations Based on Cancer Risks for the 50 Carcinogens Among the 100 Highest Ranked Substances on the 2007 CERCLA Priority List		
Source of Toxicity Value in Regional Screening Tables	Oral Cancer Slope Factor	Inhalation Unit Risk Factor
Integrated Risk Information System (IRIS)	34	25
Provisional Peer Reviewed Toxicity Values (PPRTV)	1	2
California Environmental Protection Agency	5	17
Health Effects Assessment Summary Tables (HEAST)		
Other	1	0
No Value Available	7	6

Toxicity Hierarchy

Why so many California EPA inhalation unit risk values?

Substance	Current MTCA inhalation cancer potency factor	Basis	Inhalation Unit Risk Factor (calculated from MTCA CPF _i)	California EPA Inhalation Unit Risk Factor
Benzo[a]pyrene (multiple PAHs)	6.1 (mg/kg/day) ⁻¹	HEAST	1.7E-03 (ug/m ³) ⁻¹	1.1E-03 (ug/m ³) ⁻¹ Red = CalEPA value less stringent than current MTCA value
Trichloroethylene	0.089	HEAST/CLARC	2E-06	2E-06
Tetrachloroethylene	0.021	HEAST/CLARC	5.9E-06	5.9E-06
Nickel	1.7	HEAST	4.9E-04	2.6E-04
TCDD	150,000	HEAST/Oral	4.3E+01	3.8E+01
PCBs	2	Oral slope factor	5.7E-04	5.7E-04
DDD	0.24	Oral slope factor	6.9E-05	6.9E-05
Pentachlorophenol	0.12	Oral slope factor	3.4E-05	5.1E-06
DEHP	0.014	Oral slope factor	4E-06	2.4E-06
3,3'-Dichlorobenzidine	0.45	Oral slope factor	1.3E-04	3.4E-06

Toxicity Hierarchy

Is there a difference between Cal EPA and USEPA values?

Summary of Comparison of Cancer Slope Factors in the Integrated Risk Information System and the California Environmental Protection Agency Toxicity Criteria Database	
Cancer Slope Factor Ratios (CalEPA CSF/USEPA CSF)	Number of Chemicals
Chemicals with slope factor ratio greater than 3	4
Chemicals with slope factor ratio between 2 and 3	10
Chemicals with slope factor ratio between 1 and 2	15
Chemicals with the same cancer slope factor (ratio = 1)	18
Chemicals with slope factor ratio between 0.5 and 1	6
Chemicals with slope factor ratio less than 0.5	7
Average Slope Factor Ratio (60 chemicals)	1.6

Advisory Group Comments on Application of Early Life Stage Exposure Guidelines

- General support for applying early-life stage adjustments to carcinogens with mutagenic MOA (EPA Policy)
 - Applying EPA policy is a reasonable first step (Boyden/Stoner)
- Range of opinions on whether policy should apply to all carcinogens
 - Lack of uniformity on defining mutagenic MOA; biological reasons for increased child sensitivity; err on side of caution (Dunn)
 - Reasons for not applying to all carcinogens (e.g., rapid pace of research, conclusive evidence for few compounds, EPA policies (Boyden/Stoner)
- Members identified technical and policy issues associated with application to benzo[a]pyrene/PAH compounds
 - Large uncertainties with high to low doses extrapolation; MTCA policies include conservative features; cleanup levels below background; draft EPA mixtures policy (Yost/Garry through Ernst)
 - 2007 MTCA amendments factored in early life stage exposure (Newlon)

Application of Early Life Stage Exposure Guidelines

- Draft cleanup level updates are based on applying early life stage adjustments to carcinogens with a mutagenic mode of action (MOA)
 - There a credible scientific basis for applying early life stage adjustments to carcinogens with mutagenic MOA (as well as other carcinogens)
 - The EPA policy is the appropriate science policy choice given the overall MTCA risk management framework
 - Provides a high level of protection when implemented with MTCA framework (i.e., 10^{-6} risk level)
 - Consistent with MTCA statute and Ecology's general reliance on EPA risk assessment guidance
 - Consistent with policies adopted by other state agencies
- Ecology will include both the EPA and California guidelines in the regulatory analyses required under state law

Changes Based on EPA Inhalation Risk Assessment Guidelines

- Reasons for the revisions:
 - Current rule provisions are inconsistent with 2009 EPA guidance
- Draft revisions:
 - Revise equations in Section 750 for risk-based air cleanup levels
 - Revise Section 708 to incorporate inhalation unit risk factors (IURs) and reference concentrations (RfCs)
- Rationale
 - Consistent with current scientific information
 - Consistent with current EPA guidance
 - Consistent with approaches used by many other states
 - Appears to be consistent with feedback from MTCA/SMS Advisory Group and Vapor Workgroup

Changes Based on EPA Inhalation Risk Assessment Guidelines

Example to Illustrate Possible Revision to Equation 750-2 Based on EPA Inhalation Risk Guidance

$$\text{Air cleanup level (ug/m}^3\text{)} = \frac{\text{RISK} \times \text{AT}}{\text{IUR} \times \text{ED} \times \text{EF} \times \text{ET}}$$

Where:

RISK	=	Acceptable cancer risk level (1 in 1,000,000) (unitless) (1 in 100,000 for industrial sites)
AT	=	Averaging time (70 years)
IUR	=	Inhalation unit risk factor as specified in WAC 173-340-708(8) (ug/mg ³)
ED	=	Exposure duration (30 years)
EF	=	Exposure frequency (1.0) (unitless)
ET	=	Exposure time (1.0) (unitless)

Concurrent Soil Exposure

- Reasons for the revisions:
 - Current rule provisions are confusing and redundant
- Draft revisions:
 - Collapse Standard & Modified Method B into a single Method B
 - Require that soil cleanup levels based on direct contact take into account soil ingestion and dermal contact
- Rationale
 - Consistent with current scientific information
 - Consistent with current EPA guidance and approaches used by other states
 - Consistent with reasonable maximum exposure policies
 - Falls in the range of feedback from MTCA/SMS Advisory Group

Concurrent Soil Exposure

What difference will the revisions make in cleanup levels?

	Direct Contact - Soil Ingestion		Direct Contact - Ingestion + Dermal		Ground Water	Inhalation
	Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Screening Equations
Arsenic	24	0.67	22	0.62	2.9	720
Benzene	320	18	320	18	0.03	1
Benzo[a]pyrene		0.14 (0.02)		0.1 (0.02)	0.8	
Chromium VI	240		130		19	37 (11)
DDT	40	2.9	37	2.7	0.4	30,000
PCBs	8	0.5	6	0.4	0.2	0.4

Next Steps on the Way to the Finish Line



- Review feedback and comments from MTCA/SMS Advisory Group
 - [Written comments by August 23rd](#)
- Conduct additional evaluations on potential impacts of the draft revisions
- Incorporate into draft rule for Fall discussions
- Evaluate implications in relation to other draft revisions.