DEPARTMENT OF
ECOLOGY
State of Washington

Science Policy Choices Underlying Updates to MTCA Cleanup Levels

Discussion Materials
Prepared for the MTCA/SMS Advisory Group
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Summary

Ecology developed the initial Model Toxics Control Act (MTCA) Method A ground water and soil cleanup levels when the initial cleanup standards were published in 1991. Ecology reviewed the Method A cleanup levels during the 2001 rule revision process and made several revisions to incorporate new scientific and regulatory information.

Since the 2001 rule revisions, there have been numerous scientific and regulatory developments. Ecology is evaluating this information to determine whether to update the policies and procedures for establishing MTCA cleanup levels. When evaluating potential revisions, Ecology reviewed the following factors:

- New Scientific Information. Ecology considered new scientific studies, agency evaluations, and expert scientific committee reports completed since the 2001 rule revisions.
- EPA Regulatory Guidance. Ecology considered regulatory guidance developed by the Environmental Protection Agency (EPA) and other state and federal agencies since the 2001 rule revisions.
- MTCA Requirements. Ecology considered the current MTCA statutory and rule requirements. In particular, Ecology considered the statutory requirement that cleanup standards must be at least as stringent as federal requirements and the regulatory policies for establishing MTCA cleanup standards (such as cleanup levels are based on reasonable maximum exposures).
- Other Environmental Programs. Ecology has considered risk assessment policies and procedures being used by other Ecology programs and cleanup programs in other states. These comparisons provide one measure for judging the reasonableness of potential rule revisions.
- Impacts on Cleanup Implementation. Ecology is considering how potential rule revisions will impact cleanup implementation.
- Advisory Group Comments. Ecology has considered feedback from the MTCA/SMS (Sediment Management Standards) Advisory Group and the Vapor Workgroup when evaluating potential rule revisions. This document is designed to facilitate feedback from advisory group members.

Based on that review, Ecology is considering several revisions to the policies and procedures for establishing MTCA cleanup levels. These include the topics discussed in this document (topics 1 through 5 below) plus several other issues:

1. Definition of Carcinogen. Ecology plans to propose changes to the MTCA definition to reflect changes in the EPA cancer assessment guidelines that were finalized in 2005. Specifically, the term "carcinogen" will be revised to include substances that meet the EPA criteria for "carcinogenic to humans" and "likely to be carcinogenic to humans." Based on a preliminary analysis, Ecology believes that the draft revisions would not result in significant changes in cleanup requirements.
2. Hierarchy of Toxicological Information. Ecology plans to propose changes to the MTCA toxicological information hierarchy provisions to reflect EPA guidance on this issue that was published in 2003. Specifically, Ecology plans to revise WAC 173-340-708(7) and (8) to incorporate EPA's the three-tiered toxicity hierarchy. Based on a preliminary analysis,

Ecology believes that draft revisions will have a small overall impact on cleanup requirements.

3. Early Life Stage Adjustment. Ecology plans to propose changes to the MTCA rule requirements for cancer slope factors to reflect EPA 2005 guidance on early life stage considerations. Specifically, Ecology plans to revise WAC 173-340-708(8) to require early life stage adjustments to the cancer slope factors for carcinogens that act through a mutagenic mode of action. Based on a preliminary analysis, Ecology believes that the draft revisions will have result in lower cleanup levels at some Washington sites.

4. EPA Inhalation Risk Assessment Guidance. Ecology plans to propose changes to the MTCA rule requirements for air cleanup levels to reflect new (2009) EPA inhalation risk assessment guidance. Specifically, Ecology plans to revise the cleanup level equations in WAC 173-340-750 to reflect the EPA 2009 guidance. Ecology also intends to make changes to WAC 173-340-200 and WAC 173-340-708(7) and (8) to reflect EPA terminology and support implementation of the revised methods. Based on a preliminary analysis, Ecology believes that draft revisions will have a small overall impact on cleanup requirements.

   NOTE: Ecology recognizes that the 2009 revisions to the EPA inhalation risk assessment guidelines have potential implications for the MTCA procedures for evaluating inhalation exposures resulting from domestic water use. Ecology does not intend to revise the default MTCA methods during the current rulemaking process. However, Ecology is considering this issue when evaluating changes to Method A cleanup levels for individual substances.

5. Concurrent Soil Exposure Pathways. Ecology plans to simplify the MTCA cleanup level framework by combining standard and modified Method B into a single Method B for establishing cleanup levels. In making this change, Ecology plans to require that soil cleanup levels based on direct contact consider both soil ingestion and dermal contact. Ecology is also continuing to evaluate whether rule revisions are needed to clarify the current requirement for considering soil vapor exposures when establishing soil cleanup levels. Based on a preliminary analysis, Ecology believes that the draft revisions may result in lower cleanup levels at industrial sites where ground water contamination issues are not present.

Ecology is also considering several other rule changes that are relevant to cleanup level determinations. These issues are discussed in separate documents:

- Terminology for Toxicity Parameters. Ecology plans to update the MTCA terminology to reflect current EPA risk assessment terminology. Specifically, Ecology plans to use the terms “cancer slope factor” (replacing “carcinogenic potency factor”) and “relative bioavailability” (replacing “gastrointestinal absorption fraction”). Ecology also plans to add the terms “inhalation unit risk factor” and “reference concentration” to the list of defined terms.

- Bioaccumulation Factors. Ecology plans to modify the equations for calculating surface water cleanup levels to reflect current EPA risk assessment procedures. Specifically, Ecology plans to replace the term “bioconcentration factor (BCF)” with the term “bioaccumulation factor (BAF).”

- Updates to Method A Ground Water and Soil Cleanup Level. Ecology is currently reviewing new scientific information and regulatory guidance to determine whether certain Method A cleanup levels need to be revised.

- Cleanup Levels for Lead. Ecology is planning to update the Method A soil and ground water cleanup levels for lead and incorporate methods for establishing Method B and C cleanup levels for lead.
- Cleanup Levels for Petroleum Mixtures. Ecology is currently reviewing the need for revisions to Method A cleanup levels for petroleum mixtures.
- Fish Consumption Rates. Ecology is currently reviewing the policies and methods for establishing surface water cleanup levels based on preventing human health risks associated with consumption of fish and shellfish.

1. Definition of Carcinogen

Issue

Should Ecology change the MTCA definition of "carcinogen" to maintain consistency with current EPA risk assessment guidance?

Background

The MTCA Cleanup Regulation includes methods and policies for establishing cleanup levels based on preventing human health risks. The rule includes separate methods for carcinogens and non-carcinogens. The current rule includes the following definition:

> ***"Carcinogen"*** *means any substance or agent that produces or tends to produce cancer in humans. 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.*

EPA's 1986 Guidelines for Carcinogen Risk Assessment provided alpha-numeric descriptors of the likelihood that a chemical or other agent is a human carcinogen.[1] These alpha-numeric descriptors were based on a weight-of-evidence approach that considered all available information relevant to evaluating the potential for a chemical's carcinogenicity.

On March 29, 2005, EPA issued "Guidelines for Carcinogen Risk Assessment"[2] which replaced the 1986 cancer risk guidelines. The 2005 guidelines include a new set of weight of evidence descriptors that replace the previous alpha-numeric descriptors. The new approach uses a *weight of evidence narrative* (typically one to two pages) that explains an agent's human carcinogenic potential. Using this approach, EPA's conclusions about human carcinogenic potential are summarized using one or more descriptors that represent points along a continuum of evidence. The EPA descriptors include the following:

- Carcinogenic to Humans (EPA used this descriptor in the toxicological profile for arsenic [3])

[1] "The EPA classification system for the characterization of the overall weight of evidence for carcinogenicity (animal, human, and other supportive data) includes: Group A Carcinogenic to Humans; Group B Probably Carcinogenic to Humans; Group C Possibly Carcinogenic to Humans; Group D Not Classifiable as to Human Carcinogenicity; and Group E Evidence of Noncarcinogenicity for Humans." EPA Guidelines for Carcinogen Risk Assessment, September 24, 1986, Federal Register 51(185)33992-34003.

[2] USEPA. 2005. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, Washington DC. EPA/630/P-03/001F. March 2005.

[3] USEPA. 2010. Toxicological Review of Inorganic Arsenic (CAS No.) In Support of Summary Information on the Integrated Risk Information System (IRIS). National Center for Environmental Assessment, Office of Research and Development. Washington DC.

- Likely to Be Carcinogenic to Humans (EPA used this descriptor in the toxicological profiles for methylene chloride,[4] trichloroethylene,[5] and tetrachloroethylene.[6])
- Suggestive Evidence of Carcinogenic Potential
- Inadequate Information to Assess Carcinogenic Potential
- Not Likely to Be Carcinogenic to Humans

After reviewing the new scientific and regulatory information related to the definition of carcinogen, Ecology believes it is appropriate to consider revisions to the MTCA rule.

MTCA Rulemaking Options

Ecology has considered four main options for resolving this rulemaking issue:

1. No Change. Under this option, Ecology would retain the current MTCA definition that references the cancer guidelines published by EPA in 1986.
2. Updated Definition Referencing Current EPA Guidelines: Under this option, Ecology would update the MTCA definition by referencing the EPA 2005 guidelines consistent with the original scope reflected in the current definition. Specifically, Ecology would include substances defined by EPA as "carcinogenic to humans" and "likely to be carcinogenic to humans."
3. Updated and Expanded Definition Referencing Current EPA Guidelines: Under this option, Ecology would update and expand the MTCA definition by referencing the EPA 2005 guidelines. Specifically, Ecology would include substances that are defined as "carcinogenic to humans," "likely to be carcinogenic to humans," and "suggestive evidence of carcinogenic potential."
4. Revised Definition Referencing Multiple Guidelines: Under this option, Ecology would update the MTCA definition by referencing the EPA 2005 guidelines and criteria used by other authoritative scientific bodies such as the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC). This approach has been used by other Ecology programs.

[4] USEPA. 2010. Toxicological Review of Dichloromethane (Methylene Chloride) (CAS No. 75-09-2) In Support of Summary Information on the Integrated Risk Information System (IRIS). Washington DC. March 2010.

[5] USEPA. 2009. Toxicological Review of Trichloroethylene (CAS No. 79-01-6) In Support of Summary Information on the Integrated Risk Information System (IRIS). Washington DC. October 2009.

[6] USEPA. 2008. Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4) In Support of Summary Information on the Integrated Risk Information System (IRIS). External Review Draft. Washington DC. June 2008.

Draft Revisions and Rationale

Ecology plans to update the MTCA definition of "carcinogen" by referencing the 2005 EPA cancer guidelines (Option 2). A draft of the updated definition is shown below.

Definition of "Carcinogen" (WAC 173-340-200) DRAFT

*"**Carcinogen**" means any hazardous substance ~~or agent~~ that produces or tends to produce cancer in humans. 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.*

The rationale for the draft definition is based primarily on the following:

- This draft definition is consistent with current scientific information and regulatory guidance. Ecology believes that the 2005 EPA cancer guidelines represent a sound approach that incorporates new scientific information on carcinogenicity published since the 1986 EPA guidelines. Both the MTCA Science Advisory Board and the MTCA Science Panel agreed with Ecology's proposal to update the MTCA definition by referencing the EPA cancer guidelines published in 2005.[7] They also agreed that IARC and NTP are authoritative bodies with respect to identifying carcinogens. They concluded that, if Ecology chose to use a three-part definition (EPA or NTP or IARC), that would be consistent with current scientific information. However, the MTCA Science Panel noted that the IARC and NTP evaluate different data when reaching their conclusions. Consequently, one would not expect the two lists to coincide. They also noted that IARC and NTP don't recommend slope factors which would make it difficult to develop cleanup levels for these substances.
- This draft definition promotes consistency with the federal Superfund program and complies with MTCA statutory directives. EPA uses the 2005 cancer guidelines to support decision-making at federal cleanup sites. In addition, this option provides MTCA cleanup standards that are "…at least as stringent as the cleanup standards under section 121 of the federal cleanup law, 42 U.S.C. Sec. 9621, and at least as stringent as all

[7] The Model Toxics Control Act Science Advisory Board (SAB) was established by Chapter 70.105D RCW. The Board provided advice to Ecology on hazardous substances and cleanup-related scientific issues from 1988 through 2009. The legal mandate for Ecology to maintain a Science Advisory Board was removed from law during the 2009 legislative session (Senate Bill 5995). Consistent with the intent of that legislation, Ecology continues to seek scientific input and advice on a wide range of technical issues related to the cleanup of contaminated sites. Ecology solicits this input is through a "Science Panel" appointed by the Director of the Department of Ecology. Panel members are invited by the Toxics Cleanup Program to meet up to two to four times per year to provide advice on scientific issues related to site cleanup posed by the Program. These meetings are open to the public attendance and meeting notes and materials are available on the Ecology web site.

applicable state and federal laws, including health-based standards under state and federal law…" as required under MTCA.

- This draft definition provides a workable approach as EPA moves from the 1986 guidelines to the 2005 cancer guidelines. The weight of evidence classifications in the 2005 cancer guidelines replace the alpha-numeric classification used in the 1986 cancer guidelines. However, many of the IRIS cancer assessments for individual chemicals still reflect the former classification scheme. The updated definition will enable decision-makers to use IRIS toxicity information developed under both classification systems.
- This draft definition is consistent with definitions used by other Ecology programs. The Toxics Cleanup Program (TCP) has reviewed approaches used by other Ecology programs when making regulatory decisions based on cancer risks. Most Ecology programs have adopted definitions that include one or more elements similar to the current MTCA definition.[8] [9,10] TCP believes that this draft definition is generally consistent with both the current MTCA definition and definitions used by other Ecology programs. However, we recognize there are cross-program differences that reflect differences in regulatory approaches. For example, Ecology's Waste 2 Resources (W2R) and Hazardous Waste and Toxics Reduction (HWTR) programs incorporate classifications by IARC and/or NTP into their definitions. Unlike TCP, these programs do not require quantitative information (for example, cancer slope factors) when making decisions on individual carcinogens.
- There appears to be general support for the updated definition among advisory group members: Ecology asked members of the MTCA/SMS Advisory Group and the Vapor Workgroup to review and provide comments on the draft definition. As shown in the table below, members who provided comments on this issue generally agreed with the updated definition. However, members did raise several important issues briefly discussed below:
    - Suggestive Evidence of Carcinogenic Potential: One member of the Vapor Workgroup asked for further information on why Ecology chose not to include chemicals with "suggestive evidence of carcinogenic potential" in the MTCA definition. As noted above, Ecology considered this option when deciding whether to update or revise the MTCA definition. Ecology choose not to include this descriptor because:

[8] **Ecology's Water Quality Program** defines "**Carcinogen**" as "...any substance or agent that produces or tends to produce cancer in humans. For implementation of this chapter, the term carcinogen will apply to all substances on the United States Environmental Protection Agency Integrated Risk Information System, IRIS data base, of A (known human) and B1 and B2 (probable human) carcinogens for which IRIS listed an oral slope factor."

[9] **Ecology's Hazardous Waste and Toxic Reduction (HWTR) Program** defines "**Carcinogenic**" as "...a material known to contain a substance which has sufficient or limited evidence as a human or animal carcinogen as listed in both IARC and either IRIS or HEAST."

[10] **Ecology's Waste 2 Resources (W2R) Program** defines **"Carcinogen"** as **"…**a chemical or chemical group that has been identified as "carcinogenic to humans" or "likely to be carcinogenic to humans" by the Environmental Protection Agency, as a Group 1, 2A or 2B carcinogen by the International Agency for Research on Cancer or as a "known to be a human carcinogen" or "reasonably anticipated to be a human carcinogen" by the National Toxicology Program."

  - It is inconsistent with 1991 policy decision not to include all Category C carcinogens.
  - EPA's criteria for identifying substances that are "likely to be carcinogenic to humans" provide sufficient flexibility to identify carcinogens under MTCA.

- Narrative Language: One member of the Vapor Workgroup asked for further information on why Ecology chose to delete the phrase "…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.." Ecology deleted this phrase because we believe the EPA's criteria for identifying substances that are "likely to be carcinogenic to humans" provides sufficient flexibility to identify carcinogens under MTCA.
- Practical Impact of Draft Revision: Several members said it would be helpful for Ecology to identify how the proposed revision might impact vapor intrusion screening levels. Ecology is reviewing this question. Based on a preliminary analysis, we believe that the draft updated definition will not significantly change the number of substances that will be regulated as carcinogens. The preliminary results are summarized in the textbox on the following page.

Comparison of Current and Draft Definitions for Carcinogen

Ecology has evaluated how the revised definition might impact the number of substances regulated as carcinogens under MTCA. We designed the evaluation to focus on the substances must likely to be present at hazardous waste sites. For purposes of this evaluation, we decided to focus on the 100 highest ranked substances on the 2007 CERCLA Priority List of Hazardous Substances compiled by the Agency for Toxics Substances and Disease Registry (ATSDR). This evaluation included the following steps:

1) We screened the list from 100 substances to 81 substances by eliminating chemical isomers with the same toxicity values and multiple PCB Arochlor mixtures that have common toxicity values.
2) We identified hazardous substances that appear on one or more lists of carcinogens. The list included the results from cancer hazard assessments performed by the Environmental Protection Agency (EPA), the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC).
3) We identified substances that meet the definition of carcinogen in the current MTCA rule.
4) We identified substances that would meet the draft definition of carcinogen.

Based on this evaluation, it appears that the draft definition will not significantly change the number of substances regulated as carcinogens under MTCA. Of the 81 substances considered in this review, 50 substances would be classified as carcinogens under both the current and draft MTCA definition. The preliminary evaluation results are shown below.

Estimated Number of Carcinogens Meeting Current and Draft MTCA Definition		
Number of Hazardous Substances on the 2007 CERCLA Priority List of Hazardous Substances	81	
	Current Rule	Draft Definition
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

Summary of Comments on Draft Revisions to Definition of Carcinogen[11] [Note: Most comments have been summarized to conserve space]	
Member	Comment
Patty Boyden (MTCA/ SMS Advisory Group & Vapor Workgroup)	Linking the definition to more recent EPA guidance is an improvement.
Priscilla Tomlinson (Vapor Workgroup)	The carcinogen definition appears to be an appropriate update to the existing definition.
Barbara Trejo (Vapor Workgroup)	It is unclear why chemicals with EPA's classification "suggestive evidence of carcinogenic potential" are not included in the definition. It is also unclear why the following language from the current regulation was removed (outdated, unworkable?): ". . .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. Might want to consider basing the definition on what the MTCA Science Panel agreed on.
Chris Waldron (MTCA/ SMS Advisory Group & Vapor Workgroup)	No. I think that this change is required in order to make the rule consistent with EPA's *2005 Guidelines for Carcinogen Risk Assessment*. It would be helpful for Ecology to identify the potential changes to the screening levels based on the new definition of a carcinogen. My expectation is that the slight change in the definition of a carcinogen will have minimal impact on the screening levels. I don't believe that the EPA's intention was to significantly change how carcinogens were identified but rather was to replace the Weight of Evidence approach (i.e., A, B, C – categories) with a narrative approach for classifying carcinogens.
Larry Dunn (MTCA/ SMS Advisory Group)	On the definition for a carcinogen, the proposed changes seem reasonable and acceptable.

[11] Written comments submitted by MTCA/SMS Advisory Group and Vapor Workgroup members.

2. Hierarchy of Toxicological Information

Issue

Should Ecology revise the hierarchy of information sources for toxicological parameters (cancer slope factors and reference doses) currently included in the MTCA cleanup rule?

Background

The MTCA cleanup level equations require information on the toxicological properties of each hazardous substance. There are many sources of toxicological information and the MTCA cleanup regulation establishes a general hierarchy or preferences for toxicological information. For example, WAC 173-340-708(8) states that cleanup levels must be calculated using carcinogenic potency factors (cancer slope factors) published by EPA in the Integrated Risk Information System (IRIS) database. The IRIS values must be used unless there is clear and convincing evidence that such values are inappropriate. The current rule also states that cancer slope factors published by EPA in the Health Effects Assessment Summary Table (HEAST) or developed by the National Center for Environmental Assessment (NCEA) can be used when values are not available in the IRIS database. The MTCA rule includes similar criteria for selecting toxicity parameters based non-cancer health risks (See WAC 173-340-708(7).

There have been several scientific and regulatory developments since the 2001 rule revisions. These include the following:

- EPA Guidelines on Toxicity Parameters: In 2003, the EPA's Office of Solid Waste and Emergency Response (OSWER) issued Directive 9285.7-53, which provides recommended sources of toxicity data for developing screening levels for various media and conducting site-specific human health risk assessments.[12] The hierarchy of toxicity information recommended by OSWER Directive 9285.7-53 is:

  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)

- Health Effects Assessment Summary Tables (HEAST): Shortly after the 2001 rule revisions, EPA decided to stop updating the HEAST values. Consequently, many HEAST values are now inconsistent with more recent scientific studies and regulatory guidance. For example, many of the inhalation toxicity values in HEAST were developed by using simple route-to-route extrapolation methods. This is inconsistent with current EPA guidance.[13]

[12] USEPA. 2003. *Human Health Toxicity Values in Superfund Risk Assessment*. Office of Solid Waste and Emergency Response, Washington, D.C. Publication 9285.7-53. http://rais.ornl.gov/homepage/hhmemo.pdf.

[13] USEPA. 2009. Risk Assessment Guidance for Superfund. Volume I: Part F, Supplemental Guidance for Inhalation Risk Assessment. Office of Superfund Remediation & Tech. Innovation. Washington D.C. EPA-540-R-070-002. In this guidance, EPA recommends that risk assessors not use inhalation toxicity values generated using simple route-to-route extrapolation.

- Regional Screening Tables: Several EPA regional offices and the Oak Ridge National Laboratory maintain the "Regional Screening Levels for Chemical Contaminants at Superfund Sites" which serves as source of toxicity parameters. This information is published on a website maintained by the Oakridge National Laboratory under an interagency agreement with EPA. The national lab works with EPA to update the website on a bi-annual basis. EPA uses the following data hierarchy (based OSWER Directive 9285.7-53) on for the 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.
  - Screening toxicity values in an appendix to certain PPRTV assessments.[14].
  - Health Effects Assessment Summary Table (HEAST) toxicity values.

MTCA Rulemaking Options

Ecology has reviewed the new scientific and regulatory information and believes it is appropriate to consider revisions to the toxicological information hierarchy in the MTCA cleanup regulation. Ecology has considered two main options for resolving this rulemaking issue:

1. No Revision. Under this option, Ecology would not revise the MTCA cleanup regulation provisions that establish the hierarchy of toxicological information sources.
2. Revisions to Reflect Current Information Sources: Under this option, Ecology would revise WAC 173-340-708(7) and (8) to reflect current EPA guidance and information sources used by other state and federal cleanup programs.

[14] EPA includes the following statement on the RST webpage: "While we have less confidence in a screening toxicity value than in a PPRTV, we put these ahead of HEAST toxicity values because these appendix screening toxicity values are more recent and use current EPA methodologies in the derivation, and because the PPRTV appendix screening toxicity values also receive external peer review"

Draft Revisions and Rationale

Ecology plans to revise the MTCA toxicological information hierarchy to reflect current information sources used by state and federal agencies (Option 2). A draft of the proposed revisions is shown below.

Draft Rule Provisions on Cancer Slope Factor Hierarchy and Information Updates
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 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.

Ecology's rationale for the draft revision includes the following:

- <u>This draft revision is consistent with the EPA data hierarchy used to support decisions at federal Superfund sites and complies with the MTCA statutory directives</u>. The EPA Superfund program uses the EPA data hierarchy[15] to support decisions at cleanup sites. The EPA data hierarchy also provides the foundation for updates to the Regional Screening Tables. Consequently, this option promotes consistency with the federal Superfund program and helps to ensure that MTCA cleanup standards will be "…at least as stringent as the cleanup standards under section 121 of the federal cleanup law, 42 U.S.C. Sec. 9621, and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law…"
- <u>This draft revision will allow more timely use of high quality scientific information to support MTCA decision-making</u>. The current rule provision is based on EPA performing regular reviews of new scientific information. However, resource limitations and interagency review processes have delayed numerous EPA reviews. This was highlighted by the General Accounting Office (GAO) in their review of EPA's process for performing chemical assessments. They concluded:

[15] USEPA. 2003. *Human Health Toxicity Values in Superfund Risk Assessment*. Office of Solid Waste and Emergency Response, Washington, D.C. Publication 9285.7-53. http://rais.ornl.gov/homepage/hhmemo.pdf.

> *…EPA has not been able to routinely complete credible assessments or decrease its backlog of ongoing assessments. Several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database, including the OMB/interagency review process managed by OMB, certain management decisions and issues regarding the IRIS program, and the compounding effects of delays. In addition, because the OMB/interagency review process is not transparent, this change also limits the credibility of IRIS assessments.* (GAO, 2008, p.11) [16]

- This draft revision is consistent with approaches being used by other state agencies and the Department of Defense. Many states use the EPA data hierarchy (see guidance materials prepared by New Hampshire[17] and Oregon[18]) or variations on the EPA hierarchy (New Jersey[19]) to support regulatory decisions. The Department of Defense has also adopted policies that are consistent with the EPA data hierarchy.[20]
- This draft revision provides a workable and transparent approach for integrating new scientific information into the MTCA decision-making process.

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[16] General Accounting Office. 2008. Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Risk Information System. Report to the Chairman, Committee on Environment and Public Works, U.S. Senate. GAO-08-440.

[17] The New Hampshire vapor intrusion guidance (p. 37) includes the following:

> "In 2003, the EPA's Office of Solid Waste and Emergency Response (OSWER) issued Directive 9285.7-53, which provides recommended sources of toxicity data for developing screening levels for various media and conducting site-specific human health risk assessments. The hierarchy of toxicity information recommended by OSWER Directive 9285.7-53 is:
>
> - Tier 1– EPA's Integrated Risk Information System (IRIS)
> - Tier 2 – EPA's Provisional Peer Reviewed Toxicity Values (PPRTVs)
> - Tier 3 – Other (CAL EPA, ATSDR, HEAST)
>
> The EPA's IRIS database is the generally preferred source of URi and RfCs for evaluating inhalation exposure. The PPRTVs are provisional toxicity values recommended by EPA's National Center for Environmental Assessment (NCEA). PPRTVs are the second recommended tier of toxicity values; however, EPA has restricted access to this database. When IRIS values were not available EHP consulted EPA Region 9's Preliminary Remediation Goals (PRG) table, which contains the latest recommended toxicity factors according to the OSWER directive. Please note that the toxicity values identified on IRIS are frequently updated. It is incumbent upon the users of this guidance to check IRIS and EPA Region 9's PRG Table to verify that the most current toxicity information is being when completing site-specific human health risk assessments."

[18] http://www.deq.state.or.us/lq/rbdm.htm

[19] http://www.nj.gov/dep/srp/regs/rs/bb_ingest_dermal.pdf

[20] Department of Defense. 2007. Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Site Risk Assessments in the Absence of IRIS Values. Attachment 1 to memorandum "Actions in Response to Perchlorate Releases" From Alex A. Beehler (Assistant Deputy Under Secretary of Defense) to Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health), Deputy Assistant Secretary of the Navy (Environment) and Deputy Assistant Secretary of the Air Force (Environment, Safety and Occupational Health). September 21, 2007.

- There appears to be general support for the revised approach among advisory members: Ecology asked members of the MTCA/SMS Advisory Group and the Vapor Workgroup to review and provide comments on the toxicological data hierarchy. (A summary of comments on this issue is provided later in this section.) There appears to be general agreement on several points:
  - Ecology should continue to rely on the IRIS database and NCEA toxicity values (PPTRVs) as the primary bases for cleanup level development.
  - Ecology should reduce its reliance on the HEAST database because EPA no longer updates these values.[21]
  - Ecology should provide regular updates to the Cleanup Levels and Risk Calculations (CLARC) database to incorporate new toxicity values. Ecology believes this should be a transparent process. We believe it makes sense to automatically update the CLARC database when EPA publishes a final IRIS value. We also believe that it is appropriate for the public to have an opportunity to review and comment on proposed updates not based on new IRIS or PPRTV values.

Ecology believes it will continue to be necessary to supplement the IRIS/PPRTV values with toxicity values from other sources. Decisions on the use of these values will be made when updating the CLARC database. Members provided a wide range of opinions on the use of other toxicity values (California EPA, ATSDR[22], etc.) when IRIS and PPRTV values are not available.

- Use of Draft Toxicity Values: Several reviewers recommended that cleanup levels should not be established using draft toxicity values that are undergoing scientific and/or public review. Ecology agrees that draft toxicity values are generally not an appropriate basis for establishing cleanup levels/screening levels.[23]
- Use of ATSDR Minimal Risk Levels (MRLs): One reviewer suggested that MRLs may be an appropriate basis for establishing cleanup levels. Ecology agrees that MRLs developed by ATSDR provide a credible basis for calculating cleanup levels. The ATSDR methods are similar to those used by EPA to develop oral reference doses and reference concentrations. ATSDR procedures for establishing MRLs include extensive peer review and opportunity for public review and comment. However, the practical

[21] EPA has stopped updating the HEAST database and, consequently, many values are out-of-date and/or inconsistent with current EPA guidance. However, the HEAST values for some chemicals remain consistent with current scientific information.

[22] ATSDR publishes toxicological profiles for hazardous substances found at federal Superfund sites. When preparing these documents, ATSDR publishes Minimal Risk Levels (MRLs) that are developed using procedures that are virtually identical to the EPA methods for establishing reference doses. However, the ATSDR website includes the following qualifier "It is important to note that MRLs are not intended to define cleanup or action levels for ATSDR or other Agencies…"

[23] OSWER Directive 9285.7-53 states that "In general, draft toxicity assessments are not appropriate for use until they have been through peer review, the peer review comments have been addressed in a revised draft, and the revised draft is publicly available."

impact on cleanup levels is unclear. Very few of the screening levels in the EPA Regional Screening Tables are derived using MRLs.

- Use of California EPA Toxicity Values: Several members expressed concerns about using toxicity values developed by the California EPA to establish MTCA cleanup levels. Members identified two main concerns:

  1. Peer Review and Transparency: Several members expressed concerns about the level of peer review and opportunity for public comment provided by the California EPA. Ecology has reviewed those procedures. While not equivalent to the methods used by EPA to develop IRIS toxicity values, the California EPA procedures include independent scientific reviews and opportunities for public review and comment on draft values. Similar to the EPA IRIS process, the California EPA evaluates scientific peer review and public comments before developing final toxicity values. When developing the EPA data hierarchy, EPA pointed to the California process as an example of a transparent process with opportunities for external review.
  2. Technical Methods: Several members questioned whether the California EPA method for establishing toxicity values is consistent with current scientific information and EPA regulatory guidance. We have reviewed the methods used by the two agencies. With few exceptions, the California EPA methods are very similar to the EPA methods.

Ecology performed two evaluations designed to evaluate the practical implications of using the California EPA values. First, we evaluated how frequently the California EPA toxicity values might be used to establish MTCA cleanup levels. This was done by reviewing the Regional Screening Tables to identify the cancer slope factors and inhalation unit risk factors for the 50 chemicals meeting the draft MTCA definition for carcinogen (see previous section). The results of that evaluation are summarized in the table below.

Toxicity Values Used to Develop Regional Screening Concentrations Based on Cancer Risks for the 50 Carcingoens 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

Ecology has also evaluated the reasons for the use of the California EPA values and the potential impacts associated with greater reliance on those values. The results of that evaluation are shown below. There appear to be three main reasons for the use of IUR values developed by the California EPA: (1) the California EPA value replaces an out-of-date HEAST value; (2) the California EPA value replaces an inhalation value that is based on direct extrapolation from an oral cancer slope factor; and (3) no other values are available.

As shown in the table below, the California EPA values tend to be slightly less stringent than values obtained from HEAST or derived by direct extrapolation from an oral slope factor.

Substance	Current MTCA inhalation cancer potency factor	Basis	Inhalation Unit Risk Factor (from MTCA CPFi)	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 $(ug/m^3)^{-1}$
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

Ecology has also evaluated how toxicity values developed by California EPA compare with toxicity values developed by the Environmental Protection Agency. This was done by downloading the oral slope factors included in the IRIS database and comparing those values to oral cancer slope factors developed by the California EPA. The IRIS database currently includes 88 oral cancer slope factors for 78 chemicals. The California EPA has developed oral cancer slope factors for 60 of those 78 chemicals. **NOTE: This evaluation differs from the earlier comparison because the 78 chemicals include ones that are not found or rarely found at Superfund sites.**

In general, the California EPA oral slope factors are similar (but slightly higher) than the EPA values for the same chemical. Ecology recognizes that this comparison is somewhat simplistic in that it does not consider when the different values were developed, the basis for different values, etc. However, the comparison reinforces our general conclusion that the California EPA values are consistent with current scientific information and federal risk assessment policies and procedures.

Summary of Comparison of Cancer Slope Factors in the Integrated Risk Information System and the California Environmental Protection Agency Toxicity Criteria Database	
Range of 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

Comments on Draft Revisions to MTCA Toxicological Hierarchy [Note: Most comments have been summarized to conserve space].	
	Comment
Comments (verbal) made during the March 2010 MTCA/SMS Advisory Group Meeting	Use EPA's toxicity review process that's well established and has gone through public peer review, e.g. IRIS. Don't just arbitrarily "pick up" toxicity values from other sources. Toxicity information tends to be in a state of flux. You have to be really careful about where you draw your values, sources, references, etc.
Patty Boyden/Mike Stoner	EPA's IRIS database has been recognized as the "gold standard" for toxicological data due to its rigorous external peer review process for data inclusion. Ecology should continue to rely on IRIS as the primary source of data for cleanup level development. The use of RSTs is discouraged because of the lack of standardization. As noted by the Science Panel, the use of RSTs would require Ecology to develop a process of external peer-review prior to MTCA use. Such a process would use State resources to duplicate EPA's efforts to update IRIS and is therefore not recommended.
Larry Dunn	On the hierarchy of toxicological information, IRIS is indeed the gold standard but as noted is a lengthy process to complete. Regional screening tables are reasonable to use for a basis to update the CLARC data base. Annual updates should be sufficient unless an emerging issue is identified with a new chemical.
Chris Waldron	A systematic and regular update of toxicity values should be implemented for all toxicity values on CLARC. (1) The use of provisional toxicity values that have not undergone external peer review is a significant concern because of the high degree of uncertainty. Ecology should establish a hierarchy of sources of peer-reviewed toxicity values. There have been many instances (e.g., trichloroethylene toxicity values) where project managers at Ecology have required the use of draft or provisional toxicity values on projects – which have then changed. This is costly and unnecessary. (2) The language in Figure 1 (8)(b) – 2nd sentence is vague (i.e., "and other credible sources"). Ecology should identify "other credible sources" here in order to eliminate confusion. I do not think that Ecology's goal or mission should be to perform toxicity assessments and develop toxicity values from toxicity studies. This would duplicate the work being performed by the EPA.
Mike Ehlebracht	Ecology's approach makes sense to me. I use the on-line CLARC database fairly frequently and think it is a great tool.
Neil Morton	I think the "hierarchy" included proposed by Ecology is too vague. If the intention of Ecology is to follow the EPA 2003 hierarchy, which I think makes sense, then this should be stated. Especially since the EPA Regional Screening Table values were calculated using toxicity values obtained following EPA's 2003 hierarchy.
Priscilla Tomlinson	I consider that MTCA hierarchy to be outdated and recommend that it be changed, but not as shown in Figure 1. First, I recommend reversing the order of HEAST and NCEA (PPRTV) in the hierarchy, because HEAST has become so outdated, so the hierarchy would be IRIS, NCEA, HEAST. Second, I recommend using CalEPA and EPA Region 3

	PRG table toxicity values only after evaluating them to verify that they have undergone sufficient peer review. My own experience reviewing one CalEPA toxicity value, and what I have heard from others about some of the EPA Region 3 table values, makes me inclined not to trust them without checking into their derivation. Another potential source of toxicity data is ATSDR's minimal risk levels, but I'm not familiar with their peer review process. I would be willing to investigate the ATSDR peer review process to assist you in decision making when I return from my vacation. One option for using toxicity values that are not considered as trustworthy as the IRIS/NCEA/HEAST list, either because they have undergone insufficient peer review or because their peer review status cannot be verified, would be to use them only for screening purposes to eliminate a chemical from further consideration but not to use them for establishing CULs. However this approach would add an additional layer of complexity to the process and might be difficult to implement.
Barbara Trejo	A systematic update process is necessary. However, the update should occur more frequently than annually if significant changes in toxicity values occur. This would help ensure that the regulated community is using the appropriate values Not having reviewed the various toxicity values it is not possible to comment other than stating that IRIS or Regional Screening Tables values generally undergo extensive peer review before being adopted. We suggest that Ecology modify the proposed WAC 173-340-708 language, below, as noted. According to the information noted above and below, IRIS, Regional Screening Tables, petroleum fraction sources and other credible sources would be used. Section 8(a) should be revised to reflect that fact. Suggest including the reference for developing non-carcinogenic toxicity values.
MTCA Science Panel March 25, 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.

3. Early Life Stage Adjustments

Issue

Should Ecology revise the MTCA cleanup level requirements to incorporate methods and policies that take into account new scientific information on children's susceptibility to chemical carcinogens?

Background

Most cancer slope factors are based on animal bioassays or epidemiological studies that do not account for exposures during critical periods of human development. Numerous studies over the last 20 years, however, indicate that exposure to carcinogens early in life has a much greater impact on lifetime cancer risks than exposures later in life.

The U.S. Environmental Protection Agency (EPA) [24] and the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) [25] have published guidance for evaluating childhood exposures to carcinogens. Both agencies apply age-related adjustment factors to the cancer slope factors to account for greater child susceptibility to carcinogens.

- Applicability: The California EPA policies apply to all carcinogens. EPA policies, however, are applied to carcinogens that act via a mutagenic mode of action. The EPA 2005 guidance lists chemicals that are considered to act through a mutagenic mode of action (including vinyl chloride and B[a]P). EPA also evaluates mode of action when preparing toxicological assessments. For example, EPA concluded that trichloroethylene acts through a mutagenic mode of action for some cancer types. EPA also reviews chemical-specific data to determine if it is appropriate to apply the adjustment factors to chemicals that act through a non-mutagenic mode of action.

- Methods: EPA and California EPA have developed scientific procedures and policies for adjusting existing cancer slope factors to account for children's increased susceptibility. Both agencies recommend that cancer slope factors be adjusted depending on age. The age-specific adjustments range from a factor of 10 for young children to 1 for adults and are applied according to age intervals. The default parameters in the two guidance materials are summarized in the table below. The weighted adjustment factors calculated for a 30-year drinking water exposure scenario are 3.3 (USEPA) and 4.5 (California EPA). In other words, ground water cleanup levels based on cancer risks would be 3.3-4.5 times lower than ground water cleanup levels calculated without taking into account early life stage susceptibility to carcinogens.

[24] USEPA. 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. U.S. Environmental Protection Agency, Risk Assessment Forum, March 2005. EPA/630/R-03/003F.

[25] OEHHA. 2009. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II, Technical Support Document for Cancer Potency Factors, May 2000, California Environmental Protection Agency, Office of Environmental Health Hazard Assessment.

Comparison of USEPA and CALEPA Early Life Exposure Age Adjustment Factors for Use in Ground Water Cleanup Level Calculations						
Parameter	**Parameter Definition**		**Default Exposure Parameters For Early Life Exposure**			
			Age Groupings			
			< 2 years	**2-6 years**	**6 to 16 years**	**> 16 years**
ADAF	Age-Dependent Adjustment Factor, Unitless	USEPA	10	3	3	1
		CALEPA	10	3	3	1
ED	Exposure Duration, Years	USEPA	2	4	10	14
		CALEPA	2	4	10	14
DWIR	Drinking water ingestion rate, L/day	USEPA	1	1	2	2
		CALEPA	1	1	2	2
BW	Body weight, kg	USEPA	16	16	70	70
		CALEPA	10	16	45	70
Weighted Early Life Stage Adjustment Factor for Ground Water Cleanup Levels (30 year exposure)					**USEPA**	**3.3**
					CALEPA	**4.5**

MTCA Rulemaking Options

Ecology has reviewed the new scientific and regulatory information on this issue and believes it is appropriate to consider revisions to the MTCA cleanup regulation. Ecology has considered three main options for resolving this rulemaking issue:

1. No Changes. Under this option, Ecology would not revise the MTCA rule to take into account new scientific information on cancer risks associated with early life exposures.
2. EPA Guidance used as Default Scientific Policy: Under this option, Ecology would make several changes to the MTCA cleanup regulation.
   - Revise WAC 173-340-708 to require early life stage adjustments to cancer slope factors when calculating cleanup levels for carcinogens that act via a mutagenic mode of action. For purposes of implementing this provision, carcinogens with a mutagenic mode of action would include:
     - Carcinogens identified in the EPA 2005 early life stage guidance;
     - Other carcinogens identified by EPA as acting via a mutagenic model of action. For example, EPA has concluded that trichloroethylene acts through a mutagenic mode of action for certain tumor types.
     - Other carcinogens where EPA determines that it is appropriate to apply the early life stage guidance.
   - Specify default age dependent adjustment factors (ADAFs) that are based on the EPA guidance published in 2005. The ADAFs would be used to adjust the cancer slope factor/unit inhalation risk factor when calculating cleanup levels for carcinogens that act via a mutagenic mode of action.

Under this option, Ecology would also continue to monitor EPA's work on carcinogens with non-mutagenic modes of action in order to identify criteria for departing from the default policy and applying the early life adjustments to carcinogens with other modes of action.

3. California Guidelines used as Default Scientific Policy: Under this option, Ecology would make several changes to the MTCA cleanup regulation:

   - Revise WAC 173-340-708 to require early life stage adjustments to cancer slope factors when calculating cleanup levels for all carcinogens (independent of information on mode of action).
   - Identify default age dependent adjustment factors (ADAFs) using the California guidance. The ADAFs would be used to adjust the cancer slope factor/unit inhalation risk factor when calculating cleanup levels for carcinogens.

Science Policy Choices and Inferences

One of the most important insights in the 1983 National Academy of Sciences (NAS) report is the concept of "policy judgments embodied in risk assessment". In particular, the NAS committee recognized that the risk-assessment process requires numerous decisions that can have considerable impact on the risk assessment results. Some of those decisions can be made with available data. In other cases, the decision is complicated by large gaps in our scientific understanding. In these situations, the committee noted that "… inferential bridges are needed to allow the process to continue…" These bridges represent science policy choices decisions about which of several scientifically plausible assumptions to use when performing the risk assessment. These science policy choices are largely driven by decisions on how to respond to scientific uncertainty (i.e., what is the appropriate way to balance the potential for false positives and false negatives?). The National Research Council (2008) provided a list of scientific inferences or defaults used by the Environmental Protection. For example:

- "Positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans" (EPA 2005a, p. A-3).
- "When the weight of evidence evaluation of all available data are insufficient to establish the mode of action for a tumor site and when scientifically plausible based on the available data, linear extrapolation is used as a default approach, because linear extrapolation generally is considered to be a health-protective approach. Nonlinear approaches generally should not be used in cases where the mode of action has not been ascertained. Where alternative approaches with significant biological support are available for the same tumor response and no scientific consensus favors a single approach, an assessment may present results based on more than one approach" (EPA 2005a, p. 3-21).

Draft Revisions and Rationale

Ecology believes it is appropriate to revise the MTCA cleanup regulation to incorporate EPA's guidance on this issue (Option 2). Under this option, Ecology would require early life stage adjustments to cancer slope factors when calculating cleanup levels for carcinogens identified by EPA as acting through a mutagenic mode of action. Ecology would also continue to work Ecology's rationale for this revision includes the following:

- Both the EPA Guidance and California Guidelines have a strong biological basis and are consistent with current scientific information. Several scientific committees have concluded that there is a credible scientific basis for considering increased child susceptibility to carcinogens when establishing risk-based standards or goals. These include:

- EPA Science Advisory Board (2004): The Science Advisory Board formed a panel to review the draft Supplemental Guidance for Assessing Cancer Susceptibility. The review panel agreed with EPA that the science supports the conclusion that early-life exposures result in increased susceptibility to carcinogens that act through a mutagenic mode of action as compared to adult exposures. The panel agreed with EPA use of slope factor adjustments.[26] The panel also noted that there is sufficient scientific evidence supporting increase susceptibility for certain groups of non-mutagenic chemicals with known modes of action (e.g., estrogen receptor agonist/antagonist). They concluded that non-mutagenic carcinogens with known modes of action should be assessed on a case-by-case basis as suggested by the Agency, but recommended that EPA reconsider the agency policy to limit the application of adjustment factors only to mutagenic agents and instead apply a default approach to both mutagenic and to non-mutagenic chemicals for which mode of action remains unknown or insufficiently characterized.
- Scientific Review Panel for Air Toxic Contaminants: The Scientific Review Panel for Air Toxic Contaminants reviewed and discussed the proposed California guidelines at three meetings held between October 2008 and May 2009.[27] The Panel accepted the final report at the May 2009 meeting.
- National Research Council: The National Research Council completed, in late 2008, a review of EPA risk assessment procedures. The NRC panel noted that cancer risk assessment typically lacks a quantitative description of inter-individual variability. They recommended that EPA give consideration to variations in susceptibility when evaluating cancer risks. The NRC panel also stated that "…[t]he supplemental guidance regarding children (EPA 2005c) is an important step in the right direction, but variability in the general population should also be addressed…".[28]
- MTCA Science Panel: The MTCA Science Panel concluded that there is sufficient and sound technical information regarding children's susceptibility and the potential

[26] The Review Panel reviewed age-specific human vulnerabilities and concluded that it would be useful to include an additional age grouping (age 9 –15) to recognize the potentially important vulnerabilities during puberty. Thus, four age groupings would be appropriate (0-2, 3-8, 9-15, 15+) to represent critical periods of human growth and development.

[27] The meeting notices, agendas and transcripts for the Scientific Review Panel meetings are found at the following location: http://www.arb.ca.gov/srp/srpmeetings.htm

[28] EPA (2005) stated that the decision not to apply early life adjustments to all carcinogens was in part due to "… the Agency's long-standing science policy position that use of the linear low-dose extrapolation approach (without further adjustment) provides adequate public health conservatism in the absence of chemical-specific data indicating differential early-life susceptibility or when the mode of action is not mutagenicity…" As noted in the above text, the NRC panel concluded that EPA's early life stage guidance was an important first step in the right direction. However, on a more general level, the NRC panel emphasized the importance of addressing inter-individual variability when evaluating cancer risks. They noted that current procedures reflect the implicit default assumption that human cancer susceptibility does not vary (see Chapters 4 and 6). Furthermore, the NRC panel stated that "…[t]he argument that the linear dose-response extrapolation procedure covers the omission (EPA 2005b) is unsupported and presents a separate consideration that should not be confused with the need to describe risk differences among individuals in addition to high-dose–low-dose extrapolation…"

for increased risk due to early-life exposure to chemical carcinogens.[29] They recommended that Ecology consider this information when revising the MTCA regulations. The Science Panel also concluded that there is a sound scientific basis for applying early life stage adjustments to all carcinogens.[30] In addition, the Science Panel reviewed the methods and weighting factors developed by EPA and California EPA and concluded that there doesn't appear to be a scientific basis for favoring one approach over the other.

- The EPA guidance is a reasonable approach given the overall MTCA risk management framework. Agencies must deal with considerable scientific uncertainty and inter-individual variability when establishing regulatory requirements for preventing health risks. In 1983, the National Academy of Sciences recognized that almost no risk assessment can be completed unless scientific information (data and knowledge) is supplemented with science policy choices (default guidelines) that have not been documented in relation to the particular risk assessment at hand – but are supported by substantial evidence or theory for the general case. The choice of defaults is often controversial because the choice involves a blend of science and policy.

  Ecology's decision on how to use available scientific information on early life stage susceptibility to carcinogens represents this type of scientific policy choice or assumption. If the MTCA rule simply focused on procedures for performing risk assessment, Ecology believes that it would be appropriate to adopt the California EPA guidelines. As discussed above, there is a credible scientific basis for applying this approach to all carcinogens and this option would generally provide risk assessments that err on the side of safety. [31]

  However, the MTCA rule establishes a decision-making framework that reflects a number of risk management choices. Consequently, Ecology believes the EPA methods and policies are more appropriate for use within the MTCA decision framework given Ecology's efforts to maintain consistency with EPA requirements and the risk management decision to base cleanup levels on a one-in-one million target cancer risk.

- This option is consistent with EPA Superfund policies and would comply with MTCA statutory requirements. The EPA Superfund program has adopted regulatory policies and procedures to account for early-in-life exposures to carcinogens that operate via a mutagenic mode of action. Consequently, this option promotes consistency with the federal Superfund program and helps to ensure that MTCA cleanup standards will be "…at least as stringent as the cleanup standards under section 121 of the federal cleanup law…"

[29] MTCA Science Panel, November 23, 2009 and March 25, 2010.

[30] Members noted that the USEPA's approach to limiting this adjustment to mutagens is inconsistent with EPA's own decisions on how some pesticides are being evaluated. The Panel also noted that among the scientific community, or even within EPA, there is no consensus on the definition of mutagenic, so it would be difficult to implement EPA's approach without defining the term mutagen.

[31] The National Research Council discussed missing/unstated risk assessment defaults in their report, Science and Decisions. As part of that discussion, they noted that EPA's current early life stage methods do not take into account carcinogenic activity from in utero exposure and, consequently, risks from in utero exposure are not calculated (EPA 2005b; EPA 2006a, p. 29).

- This option is consistent with approaches being used by other states. Ecology evaluated how several other states with well-developed and experienced programs were dealing with this issue. Ecology found that the majority of state programs reviewed are (or are considering) using the EPA guidance materials to establish cleanup levels for carcinogens acting by a mutagenic mode of action. California appears to be the only state that applies early life stage adjustments to all carcinogens. Specifically, OEHHA applies the early life stage adjustments when establishing air screening levels and public health goals for drinking water for some compounds. However, OEHHA recently proposed revisions to the public health goals for benzo[a]pyrene and hexavalent chromium in drinking water. In both cases, OEHHA chose not to make early life stage adjustments when calculating the public health goals. Furthermore, it is not clear how California agencies use the early life stage guidelines when establishing site-specific cleanup levels.

Summary of State Policies for Early Life Stage Exposure to Carcinogens

State	Risk Level	All	Mutagenic MOA	Comment/References
CA	10^{-6}	yes		OEHHA Soil Screening Table 1 [http://oehha.ca.gov/risk/chhsltbl091709.html]
CO	10^{-6}		yes	http://www.cdphe.state.co.us/hm/csev/pdf
MA	10^{-6}		no	Risk-based CUL = 7.5E-01 mg/kg adjusted to background 2 mg/kg; in the process of considering ELE
MD	10^{-6}		yes	Department of the Environment. Cleanup Standards for Soil and Ground Water (June 2008 Interim Final Guidance).
ME	10^{-5}		yes	Maine Remedial Action Guidelines, Appendix 1 includes BaP soil level of 0.26 mg/kg (10^{-5} risk); Appendices 2 & 3 levels based on 10-6.
MI	10^{-5}		no	April 2005, Remediation and Redevelopment Division Operations Memo. No.1,Technical Support Document, Attachment No. 6
MN	10^{-5}		no	Minnesota is in the process of incorporating age dependent adjustment factors for ELE for different media.
NJ	10^{-6}		no	New Jersey Department of Environmental Protection. 2009. Remediation Standards. NJAC 7:26D. November 4, 2009.
NY	10^{-6}		yes	Subpart 375-6: Remedial Program Soil Cleanup Objective for B[a]P is 1 mg/kg from Table 375-6.8 (a) based rural background.
OR	10^{-6}		yes	http://www.deq.state.or.us/lq/pubs/docs/EarlyLifeExposureRBDM.pdf
TX	10^{-5}		no	ELE under consideration for future rule making

- The draft approach is likely to significantly alter cleanup requirements at some Washington cleanup sites. Ecology is in the early stages of evaluating the impacts of the draft rule revisions as required by the Washington Administrative Procedures Act. However, the preliminary analysis indicates that implementing the EPA early life stage policy will alter cleanup requirements at some Washington sites. The rationale for this preliminary conclusion includes:

- Nine of the 50 carcinogens that appear among the 100 highest ranked hazardous substances on the ATSDR list are considered to operate through a mutagenic mode of action. These include several PAH compounds, hexavalent chromium, vinyl chloride, benzidine and 1,2 dibromo-3-chloropropane.
- Risk-based ground water cleanup levels calculated using the EPA early life stage adjustments would be @ 3 times lower than ground water cleanup levels calculated under the current MTCA. However, cleanup levels must also take into account analytical limits, background concentrations and applicable state and federal laws. Ecology is still evaluating the impacts when all of the MTCA requirements are taken into account.
- For unrestricted site use, risk-based soil cleanup levels based on the direct contact pathway would be @ 5 times lower than soil cleanup levels calculated under the current MTCA. However, cleanup levels must also take into account analytical limits, background concentrations and applicable state and federal laws. Ecology is still evaluating the impacts when all of the MTCA requirements are taken into account.
- Risk-based soil cleanup levels based on the direct contact pathway would not be affected by this rule change.

- <u>The revised approach falls within the range of opinions on this issue expressed by advisory group members</u>: This issue was discussed by the MTCA/SMS Advisory Group at the March 22nd Advisory Group meeting. Several members also provided written comments on this issue. Ecology also received one comment on this issue which was summarized in the risk assessment scoping paper distributed in 2009.

Summary of Comments on Early Life Stage Adjustments for Carcinogens [Note: Most comments have been summarized to conserve space].	
Member	Comment
Scoping Comments Timothy Bingham (Dupont Corporate Remediation Group)	We agree with the option of updating MTCA to retain consistency with USEPA risk assessment and cancer risk assessment guidelines. This should include recent inhalation Risk Assessment Guidance, as well as age-dependent adjustment factors for modifying cancer toxicity factors for early life exposures for genotoxic materials.
MTCA/SMS Advisory Group (Summary of Feedback from January 11, 2010 and March 22, 2010 Meetings)	• Several members support the application of early life exposure age adjustments for all carcinogens. Reasons for this approach include (1) Lack of uniformity on defining mutagenic MOA; (2) biological reasons for increased child sensitivity; and (3) the importance of erring on side of caution. • Some members believe policy should be limited to carcinogens with mutagenic MOA. In general, these members believe that applying the EPA guidance is a reasonable first step. They provided reasons for not applying to all carcinogens (e.g., rapid pace of research, conclusive evidence for few compounds, etc.). • Several members identified technical and policy issues associated with applying this policy to BaP/ PAH compounds. These include (1) large uncertainties in extrapolating from high to low doses; (2) existing MTCA policies include conservative features; (3) adjustments lead to cleanup levels below background; (4) draft EPA mixtures policy and (5) the 2007 MTCA revisions already factored in early life susceptibility.
Patty Boyden and Mike Stoner (MTCA/ SMS Advisory Group)	Ecology should consider applying age-dependent adjustments in the current rule making to carcinogens with a known mutagenic mode of action, consistent with current EPA guidance on early life exposures. MTCA revisions are an ongoing process and there will be future opportunities to update cancer slope factors based on new research.
Larry Dunn (MTCA/ SMS Advisory Group)	Ecology should apply early life stage adjustment factors to cancer slope factors for all carcinogens.
Will Ernst (MTCA/ SMS Advisory Group) – Prepared by Lisa Yost and Michael Garry	Ecology should consider several technical and policy issues before applying early life stage adjustments to benzo[a]pyrene/ PAH compounds. These include (1) large uncertainties in extrapolating from high to low doses; (2) existing MTCA policies include conservative features; (3) adjustments lead to cleanup levels below background; (4) draft EPA mixtures policy.
Tom Newlon (MTCA/SMS Advisory Group)	One member pointed out that Ecology already considered early-life stage susceptibility when preparing the 2007 rule revisions. He noted that early life stage susceptibility was one justification provided by Ecology for what amounts to a 10-fold decrease in cleanup levels for PAH compounds: "Ecology believes that the proposed approach provides a margin of safety that minimizes the potential health risks resulting from early-life exposures to carcinogenic PAHs." (CES Issue 4-3, page 92) In light of the 2007 rule revisions, he recommended that Ecology review the need for additional conservatism that will push the cleanup levels even lower (and in many instances to levels that may be below background levels in urban and other areas).

4. EPA Inhalation Risk Assessment Guidance

Issue

Should Ecology revise the equations for calculating air cleanup levels to reflect current EPA methods and policies for performing inhalation risk assessments?

Background

The Model Toxics Control Act (MTCA) cleanup regulation includes policies and procedures for establishing cleanup levels based on inhalation exposure (WAC 173-340-750). These procedures were developed in 1990 and are based on the methodologies included in the *Risk Assessment Guidance for Superfund (RAGS) Part A*[32] (referred to as Part A). The current MTCA equation for air cleanup levels based on carcinogenic effects is summarized below. The rule includes a similar equation for non-cancer effects.

Current MTCA Equation for Air Cleanup Levels Based on Carcinogenic Risks[33]

$$\text{Air cleanup level } (ug/m^3) = \frac{RISK \times ABW \times AT \times UCF}{CPF \times BR \times ABS \times ED \times EF}$$

Where

RISK	=	Acceptable cancer risk level (1 in 1,000,000) (unitless)
ABW	=	Average body weight over the exposure duration (70 kg)
AT	=	Averaging time (75 years)
UCF	=	Unit conversion factor (1,000 ug/mg)
CPF	=	Carcinogenic potency factor[34] as specified in WAC 173-340-708(8) (kg-day/mg). Ecology generally uses toxicity values for published in the IRIS database.[35,36]
BR	=	Breathing rate (20 m^3/day)
ABS	=	Inhalation absorption fraction (1.0) (unitless)
ED	=	Exposure duration (30 years)
EF	=	Exposure frequency (1.0) (unitless)

[32] USEPA. 1989. Risk Assessment Guidance for Superfund. Volume I. Part A. Office of Emergency and Remedial Response, Washington D.C. EPA-540/1-89/-002.
[33] See WAC 173-340-750 for the similar equation for calculating air levels based on non-cancer health effects.
[34] **"Carcinogenic potency factor"** or **"CPF"** means the upper 95th percentile confidence limit of the slope of the dose-response curve and is expressed in units of (mg/kg-day)-1. When derived from human epidemiological data, the carcinogenic potency factor may be a maximum likelihood estimate. (WAC 173-340-200)
[35] WAC 173-340-708(8) includes procedures for calculating CPF values when such values are not available in the IRIS database.
[36] The rule notes the complexity in calculating inhalation toxicity values: "…[t]he procedure to derive a human equivalent concentration of inhaled particles and gases shall take into account, where available, the respiratory deposition and absorption characteristics of the gases and inhaled particles. Where adequate pharmacokinetic and metabolism studies are available, data from these studies may be used to adjust the interspecies scaling factor."

In 2009 EPA published revisions to the Superfund procedures for evaluating health risks resulting from inhalation exposure. The updated guidance (*Risk Assessment Guidance for Superfund: Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*[37]). Part F is designed to promote consistent implementation of EPA's procedures for assessing inhalation risks[38]. Key differences between the MTCA rule and the updated EPA guidance include the following:

1. EPA recommends that risk assessors use the air concentration of a chemical as the exposure metric (e.g., ug/m^3) when evaluating inhalation risks. This differs from RAGS Part A and MTCA equations that use intake (mg/kg-d) as the exposure metric.
2. EPA recommends that risk assessors not use inhalation toxicity values generated using simple route-to-route extrapolation.

MTCA Rulemaking Options

Ecology has reviewed the new scientific and regulatory information on this issue and believes it is appropriate to consider revisions to the MTCA cleanup regulation. Ecology has considered two options for resolving this rulemaking issue:

1. No Revision. Under this option, Ecology would not revise the air cleanup level equations to incorporate the methods and policies included in the EPA risk assessment guidance published in January 2009.
2. Revisions Based on EPA Inhalation Risk Assessment Guidance: Under this option, Ecology would revise the MTCA rule to incorporate the methods and policies included in the EPA risk assessment guidance published in January 2009. These changes include:
   - Adding new terms and definitions for inhalation unit risk factor and reference concentration based on the EPA definitions provided in the Part F guidance.
   - Revise the MTCA air cleanup level equations to incorporate the methods and policies in EPA inhalation risk assessment guidance published in 2009. The draft revised equation for air cleanup levels based on cancer risks is shown below. Ecology would similarly modify the equation for calculating air cleanup levels based on non-cancer risks.

[37] USEPA. 2009. Risk Assessment Guidance for Superfund. Volume I: Part F, Supplemental Guidance for Inhalation Risk Assessment. Office of Superfund Remediation & Tech. Innovation. Washington D.C. EPA-540-R-070-002.
[38] USEPA.1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry

Example to Illustrate Possible Revision Based on EPA Inhalation Risk Guidance

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

Where:

RISK	=	Acceptable cancer risk level (1 in 1,000,000) (unitless)
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)

Draft Revisions and Rationale

Ecology plans to revise the MTCA air cleanup level equations to incorporate the methods and policies in EPA inhalation risk assessment guidance published in 2009 (Option 2). Ecology's rationale for these revisions includes the following:

- The revised approach is consistent with current scientific information on inhalation health risk assessment. Ecology discussed the EPA guidance and implications for the MTCA rule at the March 25, 2010, Science Panel meeting. The Science Panel concluded that the new EPA guidance provides a solid scientific foundation for evaluating revisions to the MTCA rule. They agreed with Ecology's conclusions that MTCA equations should be updated to reflect 2009 EPA inhalation risk guidance. The Panel also agreed that it is inappropriate to automatically use oral toxicity values to assess inhalation risks (and vice versa) without considering differences in absorption, distribution, metabolism, etc.
- This approach is consistent with the EPA Superfund methods and policies and complies with MTCA statutory requirements. The EPA Superfund program uses these methods and policies to support cleanup decisions at federal cleanup sites.[39] EPA Regions 3, 6, and 9 have developed cleanup screening levels based on the EPA Inhalation Risk Assessment Guidance. Consequently, this option promotes consistency with the federal Superfund program and helps to ensure that MTCA cleanup standards that are "…at least as stringent as the cleanup standards under section 121 of the federal cleanup law, 42 U.S.C. Sec. 9621, and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law…"

[39] Risk-Based equations, levels and background information found at the following Link: http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

- The draft approach is similar to approaches used by the Ecology Air Quality Program and environmental agencies in other states. Many states have adopted (or are in the process of adopting) approaches that are consistent with the 2009 EPA inhalation risk assessment procedures. For example, Oregon publishes risk-based cleanup level tables that use the EPA methodology to derive air screening levels. This approach is also consistent with the methods used by the Ecology air quality program to establish the Acceptable Source Impact Levels (ASILs) used to evaluate new sources of air emissions.
- There appears to be general support for the revised approach among advisory group members: Ecology asked members of the MTCA/SMS Advisory Group and the Vapor Workgroup to review and provide comments on the revised approach. As summarized below, there appears to be general support for this revision. However, members identified several issues that will need to be addressed when preparing the MTCA rule revisions:
  1. Adult vs. Child Exposures: There appears to be general support for Ecology's proposal to revise MTCA equations consistent with EPA guidance. Ecology agrees that separate equations may be appropriate for residential and industrial/commercial scenarios. Ecology is also evaluating the comments regarding the EPA procedures for calculating reference concentrations (see textbox below). Ecology will consider the comments on applying the EPA guidance when establishing cleanup levels or screening levels based on child exposure.
  2. Route-to-Route Extrapolation: Ecology agrees with members who said that toxicity values developed based on route to route extrapolation should not be used to establish cleanup levels unless those values take into account differences (inhalation vs. ingestion) in uptake, absorption, metabolism and distribution.
  3. Averaging Times: Ecology agrees with members who said that the exposure parameters included in the draft revised MTCA equations are consistent with underlying assumptions used in developing the toxicity values (e.g., 70 year lifetime).

Comments on EPA Procedures for Calculating Reference Concentrations

Several members have expressed general concerns that approaches used by Ecology do not adequately consider differences between children and adults. One member raised specific questions regarding the use of the EPA inhalation risk assessment methodology.

EPA discussed this issue in Appendix A of the 2009 Inhalation Risk Assessment Guidelines. EPA presented three case studies to illustrate how age-related differences are considered when establishing reference concentrations. In general, EPA found that human equivalent concentrations for children (HEC_{child}) tend to be lower than those for adults (HEC_{adult}). However, the EPA examples also indicate that EPA default procedures result in toxicity values ($HEC_{default}$) that are similar to age-specific HEC_{child} values. EPA concluded that

- $HEC_{default}$ values are generally protective (particularly given assumption of 100% deposition)
- Developing reference concentrations involves applying uncertainty factor to HEC that accounts for human variability
- Methods for calculating Inhalation Unit Risk (IUR) includes several conservative assumptions that minimize the potential for underestimating risks to children.

Summary of Comments on EPA Inhalation Risk Assessment Guidance [Note: Most comments have been summarized to conserve space].	
	Comment
Timothy Bingham (Dupont Corporate Remediation Group) – Scoping Comments	We agree with the option of updating MTCA to retain consistency with USEPA risk assessment and cancer risk assessment guidelines. This should include recent inhalation Risk Assessment Guidance, as well as age-dependent adjustment factors for modifying cancer toxicity factors for early life exposures for genotoxic materials.
Patty Boyden	The IUR factor is a change to the equation. Draft equation is acceptable. MTCA currently uses 75 years - slightly more stringent using 70 years as default.
Priscilla Tomlinson	I support the revision of Equations 750-1 and 750-2 to make them consistent with the way inhalation toxicity data are presented in IRIS. I noted that the adult bodyweight is shown as 70 kg. Although this makes it inconsistent with the other media, which use an adult bodyweight of 75 kg, I support the change because it makes the bodyweight consistent with the derivation of the IUR. I recommend you establish a goal of updating the adult bodyweights for other media to 70 kg, to be consistent with the derivation of carcinogenic potency factors, when you have reasons to update the other equations. The units shown for the IUR are incorrect; they should be m^3/ug for proper unit cancellation and to be consistent with how IUR values are presented in IRIS.
Barbara Trejo	No specific issues at this time. 70 years is consistent with the 2009 Exposure Factors Handbook for inhalation and what is used throughout EPA risk assessments. However, averaging time could be updated to reflect the current average lifespan in the US.
Chris Waldron	(1) I do not think that the EPA has done enough work to address the question of how the changes in evaluating inhalation risks apply to children. Children have a higher inhalation rate to body weight ratio than adults due to higher activity levels. This is not reflected in the development of reference concentrations and unit risks and is not adequately discussed in the EPA Guidance. Ecology should consider this when considering revising equations 750-1 and 750-2. (2) Ecology should consider establishing industrial/commercial cleanup levels for air in MTCA (i.e., similar to the approach that is currently used for establishing cleanup levels for soil). These should be based on a 10 m^3/day inhalation rate, 250 days/year exposure frequency, and 25 year exposure duration. Under the current version of MTCA, inhalation risks/cleanup levels at industrial/commercial sites are calculated using residential or unrestricted exposure parameters (e.g., 20 m^3/day inhalation rate, 365 days/year exposure frequency, etc), which are not consistent with the "actual" exposures at these locations. Note: A deed restriction would be required on these sites (similar to soil) so that if the land use changes in the future then the inhalation risks/cleanup levels would be reevaluated to ensure that they are protective of the "new" land use. (3) Ecology should clearly state in MTCA that route-to-route extrapolation of toxicity values (i.e., using oral toxicity values as surrogate inhalation toxicity values when inhalation toxicity values are not available and vice-versa) is inappropriate and should not be performed. Unfortunately, the EPA has (at times) used route-to-route extrapolation to develop Regional Screening Levels and other Risk-Based Screening Concentrations. Ecology should check the basis of the toxicity values obtained from the EPA and other sources that will be used in MTCA/CLARC to ensure that they are not the result of route-to-route extrapolation. If they are, they should not be included in MTCA/CLARC.

5. Concurrent Soil Exposure

Issue

Should soil cleanup levels based on the direct contact pathway take into account soil ingestion, dermal contact, and inhalation of soil particulates and/or volatilized chemicals?

Background

The MTCA cleanup regulation provides methods and policies and procedures for establishing cleanup levels based on human health protection. The cleanup standards were originally adopted in 1991. The cleanup standards provisions include a number of key features.

- Cleanup levels are based on protecting sensitive population groups, including pregnant women, developing fetuses, and children.
- Cleanup levels for ground water, surface water, soil, and air are based on the "reasonable maximum exposure" that a person might encounter. The reasonable maximum exposure is designed to represent a high end (but not worst case) estimate of individual exposures.
- Cleanup levels corresponding to the reasonable maximum exposure are based on exposure parameters (for example, the soil ingestion rate) included in EPA guidance and the scientific literature.
- Cleanup levels are based on toxicological parameters (cancer slope factors and reference doses) developed by EPA or other authoritative scientific organizations.

The 1991 rule includes equations for calculating soil cleanup levels based on incidental soil ingestion. Ecology reviewed the available scientific literature and regulatory guidance when researching options for the 2001 rule amendments. Based on that review, Ecology concluded that there was a credible scientific basis for also considering exposures resulting from dermal contact and inhalation of vapors and re-suspended soil particulates when establishing soil cleanup levels. Ecology subsequently made several changes to the MTCA methods for establishing soil cleanup levels.

- Dermal contact: Ecology added procedures for considering both soil ingestion and dermal contact when establishing soil cleanup levels. For petroleum mixtures, the rule includes a standard cleanup level equation that includes both pathways. For other chemicals, dermal contact is evaluated only when changes to the standard equation results in site-specific cleanup levels that are significantly higher than those calculated using standard equations that are based on soil ingestion.
- Soil vapors: Ecology amended the procedures for establishing soil cleanup levels to require evaluation of risk posed by inhalation of soil vapors.[40]

[40] For example, WAC 173-340-740(3)(b)(iii)(C) and related sections require that soil cleanup levels are protective of both indoor air (exposures resulting vapor intrusion pathway) and ambient air (exposures resulting from inhalation of soil vapors and/or re-suspended particulates)

Since the 2001 rule amendments, there have been several scientific and regulatory developments relevant to this rulemaking issue.

- EPA Risk Assessment Guidance: EPA has published several new human health risk assessment guidance materials relevant to the methods used to establish soil cleanup levels. This includes cancer risk assessment guidelines, methods for evaluating dermal exposure, child exposure assessment, and methods for evaluating inhalation risks.[41] [42] [43] [44]
- Risk Equations: EPA Regions 3, 6, and 9 and the Oak Ridge National Laboratory (ORNL) have jointly developed risk-based equations that evaluate the toxicity and assess the risks from concurrent ingestion, dermal, and inhalation routes of exposure to chemical contaminants. [45]
- Implementation Experience: Exposure resulting from dermal contact is rarely considered when establishing soil cleanup levels for non-petroleum substances. In other words, we believe that the modified Method B soil cleanup equations are not being used as originally intended.

MTCA Rulemaking Options

Ecology has reviewed the new scientific and regulatory information on this issue and believes it is appropriate to consider revisions to the MTCA soil cleanup level equations for the direct contact pathway. Ecology is considering revisions for both unrestricted land uses (Section 740) and industrial sites (Section 745).

Ecology has considered five main options for resolving this rulemaking issue:

1. No Revisions: Under this option, soil cleanup levels for non-petroleum contaminants would continue to be based on soil ingestion only. Cleanup levels would continue to be calculated using Equations 740-1 (non-cancer risks) and 740-2 (cancer risks). In limited circumstances, the dermal contact pathway would also be considered when calculated soil cleanup levels based on direct contact (Equations 740-4 (non-cancer risks) and 740-5 (cancer risks). Soil cleanup levels for petroleum mixtures would continue to be based on Equation 740-3. Similar equations are provided in WAC 173-340-745 for industrial soil cleanup levels.

[41] USEPA. 2005. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum. EPA/630/P-03/001F.

[42] USEPA. 2004. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Final July 2004. EPA/540/R/99/005.

[43] USEPA. 2006. Child-Specific Exposure Factors Handbook (External Review Draft). National Center for Environmental Assessment. Office of Research and Development. EPA/600/R/06/096A.

[44] USEPA. 2009. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment) Final January 2009. EPA/540/R/070/002.

[45] EPA Region 3/6/9 Risk Based Equations: http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

2. Soil Ingestion + Dermal Contact Exposure Model (All hazardous substances with current exposure durations): Under this option, Ecology would make several changes:

    - Simplify the rule by eliminating modified Method B and modified Method C.
    - Revise WAC 173-340-740 by replacing Equations 740-1 and 740-2 with Equations 740-4 (non-cancer risks) and 740-5 (cancer risks), respectively. These equations consider both soil ingestion and dermal contact for a six (6) year exposure duration (child exposure scenario). Similar changes would be made to the equations in WAC 173-340-745 which are based on a 20 industrial worker exposure scenario. Cleanup levels for petroleum mixtures would continue to be established using Equation 740-3 and 745-3.
    - Equations 740-4, 740-5, 740-4 and 740-5 include default values for gastrointestinal absorption rates and dermal absorption rates that are used when chemical-specific data are not available. Under this option, the default assumptions would not be revised. However, the rule would continue to provide the flexibility to consider new chemical-specific information gastrointestinal absorption rates and dermal absorption rates.
    - Modify the rule to require an evaluation of vapor exposure resulting from the release of volatile hazardous substances from contaminated soils.

3. Soil Ingestion + Dermal Contact Exposure Model (Semi-volatile hazardous substances with current exposure duration): Under this option, Ecology would make several changes:

    - Simplify the rule by eliminating modified Method B and modified Method C.
    - Revise WAC 173-340-740 by replacing Equations 740-1 and 740-2 with Equations 740-4 (non-cancer risks) and 740-5 (cancer risks), respectively. These equations consider both soil ingestion and dermal contact for a six (6) year exposure duration (child exposure scenario). Similar changes would be made to the equations in WAC 173-340-745 which are based on a 20 industrial worker exposure scenario. Cleanup levels for petroleum mixtures would continue to be established using Equation 740-3 and 745-3.
    - Equations 740-4, 740-5, 740-4 and 740-5 include default values for gastrointestinal absorption rates and dermal absorption rates that are used when chemical-specific data are not available. Under this option, the default assumptions for semi-volatile organic hazardous substances would not be revised. However, the default values for metals and volatile organic hazardous substances would be changed to zero to reflect the relative contribution of the dermal pathway and uncertainties surrounding the dermal absorption factors for these types of substances. The rule would continue to provide the flexibility to consider new chemical-specific information gastrointestinal absorption rates and dermal absorption rates.
    - Modify the rule to require an evaluation of vapor exposure resulting from the release of volatile hazardous substances from contaminated soils.

4. Soil Ingestion + Dermal Contact Exposure Model (All hazardous substances with revised exposure duration): Under this option, Ecology would make several changes:

    - Simplify the rule by eliminating modified Method B and modified Method C.

- Specify that soil cleanup levels based on the direct contact pathway must be calculated using equations that consider both soil ingestion and dermal contact using a 30-year exposure duration (child and adult exposure). The exposure duration for calculating soil cleanup levels at industrial sites would remain 20 years.
- The methods and equations would continue to provide the flexibility to consider new chemical-specific information on toxicity, gastrointestinal absorption rates, and dermal absorption rates.

5. Soil Ingestion + Dermal Contact + Inhalation Exposure Model: Under this option, Ecology would make several changes:
   - Simplify the rule by eliminating modified Method B and modified Method C.
   - Specify that soil cleanup levels based on the direct contact pathway must be calculated using equations that consider soil ingestion, dermal contact and inhalation of wind-blown dust/volatilized hazardous substances for a 30-year exposure duration (child and adult exposure). Similar adjustments would be made to Equations 745-4 and 745-5 which are based on a 20-year exposure duration.
   - Assign a default dermal absorption fraction of zero for metals and volatile organic hazardous substances. Dermal absorption fraction for non-volatile organic hazardous substances would be based on chemical-specific information and/or derived from information on chemicals with similar chemical properties.
   - The methods and equations would continue to provide the flexibility to consider chemical-specific information on toxicity, gastrointestinal absorption rates and dermal absorption rates.

[Equation 740-2]

$$\text{Soil Cleanup Level (mg/kg)} = \frac{\text{RISK x ABW x AT x UCF}}{\text{CPF x SIR x AB1 x ED x EF}}$$

[Equation 740-5]

$$C_{soil} = \frac{RISK \times ABW \times AT}{EF \times ED\left[\left(\frac{SIR \times AB1 \times CPFo}{10^6 mg/kg}\right) + \left(\frac{SA \times AF \times ABS \times CPFd}{10^6 mg/kg}\right)\right]}$$

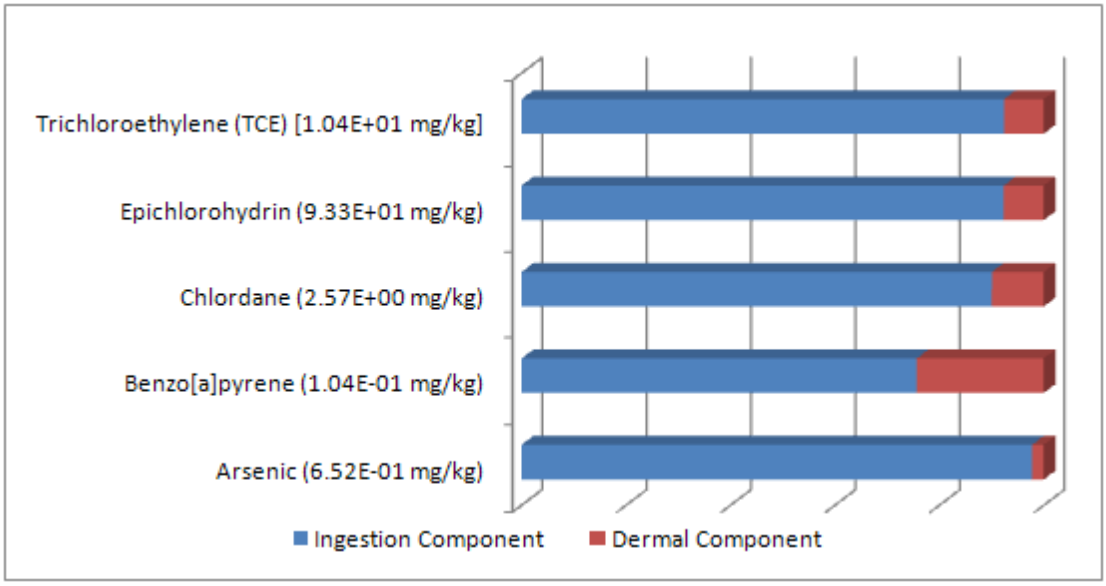
C_{soil} =	Soil cleanup level (mg/kg)
RISK =	Acceptable cancer risk (1 in 1,000,000) (unitless)
ABW =	Average body weight over the exposure duration (16 kg)
AT =	Averaging time (75 years)
EF =	Exposure frequency (1.0) (unitless)
ED =	Exposure duration (6 years)
SIR =	Soil ingestion rate (200 mg/day)
AB1 =	Gastrointestinal absorption fraction (1.0) (unitless). May use 0.6 for mixtures of dioxins and/or furans
CPFo =	Oral cancer potency factor as defined in WAC 173-340-708(8) (kg-day/mg)
CPFd =	Dermal cancer potency factor (kg-day/mg) derived by CPFo/GI
GI =	Gastrointestinal absorption conversion factor (unitless). May use chemical-specific values or the following defaults:
	0.2 for inorganic hazardous substances
	0.8 for volatile organic compounds and for mixtures of dioxins and/or furans
	0.5 for other organic hazardous substances
SA =	Dermal surface area (2,200 cm^2)
AF =	Adherence factor (0.2 mg/cm^2 – day)
ABS =	Dermal absorption fraction (unitless). May use chemical-specific values or the following defaults:
	0.01 for inorganic hazardous substances
	0.0005 for volatile organic compounds with vapor press > = benzene
	0.03 for volatile organic compounds with vapor press < benzene and for mixtures of dioxins and/or furans
	0.1 for other organic hazardous substances

Draft Revisions and Rationale

Ecology plans to simplify the rule by eliminating modified Method B and modified Method C. Under this approach, (Option 2) soil cleanup levels based on the direct contact pathway would be calculated using Equations 740-4 (non-cancer risks) and 740-5 (cancer risks). Similar revisions would be made to the industrial soil cleanup level equations in WAC 173-340-745. Under this option, Ecology would not modify the equations for calculating soil cleanup levels for petroleum mixtures based on the direct contact pathway (Equations 740-3 and 745-3). The methods and equations would continue to provide the flexibility to consider chemical-specific information on toxicity, gastrointestinal absorption rates and dermal absorption rates.

Ecology's rationale for this revision includes the following:

- The revised approach is consistent with current scientific information that indicates that the dermal contact pathway can be a significant contributor to overall exposure to contaminated soil. During the 2001 rule revision process, MTCA Science Advisory Board reviewed this issue and concluded that consideration of the dermal contact pathway was consistent with current scientific information. More recently, Ecology has discussed this issue with the MTCA Science Panel who reached similar conclusions. Both reviews indicate that dermal contact can be a significant contributor to overall soil exposure. This is particularly true for semi-volatile hazardous substances. Calculations performed using standard risk assessment methods indicate that dermal exposure represents about 25 - 30% of total soil related exposure for benzo[a]pyrene for a residential exposure scenario (see figure below). The dermal contribution for benzo[a]pyrene and similar contaminants is higher for industrial exposure situations where assumptions include lower soil ingestion rates and higher skin contact areas.



- The revised approach is consistent with current EPA guidance and MTCA statutory requirements: The revised equations are consistent with the current EPA guidance for evaluating the dermal contact pathway. [46] EPA Regions 3, 6, and 9 have developed methods and policies that consider concurrent soil exposure due to soil ingestion, dermal contact and inhalation of vapors and particulates. The EPA Superfund program uses these methods and policies to support cleanup decisions at federal cleanup sites.[47] Consequently, this option promotes consistency with the federal Superfund program and helps to ensure that MTCA cleanup standards comply with the statutory requirement that MTCA cleanup standards.[48]

- The revised approach is consistent with the reasonable maximum exposure (RME) policies in the MTCA rule. In 2009, Ecology worked with the MTCA Science Panel to assess the variability in soil-related exposures. The results indicate that risk-based concentration calculated using the current Method B soil cleanup equations are consistent with the MTCA policy choice to base cleanup levels on the "reasonable maximum exposure" (RME).[49] The RME concept is based on the fact that no two people are identical. The RME is defined as reasonable because it is a product of several factors that are an appropriate mix of average and upper-bound estimates. RME estimates typically fall between the 90th and 99.9 percentile of the exposure distribution.[50] The selection of the percentile used to characterize the RME is a policy choice[51] that takes into account the risk policies, statutory directives and other decision factors.

  The assessment involved the following steps:

  1. Establish equations for calculating soil cleanup levels based on soil ingestion, dermal contact and inhalation of dust and/or vapors.
  2. Define the point estimates and probability distributions to be used in the assessment. We used the point estimates and distributions for key exposure variables.
     - The point estimate for the exposure parameters were based on parameters specified in the MTCA Cleanup Regulation or EPA exposure guidance.

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[46] USEPA. 2004. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Final July 2004. EPA/540/R/99/005.

[47] Risk-based equations, levels and background information found at the following Link: http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm

[48] MTCA states that cleanup standards must be "…at least as stringent as the cleanup standards under section 121 of the federal cleanup law, 42 U.S.C. Sec. 9621, and at least as stringent as all applicable state and federal laws, including health-based standards under state and federal law…"

[49] MTCA defines the RME as "…the highest exposure that can be reasonably expected to occur for a human or other living organisms at a site under current and potential future site use." CERCLA provides a similar definition "…the highest exposure that is reasonably expected to occur at a Superfund site…"

[50] USEPA. 2004. An Examination of EPA Risk Assessment Principles and Practices. EPA/100/B-04/0001.

[51] The use of the RME to establish cleanup levels is a policy choice. With this choice, Ecology decided to base decisions on a high end (but not worst case) estimate of individual exposures. The RME is designed to provide conservative estimate that falls within a realistic range of exposures

- Ecology reviewed the scientific literature and available regulatory guidance to identify what types of distributions have been used to characterize various input parameters. Based on that review, we selected distributions to characterize the variability in key exposure variables.

3. Perform computer simulation (Monte Carlo Analysis) to generate simulated distributions of soil cleanup levels. We then combined the point estimates and probability distributions and produced simulated distributions using several different combinations of probability distributions. We identified the 50th, 90th, 95th and 99th percentile values for each simulated distribution.[52]
4. Compare cleanup levels calculated using the MTCA soil cleanup level equations with the simulated range of cleanup levels. The evaluation results for benzo[a]pyrene are summarized below. Key conclusions:

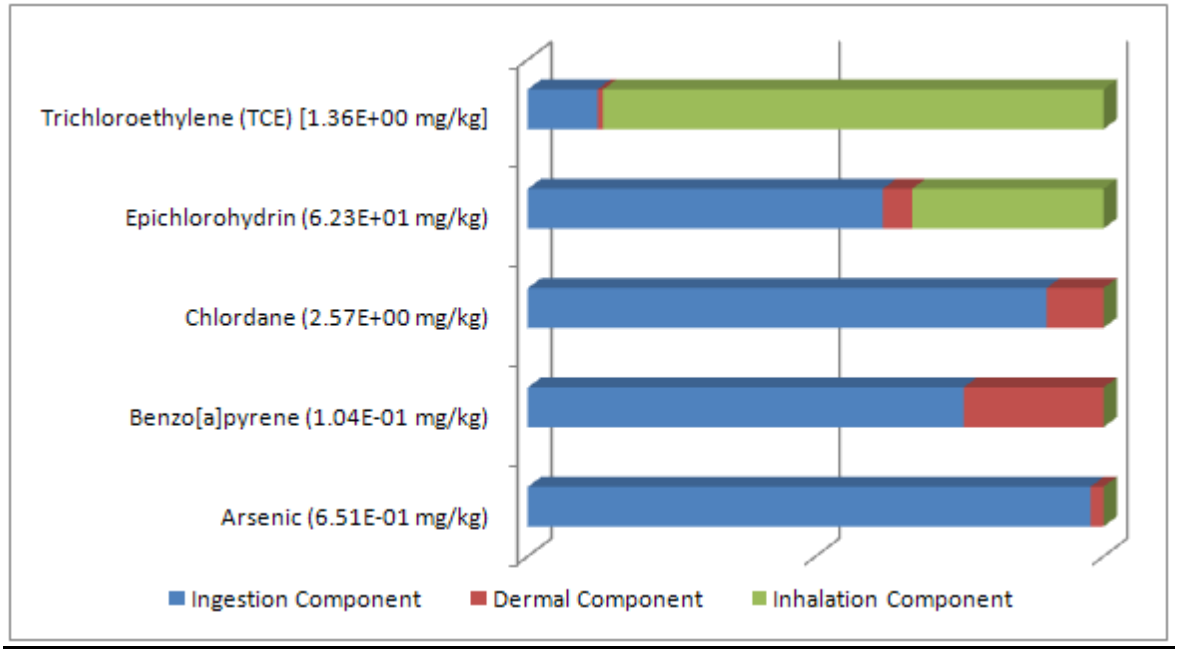
   - Dermal contact contributes almost 30% of total soil-related benzo[a]pyrene exposure. Dermal exposure contributes much less to overall soil exposure for metals and volatile hazardous substances.
   - The risk-based concentration calculated using the Method B soil cleanup equation (soil ingestion only) falls at the lower end of the simulated distribution of risk based concentrations (somewhere between the 1st and 5th percentile of the simulated distribution). This corresponds to the 95th to 99th percentile of the exposure distribution. The results for benzo[a]pyrene are shown below.

Benzo(a)pyrene
Risk-Based Soil Concentrations Corresponding to Percentiles on a Simulated Exposure Distribution (mg/kg)

		Percentiles						
Exposure Model	Mean	10%	5%	1%	Point Estimate	Point Estimate Percentile	Current Method B Soil CUL	Method B Percentile
Child – Soil Ing. (1 Pathway)	No Calculations Performed							
Child – Soil Ing + Dermal (2 Pathways)	1.5E+00	4.0E-01	2.8E-01	1.4E-01	9.8E-02	<1st	1.4E-01	1st
Child – Soil Ing + Dermal + Inhalation (3 Pathways)	1.5E+00	4.0E-01	2.9E-01	1.5E-01	9.8E-02	<1st	1.4E-01	<1%
Adult – Soil Ing. + Dermal (2 Pathways)	1.3E+00	2.1E-01	1.5E-01	8.0E-02	0.0E+00		1.4E-01	<5th
Adult – Soil Ing. + Dermal + Inhalation (3 Pathways)	1.3E+00	2.1E-01	1.5E-01	8.0E-02	0.0E+00		1.4E-01	<5th
Child and Adult – Soil Ing + Dermal (2 Pathways)	6.2E-01	1.8E-01	1.4E-01	8.3E-02	1.5E-02	<1st	1.4E-01	<5th
Child and Adult – Soil Ing + Dermal + Inh (3 Pathways)	6.2E-01	1.9E-01	1.1E-01	5.8E-02	1.5E-02	<1st	1.4E-01	<10th

[52] Reference

- Inhalation of vapors is an important contributor to overall exposure to trichloroethylene and other volatile hazardous substances. This illustrated in the Figure below which indicates that the inhalation pathway contributes over 80 percent of total soil related exposure to trichloroethylene.



- The revised approach is similar to approaches used by environmental agencies in other states. Many states have established rules and guidance for calculating soil cleanup or screening levels based on the direct contact pathway. In most cases, states have adopted procedures that consider concurrent exposure from soil ingestion, dermal contact and (in many cases) inhalation of vapors and soil particulates (see below)

Summary of Soil Cleanup Policies Used in Other Selected States				
State	**Pathways Considered when Establishing Soil Cleanup Levels or Screening Levels for the Direct Contact Pathway**			**Target Risk Level**
	Ingestion	Dermal	Inhalation	
CA	✓	✓	✓	10^{-6}
CO	✓	✓	✓	10^{-6}
MA[53]	✓	✓		10^{-6}
MD[54]	✓	✓		10^{-6}
ME	✓	✓	✓	10^{-5}

[53] http://www.mass.gov/dep/cleanup/laws/prop_s1.htm

[54] http://www.mde.maryland.gov/assets/document/Final%20Update%20No%202.1%20dated%205-20-08(1).pdf

MI[55]	✓	✓	✓ (draft)	10^{-5}
MN	✓	✓	✓	10^{-5}
NJ[56]	✓	✓		10^{-6}
NY	✓	✓	✓	10^{-6}
NM	✓	✓	✓	10^{-5}
OR[57]	✓	✓	✓	10^{-6}
TX	✓	✓	✓	10^{-5}

- The revised approach falls within the range of opinions on this issue expressed by advisory group members: This issue was discussed by the MTCA/SMS Advisory Group as part of a discussion on benzo[a]pyrene cleanup levels at the March 22nd Advisory Group meeting. Ecology also received one comment on this issue which was summarized in the risk assessment scoping paper distributed in 2009.

Summary of Comments on Concurrent Exposure Pathway Issue	
Member	Comment
Timothy Bingham (Dupont Corporate Remediation Group) – Scoping Comments	It is a significant policy issue on whether to evaluate cumulative risks for all exposure pathways versus conservative assumptions for incidental soil ingestion. There are significant uncertainties associated with dermal contact exposure modeling, as well as determining the appropriate dermal toxicity values. We recommend retaining the current approach of focusing on the ingestion pathway, and only including dermal exposure in situations where a given chemical is known to exhibit significant dermal permeability.
MTCA/SMS Advisory Group (March 22, 2010, Meeting Discussion)	Members expressed a wide range of opinions on this issue (always consider both soil ingestion and dermal, consider both soil ingestion and dermal contact for some chemicals, never consider both pathways and base cleanup levels on soil ingestion only). Several members noted the large uncertainties and limited data for dermal absorption.

- The revised approach is unlikely to significantly alter cleanup requirements at most Washington cleanup sites. Ecology is in the early stages of evaluating the impacts of the proposed rule revisions as required by the Washington Administrative Procedures Act. However, the preliminary analysis indicates that revising the soil cleanup level equations to include consideration of the dermal contact pathway will not significantly alter cleanup requirements at most cleanup sites. The rationale for this preliminary conclusion includes:

[55] http://www.michigan.gov/documents/deq/deq-rrd-PART201-DraftSstatLanguageSoilCriteria-9-24-09_293420_7.pdf

[56] http://www.nj.gov/dep/srp/regs/rs/bb_ingest_dermal.pdf

[57] http://www.deq.state.or.us/lq/rbdm.htm

- The primary impact will be at industrial sites where semi-volatile hazardous substances are contaminants of concern and ground water protection is not an important issue.
- There may be small changes in soil cleanup levels for semi-volatile hazardous substances based on unrestricted site use. However, Appendix B indicates that impacts will be small when cleanup levels are rounded to one significant figure. In many cases, soil cleanup levels will be based on other exposure pathways.
- Soil cleanup levels for metals and volatile hazardous substances will not be significantly altered under this option. Cleanup levels for these types of contaminants will often be based on other exposure pathways (See Appendix B). Even in situations where cleanup levels are based on the direct contact pathway, this revision is not likely to significantly alter cleanup level requirements for these types of contaminants. For these contaminants, the dermal pathway is not a significant contributor (relative to soil ingestion) to overall soil exposure. Consequently, cleanup levels based on dermal + soil ingestion are not significantly different than those calculated based on soil ingestion only.
- The standard equations for petroleum mixtures (Equations 740-3 and 745-3) currently include both the soil ingestion and dermal pathway.

6. Appendix A - Glossary of Acronyms Used in This Document

ATSDR	Agency for Toxics Substances and Disease Registry
CalEPA	California Environmental Protection Agency
BaP	Benzo[a]pyrene
CPF	Cancer Potency Factor (Cancer Slope Factor)
CPAH	Carcinogenic Polycyclic Aromatic Hydrocarbons
DOH	Washington Department of Health
EDB	Ethylene dibromide
EPA	U.S. Environmental Protection Agency
HEAST	Health Effects Assessment Summary Tables
IARC	International Agency for Research on Cancer
INH	Inhalation Correction Factor
IRIS	Integrated Risk Information System
IUR	Inhalation Unit Risk
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MTCA	Model Toxics Control Act
NTP	National Toxicology Program
OEHHA	Office of Environmental Health Hazard Assessment
ORNL	Oak Ridge National Laboratory
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	Polychlorinated Biphenyls
PCE	Perchloroethylene/Tetrachloroethylene
PHG	California Public Health Goal for Drinking Water

PPRTV	Provisional Peer-Reviewed Toxicity Values
PQL	Practical Quantitation Limit
RfC	Reference Concentration
RfDi	Reference Dose (inhalation pathway)
RME	Reasonable Maximum Exposure
SAB	Model Toxics Control Act Science Advisory Board
SMS	Sediment Management Standards (Chapter 173-204 WAC)
TCE	Trichloroethylene
TSCA	Toxic Substances Control Act
WHO	World Health Organization

7. Appendix B - Comparison of Soil Cleanup Levels Based on Different Exposure Pathways (WAC 173-340-740)

Ecology is considering revisions to the MTCA rule that would require that soil cleanup levels account for concurrent exposure from soil ingestion and dermal contact. When evaluating those revisions, Ecology is considering how the change will impact cleanup levels based on the direct contact pathway and how those cleanup levels compare with cleanup levels based on other pathways. The following table compares the soil cleanup levels for different exposure pathways.

- Non Cancer Risks - Direct Contact – Soil Ingestion. Equation 740-1 was used to calculate soil cleanup levels that are based on soil ingestion. Ecology used the current oral reference doses published in the EPA Regional Screening Tables and other chemical-specific data (e.g., gastrointestinal absorption fraction) included in Appendix D of the 2001 Concise Explanatory Statement.
- Cancer Risks - Direct Contact – Soil Ingestion. Equation 740-2 was used to calculate soil cleanup levels that are based on soil ingestion. Ecology used the current oral cancer slope factors published in the EPA Regional Screening Tables and other chemical-specific data included in Appendix D of the 2001 Concise Explanatory Statement.
- Non Cancer Risks - Direct Contact – Soil Ingestion + Dermal Contact. Equation 740-4 was used to calculate soil cleanup levels that are based on soil ingestion and dermal contact. Ecology used the current oral reference doses published in the EPA Regional Screening Tables and other chemical-specific data included in Appendix D of the 2001 Concise Explanatory Statement.
- Cancer Risks - Direct Contact – Soil Ingestion + Dermal Contact. Equation 740-5 was used to calculate soil cleanup levels that are based on soil ingestion and dermal contact. Ecology used the current oral cancer slope factors published in the EPA Regional Screening Tables and other chemical-specific data included in Appendix D of the 2001 Concise Explanatory Statement.
- Ground Water Protection. The 3-phase model (Equation 747-1) was used to calculate soil cleanup levels that are based on ground water protection. When performing these calculations, Ecology used the ground water cleanup levels identified in "Draft Revisions MTCA Method A Groundwater Cleanup Levels" and other chemical-specific data included in Appendix D of the 2001 Concise Explanatory Statement.
- Inhalation of Particulates and Vapors. The MTCA exposure parameters and the equations in the EPA Regional Screening Tables were used to calculate soil cleanup levels based on preventing cancer risks greater than 10^{-6} and an hazard quotient of 1 resulting from the inhalation of re-suspended soil particulates and vapors.
- Comments. Ecology is still evaluating whether certain Method A soil cleanup levels need to be updated. This column provides a brief status of those evaluations.

Draft			Direct Contact - Soil Ingestion		Direct Contact - Soil Ingestion + Dermal		Ground Water	Inhalation	Draft	
Chemical	CAS		Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Regional Screening Equations	Current Method A	Comments
Arsenic	7440-38-2		24	0.67	22	0.62	2.9	720	20	Current Method A value based on background. Consideration of dermal contact will not require revisions to Method A.
Benzene	71-43-2		320	18	320	18	0.03	1	0.03	Current Method A value based on ground water protection requirements in WAC 173-340-747(4) and -747(6). 3-phase modeling indicates no changes are needed. Ecology is working on evaluations using the 4-phase model. Consideration of dermal contact will not require revisions to Method A.
Benzo[a]pyrene	50-32-2			0.14 (w/o ELSA) 0.02 (with ELSA)		0.1 (w/o ELSA) 0.02 (with ELSA)	0.8		0.1	Current Method A based on direct contact pathway. Early life stage adjustments result in lower risk-based cleanup levels. Ecology is currently evaluating information on soil background levels. Soil cleanup level using California EPA Inhalation Unit Risk factor is much higher than cleanup level based on other pathways.
Cadmium	7440-43-9		40	NA	37	NA	0.7	1700	2	Current Method A value is based on ground water protection with adjustments for PQL. Ecology is reviewing current analytical limits. Direct contact cleanup levels are lower than 2001 values due to updated RfD. Consideration of dermal contact will not require revisions to Method A.

Draft			Direct Contact - Soil Ingestion		Direct Contact - Soil Ingestion + Dermal		Ground Water	Inhalation	Draft	
Chemical	CAS		Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Regional Screening Equations	Current Method A	Comments
Chromium VI	18540-29-9		240	???	130	???	19	37	19	Current Method A value is based on ground water protection requirements in 747(4). Ecology is currently evaluating how the EPA early life stage adjustments would impact the soil cleanup level based on inhalation exposure. Remaining issues include use of NJDEP oral cancer slope factor.
Chromium III	16065-83-1		120,000	NA	0.0	NA	2000	0	2000	Current Method A value is based on ground water protection requirements in 747(4). No revisions planned. Consideration of dermal contact will not require revisions to Method A.
DDT	50-29-3		40	2.9	37	2.7	0.4	30200	3	Current Method A based on direct contact pathway. No new toxicological data is available. Consideration of dermal contact will not require revisions to Method A.
Ethylbenzene	100-41-4		8000	0.0	7390	0.0	6	6	6	Current Method A value is based on ground water protection in 747(4). 3-phase modeling results indicate no changes are needed. Ecology is still performing evaluations using the 4-phase model. Consideration of dermal contact will not require revisions to Method A.

Draft			Direct Contact - Soil Ingestion		Direct Contact - Soil Ingestion + Dermal		Ground Water	Inhalation	Draft	
Chemical	CAS		Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Regional Screening Equations	Current Method A	Comments
Ethylene dibromide (EDB)	107-06-2		720	0.5	0.0	0.46	0.0003	0.04	0.005	Current Method A value is based on ground water protection with adjustments for PQL. Ecology is reviewing current analytical limits. Consideration of dermal contact will not require revisions to Method A.
Lead	7439-92-1						3000		250	Current Method A value is based on preventing unacceptable blood lead levels. Ecology is currently reviewing implementation issues and comments on March 2010 discussion materials.
Lindane	58-89-9		24	0.9	20	0.8	0.006	10000	0.01	Current Method A value is based on ground water protection requirements in 747(4) (adjusted for PQL). No revisions planned. Ecology is reviewing current analytical limits. Consideration of dermal contact will not require revisions to Method A.
Mercury	7439-97-6		24	NA	18	NA	2	10	2	Current Method A value is based on ground water protection requirements in 747(4). No revisions planned. Consideration of dermal contact will not require revisions to Method A.
Methylene chloride	75-09-2		4800	130	4800	130	0.02	12	0.02	Current Method A value is based on ground water protection requirements in 747(4). No revisions planned. Consideration of dermal contact will not require revisions to Method A.

Draft			Direct Contact - Soil Ingestion		Direct Contact - Soil Ingestion + Dermal		Ground Water	Inhalation	Draft	
Chemical	CAS		Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Regional Screening Equations	Current Method A	Comments
MTBE	1634-04-4						0.1	47	0.1	Current Method A value is based on ground water protection requirements in 747(4). No revisions planned. Consideration of dermal contact will not require revisions to Method A.
Naphthalenes	91-20-3		1600	???	1200	???	4.5	3	5	Current Method A value is based on ground water protection in 747(4). No revisions appear to be needed based on non-cancer risks. However, Ecology is continuing to evaluate requirements based on cancer risks. Consideration of dermal contact unlikely to impact final revisions.
PAHs (carcinogenic)										Ecology is currently reviewing information on soil background levels and comments from the June 2010 Advisory Group meeting on PAH mixtures.
PCB mixtures			8	0.5	6	0.4	0.2	0.4	1	Current Method A value based on applicable state and federal law. Consideration of dermal contact will not require revisions to Method A.
Tetrachloroethylene	127-18-4		800	1.9	740	1.7	0.05	1	0.05	Current Method A value is based on ground water protection requirements in 747(4). 3-phase modeling results indicate no changes are needed. Consideration of dermal contact will not require revisions to Method A.

Draft			Direct Contact - Soil Ingestion		Direct Contact - Soil Ingestion + Dermal		Ground Water	Inhalation	Draft	
Chemical	CAS		Equation 740-1	Equation 740-2	Equation 740-4	Equation 740-5	Equation 747-1	EPA Regional Screening Equations	Current Method A	Comments
Toluene	108-88-3		6400	NA	5900	NA	7	23000	7	Current Method A value is based on ground water protection requirements in 747(4). 3-phase modeling results indicate no changes are needed. Ecology is still performing evaluations using the 4-phase model. Consideration of dermal contact will not require revisions to Method A.
1,1,1-Trichloroethane	71-55-6		72000	NA	71900	NA	2	88000	2	Current Method A value is based on ground water protection requirements in 747(4). 3-phase modeling results indicate no changes are needed. Consideration of dermal contact will not require revisions to Method A.
Trichloroethylene	79-01-6		0	77	0	71	0.03	3	0.03	Current Method A value is based on ground water protection requirements in 747(4). 3-phase modeling results indicate no changes are needed. Ecology plans to review this determination when EPA publishes a final IRIS slope factor. Consideration of dermal contact will not require revisions to Method A.
Xylenes	1330-20-7		16000	NA	15000	NA	9	630	9	Current Method A value is based on ground water protection requirements in 747(4). 3-phase modeling results indicate no changes are needed. Ecology is still performing evaluations using the 4-phase model. Consideration of dermal contact will not require revisions to Method A.