

Department of Toxic Substances Control (DTSC)



Pre-Rulemaking Workshop Toxicity Criteria Draft Regulation

December 12, 2016 ~ 1:00-4:00 pm
Sacramento, California & Webcast

Today's Agenda

□ Opening Remarks

Nathan Schumacher, Public Participation Specialist

□ The Proposed Draft Regulation and Narrative Standard – Presentation

Peter Bailey, Senior Engineering Geologist (Supervisor)

□ Discussion

Kimberly Gettmann, Toxicologist
Kevin Depies, Project Manager
Vivian Murai, Attorney
Peter Bailey and
Audience Members



Proposed Draft Regulation

- New Chapter or Article within Division 4.5, Title 22 “Human Health Toxicity Criteria for Cleanup”
- Provides Clearer Objectives for Risk Assessment and Remediation Goals
- Applies to all Hazardous Waste & Hazardous Substance Cleanup Sites in California



12/12/2016 3

Proposed Draft Regulation

- Codify past and existing practice of applying the more protective toxicity criteria
- To all sites in California

Chapter 21.1 Human Health Toxicity Criteria for Cleanup

Article 1

§9900.1 Purpose and Applicability
This chapter applies to hazardous waste and hazardous substance release sites subject to the provisions of Health and Safety Code, Division 20, chapters 6.3, 6.8 and/or 6.86. It requires that the toxicity factors specified in §9900.2 be used to establish human health risk-based action levels and remediation goals.

§9900.2 Action Levels, Screening Levels, Remediation Goals, and Point of Departure for Evaluation of Cleanup Alternatives
(a) The point of departure for action level and screening level determinations, and remediation goals, based on human health risk is:
 (1) An incremental excess lifetime cancer risk to an individual of 1×10^{-6} , and
 (2) A cumulative hazard index across all pathways and contaminants of concern (COCs) of 1.0.
(b) The above action levels, screening levels and remediation goals shall be calculated using the toxicity criteria specified in section §9900.3.

§9900.3 Applicable Toxicity Criteria
Any human health risk screening or human health risk assessment shall use the most protective of the following three toxicity criteria sources for each cancer and noncancer contaminant of concern:
 (a) The most protective unit risk factors, inhalation and oral slope factors and chronic reference exposure levels (RTELs, both inhalation and oral) from the Office of Environmental Health and Hazard Assessment Chemical Database, or its successor;
 (b) The unit risk factors, inhalation and oral slope factors, reference doses (RfD), and reference concentrations (RfC), from the US EPA Integrated Risk Information System (IRIS) database, or its successor;
 (c) The unit risk factors, inhalation and oral slope factors, reference doses (RfD), and reference concentrations (RfC), from the US EPA Provisional Toxicological Toxicity Index (PPTI) database, or its successor.



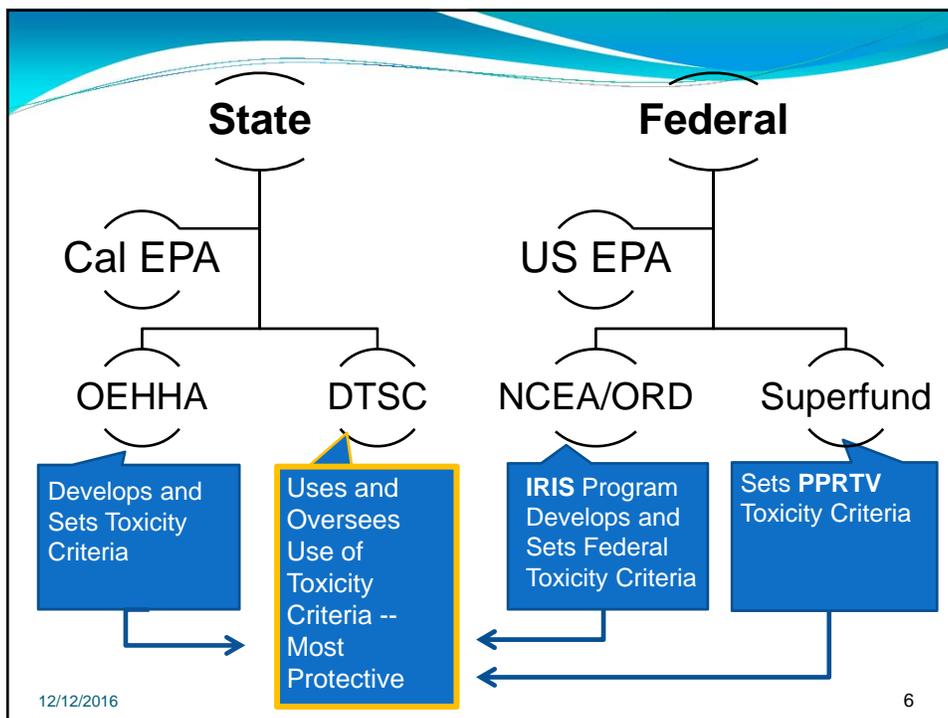
12/12/2016 4

Toxicity Criteria/Values

- Use:
 - Human Health Risk Assessments
 - Risk-Based Screening Levels
 - Cleanup Goals/Remediation Goals
- Types of Toxicity Values:
 - Noncancer Value – the amount of a chemical that one can ingest or breathe everyday for a lifetime that is not anticipated to cause harmful health effects.
 - Cancer Value – quantifies the upper bound estimate of the excess cancer risk resulting from a lifetime oral or continuous inhalation exposure to a chemical.

5 

12/12/2016



DTSC Practice

- DTSC uses peer reviewed, scientifically credible and protective criteria. We use the more health protective value if both an OEHHA and IRIS value exist.
 1. In all Human Health Risk Assessments and Decision Documents.
 2. At all Federal and non-Federal, sites in California.
- Since 1994, DTSC and US EPA Region 9 have used the more health protective toxicity criteria value at California sites.

12/12/2016

7



Regulation Summary

- 1) Set the “point of departure” for cancer risk at 1×10^{-6} and noncancer hazard at 1.
- 2) Require the most protective toxicity criteria in human health risk assessments, risk-based screening levels, and remediation goals.

12/12/2016

8



US EPA's OSWER Directive 9285.7-53

(2003)

- “Should use the best science available...”
 - Tier 1 - EPA's Integrated Risk Information System (IRIS)
 - Tier 2 - EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs)
 - Tier 3 - Other Toxicity Values such as the California Environmental Protection Agency (OEHHA) values

12/12/2016

9



Example – Tetrachloroethylene (PCE)

- Potential Impact
 - In California, State and Federally owned/NPL sites could use different toxicity criteria
 - Affects screening levels and cleanup goals
 - More than an order of magnitude difference

PCE Indoor Air Screening Levels ($\mu\text{g}/\text{m}^3$)

| | Residential | Commercial/ Industrial |
|-------------------------|-------------|---------------------------|
| OEHHA Toxicity Criteria | 0.46 | 2 |
| IRIS Toxicity Criteria | 11 | 47 |

12/12/2016

10



Narrative Standard

- Concept of a narrative standard that incorporates the required toxicity criteria

12/12/2016

11



Next Steps

- Finish Regulation Development
 - Collect and consider pre-rulemaking comments
 - Develop revised regulation for formal rulemaking
- Expected Rulemaking Activities
 - Noticed comment period and rulemaking hearings in Northern and Southern California
 - California Office of Administrative Law review
 - Adoption of final rule

12/12/2016

12



DTSC is accepting comments
until January 16, 2017*

Comments can be submitted to:
Department of Toxic Substances Control
8800 Cal Center Drive
Sacramento, CA 95826
Attn: Mr. Kevin Depies
Or E-mail to
Kevin.Depies@dtsc.ca.gov

Please include your contact information, email and phone with your comments

*Please note, DTSC will not be preparing formal responses to comments received during this informal regulation process.

12/12/2016

13

