

Use of California EPA Toxicity Values to Establish MTCA Cleanup Levels

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**Toxics Cleanup Program
Department of Ecology**

Organization of the Presentation



- Regulatory Dilemma
- Use of California EPA toxicity values under current MTCA rule
 - Draft approach for review of California EPA values
- Questions for Science Panel

Regulatory Dilemma

- Current MTCA rule identifies three main sources of toxicity values.
 - No toxicity values for many frequently-encountered substances.
 - Some out-of-date toxicity values (particularly HEAST)
- California EPA has developed toxicity values for a wide range of substances using policies/procedures that are similar to those used by the United States EPA.
- Current MTCA rule allows people to use these values
 - Consultation
 - Public review
 - Transparency

Current MTCA Toxicity Hierarchy

Reference Doses/Reference Concentrations

Hierarchy Used to Select Reference Doses or Reference Concentrations Under the MTCA Cleanup Regulation (WAC 173-340-708(7))

1. Integrated Risk Information System (IRIS)
2. Health Effects Assessment Summary Tables (HEAST) or, if more appropriate, the National Center for Environmental Assessment (NCEA)
3. Other Values

Established using methods described in EPA Guidance (“Reference Dose (RfD): Description and Use in Health Risk Assessment: Background Document 1A, USEPA, March 15, 1993)

Consultation with Science Advisory Board, Department of Health and U.S. Environmental Protection Agency (as appropriate)

Evaluation performed in accordance with MTCA procedures for considering new scientific information in WAC 173-340-702 (14), (15) and (16)

Current MTCA Toxicity Hierarchy

Carcinogenic Potency Factors

Hierarchy Used to Select Carcinogenic Potency Factors Under the MTCA Cleanup Regulation (WAC 173-340-708(8))

1. Integrated Risk Information System (IRIS)
2. Health Effects Assessment Summary Tables (HEAST) or, if more appropriate, the National Center for Environmental Assessment (NCEA)
3. Other Values

Established using methods described in MTCA rule or other methods where Ecology determines that there is clear and convincing scientific data which demonstrates an alternate method is more appropriate

Consultation with Science Advisory Board, Department of Health and U.S. Environmental Protection Agency (as appropriate)

Evaluation performed in accordance with MTCA procedures for considering new scientific information in WAC 173-340-702 (14), (15) and (16)

Toxicity Hierarchy – Draft Rule Revisions

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.

EPA Toxicological Hierarchy – OSWER Directive

- Tier 1– EPA’s Integrated Risk Information System (IRIS)
- Tier 2 – EPA’s Provisional Peer Reviewed Toxicity Values (PPRTVs)
- Tier 3 – Other ([California EPA](#), ATSDR, HEAST)

EPA Toxicological Hierarchy

Regional Screening Tables

- EPA's Integrated Risk Information System (IRIS).
- The Provisional Peer Reviewed Toxicity Values (PPTRVs) derived by EPA's Superfund Health Risk Technical Support Center (STSC).
- The Minimal Risk Levels (MRLs) developed by the Agency for Toxic Substances and Disease Registry (ATSDR).
- The California Environmental Protection Agency (OEHHA) Office of Environmental Health Hazard Assessment's Chronic Reference Exposure Levels from December 18, 2008 and the Cancer Potency Values from December 17, 2008 (May 2009).
- Screening toxicity values in an appendix to certain PPRTV assessments.
- Health Effects Assessment Summary Table (HEAST) toxicity values.

Science Panel Comments (March 2010)

- Regional Screening Tables (RST) may be a reasonable source of toxicity values. However, the tables include toxicity values from several different sources with varying degrees of scientific peer review. Panel is not familiar enough with tables to provide a generic answer.
- Panel appeared to be supportive of using the RST values as a starting point for updating MTCA cleanup levels. However, the rationale for updates needs to reflect more than the fact that a particular toxicity values appears in the RST.
- Internal peer review within EPA is not equivalent to the external peer review used for IRIS updates. Panel was unclear on RST review process.
- Panel appeared to support some type of external review process surrounding the use of some or all RST values prior to use under MTCA. They thought that once-a-year updates were sufficient. In terms of mid-year changes, they thought that changes less than an order of magnitude could wait for annual updates.
- HEAST should not be used as a general reference. However, some HEAST values may still reflect current science on particular chemicals.

Toxicity Hierarchy

Why is it necessary to use California EPA Toxicity Values?

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	9	6

Why do we believe the California EPA toxicity values provide a reliable basis for MTCA cleanup levels?

- California uses methods that are consistent with current EPA guidance and methods used to develop toxicity values published in the Integrated Risk Information System (IRIS).
- Comparisons of IRIS values and California EPA values demonstrates that California's use of these methods yields values similar to those developed for the IRIS program.
- The process used by the California EPA is very transparent and includes scientific peer review and opportunities for public review and comments.
- Use of the California EPA toxicity values is consistent with:
 - EPA guidance published in 2003 (OSWER Directive 9285.7-53)
 - Approach used by EPA and the Oakridge National Laboratory to prepare the Regional Screening Tables.
 - Approaches used by other state superfund programs

Draft Ecology Approach for Deciding Whether to Use Individual California EPA Toxicity Values to Establish MTCA Cleanup Levels

1. Screen available California EPA values and place substances/toxicity values into one of 3 review categories or bins
2. Perform reviews for priority substances using the quality of information criteria specified in the MTCA rule (WAC 173-340-702(16))
3. Consult with Science Panel, Department of Health and Environmental Protection Agency, as appropriate.
4. Provide opportunity for public comment
5. Prepare final decision and update CLARC database (if decide it is appropriate to use California EPA toxicity value)
6. Provide a clear statement in site-specific documents when California EPA values are used to establish cleanup levels for individual sites.

Screening California EPA Toxicity Values

High Priority for Review	Medium Priority	Low Priority For Review
<ul style="list-style-type: none">• Toxicity value not available in IRIS, NCEA or HEAST• IRIS review process has not been initiated or will not be completed in next 12 months.• Substance is frequently identified as a contaminant of concern at MTCA sites.• CalEPA value included in EPA Regional Screening Tables• CalEPA value was developed in 2001 or later.• CalEPA value is similar to values developed by other agencies (e.g. WHO, etc.)	<ul style="list-style-type: none">• EPA/ORNL have included California EPA toxicity value in the Regional Screening Tables instead of HEAST toxicity value.	<ul style="list-style-type: none">• Ongoing IRIS review scheduled to be completed in next 6-12 months• Low frequency of detection at MTCA sites.• Significant scientific and policy issues associated with development and/or Ecology use of the CalEPA value• California EPA toxicity value was developed before 2001.

MTCA Quality of Information Criteria

- 1. Whether the information is based on a theory or technique that has widespread acceptance within the relevant scientific community.***
- 2. Whether the information was derived using standard testing methods or other widely accepted scientific methods.***
- 3. Whether a review of relevant scientific information, both in support of and not in support of the proposed modification, has been provided along with the rationale explaining the reasons for the proposed modification.***
- 4. Whether the assumptions used in applying the information to the facility are valid and would ensure the proposed modification would err on behalf of protection of human health and the environment.***
- 5. Whether the information adequately addresses populations that are more highly exposed than the population as a whole and are reasonably likely to be present at the site.***
- 6. Whether adequate quality assurance and quality control procedures have been used, any significant anomalies are adequately explained, the limitations of the information are identified and the known or potential rate of error is acceptable.***

Opportunity for Public Review and Scientific Peer Review

1. Consult with Science Panel, Department of Health and Environmental Protection Agency, as appropriate.
2. Provide opportunity for public comment
 - Publish in Ecology Site Register
 - Post on Ecology Website
3. Review public comments

Ecology Decision and Use at MTCA Cleanup Sites

1. Prepare final decision
 - Decide it is appropriate to use California EPA toxicity value
 - Decide it is not appropriate to use California EPA toxicity value
 - Decide it is appropriate to use a modified version of the California EPA toxicity value that is consistent with current MTCA policies (e.g. use of cancer slope factor without early life stage adjustment for carcinogens with non-mutagenic MOA)
2. Update CLARC database (if decide it is appropriate to use California EPA toxicity value)
3. Develop boilerplate statement explaining the rationale for Ecology's decision on the use of the California EPA toxicity value
4. Ecology includes statement in site-specific documents when California EPA values are used to establish cleanup levels for individual sites.

Questions for MTCA Science Panel

1. Do you continue to believe that the EPA toxicity hierarchy provides a reliable and defensible approach for selecting toxicity values that are used to establish MTCA cleanup levels and remediation levels?
2. Should Ecology consider other factors when screening California EPA toxicity values for further review?
3. Do you agree that the MTCA quality of information criteria provide a reliable and defensible approach for evaluating the use of California EPA toxicity values to support MTCA cleanup decisions?
4. Are there other issues that Ecology should consider when implementing the toxicity hierarchy in the current MTCA rule?