Status Summary of Human Health Risk Issues Discussed at the March 22nd MTCA/SMS Advisory Group Meeting

Human Health Risk Issues (Not Listed in Priority Order)	Initial Ecology Technical Evaluation	Initial MTCA/SMS Advisory Group Review of Issues	MTCA Science Advisory Board/ Science Panel Review	Ecology Evaluation of Implementation Impacts	Ecology Draft Revision	MTCA/SMS Advisory Group Review	Revised Proposal	Other (e.g., additional scientific review, regulatory analyses, etc.)
1. Definition of Carcinogen	√	√	√	Ongoing	√ (4/26)			
2. Toxicological Hierarchy	√	√	√	Ongoing				
3. Early-Life Stage Considerations	√	√	√	Ongoing				
4. Concurrent Soil Exposure Pathways	√	√	√	Ongoing				
5. Lead Cleanup Levels	√	√	√	Ongoing				
6. Inhalation Risks	√	√	√	Ongoing				
7. Method A Ground Water Cleanup Levels	√	√	Revisions to Method A values are impacted by Issues 1-6 & 9					
8. Method A Soil Cleanup Levels	√	√	Revisions to Method A values are impacted by Issues 1-7					
9. Vapor Work Group	√	Vapor Work Group will need to address Issues 1-3 and 6 when reviewing Appendix B of the Draft VI Guidance						

April 26, 2010
Status Update on MTCA Risk Issues Discussed at March 22nd Meeting

1. Definition of Carcinogen (WAC 173-340-200)

- Ecology has concluded that the current definition needs to be revised because EPA published new cancer guidelines in March 2005. The 2005 EPA cancer guidelines replaced the 1986 EPA cancer guidelines referenced in the current MTCA rule.[1]
- Ecology has discussed this issue with the MTCA Science Advisory Board (June 2008), MTCA/SMS Advisory Group (March 2010) and Science Panel (March 2010). Key points from those discussions:
  - Designation as a carcinogen has a large practical impact because cleanup levels based on carcinogenic risks are generally more stringent than cleanup levels based on non-cancer risks.
  - The 2005 EPA cancer guidelines are consistent with current scientific information.
  - EPA is resource-limited. Staffing and politics have delayed cancer assessments for several high profile chemicals.
  - The National Toxicology Program and the International Agency for Research on Cancer are recognized as authoritative scientific bodies on cancer assessment issues (hazard evaluation). Their evaluation criteria are similar to the weight of evidence criteria used by EPA.
- Ecology is considering the following changes to the definition of carcinogen:

  *"**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.*

- Next steps:
  - Complete comparison of carcinogens identified using current definition and draft revision;
  - Discuss with Vapor Work Group as they review Appendix B of the draft vapor intrusion guidance;
  - Distribute to MTCA/SMS Advisory Group for review and discussion during May and June.

[1] **"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.

2. Hierarchy of Toxicological Information (WAC 173-340-708)

- The MTCA cleanup level equations include a series of exposure and toxicity parameters. The MTCA rule identifies a hierarchy of toxicity information sources. For example, WAC 173-340-708(8) states:

  For purposes of establishing cleanup levels and remediation levels for hazardous substances under this chapter, a carcinogenic potency factor established by the United States Environmental Protection Agency and available through the IRIS data base shall be used. If a carcinogenic potency factor is not available from the IRIS data base, a carcinogenic potency factor from HEAST or, if more appropriate, from the NCEA shall be used.

- Ecology has discussed this issue with the MTCA/SMS Advisory Group (March 2010) and Science Panel (March 2010). Key points from those discussions:
  - The Integrated Risk Information System (IRIS) remains the "gold standard". However, several members acknowledged that IRIS updates are resource intensive and can take years to complete.
  - HEAST should not be used as a general source of toxicological parameters. However, the HEAST values for some chemicals still reflect the most current scientific information.
  - Ecology should maintain a high standard for use of toxicity data. EPA hierarchy should be reviewed. MTCA is a very restrictive rule already – this is one of the toughest cleanup rules in the country. Therefore, lowering cleanup levels using lower quality toxicity data may create problems.
  - The Regional Screening Tables (RST) prepared by scientists from several EPA Regions and the Oak Ridge National Laboratory are commonly used by risk assessors. The tables include toxicological information from a wide range of sources with varying degrees of scientific and public review. Both the Science Panel and MTCA/SMS advisory group stated that external review was important.
  - The Science Panel said the RST provide a reasonable starting point for updating the Method A values. However, the rationale for values will need to include more than a reference to the RST.
  - The Science Panel said that internal peer review within EPA or other agencies was not equivalent to external peer review (as done when updating the IRIS toxicity values).
  - The panel appeared to support the use of the toxicity values in the RST if Ecology provided for external review prior to MTCA use. The panel discussed a process where Ecology would use the RST values as the basis for annual updates to the CLARC database. Under this process, Ecology would publish draft updates to the CLARC database, review public comments and finalize changes to the CLARC values. The panel thought annual updates were sufficient.
- Ecology is considering changes to the hierarchy of toxicological information:
  - The IRIS data base should continue to be the primary basis for cleanup levels/remediation levels.
  - Ecology plans to remove references to the HEAST database.
  - Ecology is considering a process where toxicity values would be published and annually updated in the CLARC database (similar to approach discussed at March 25th Science Panel meeting)
- Next steps:
  - Prepare draft rule revision based on approach discussed at the March 25th Science Panel meeting;
  - Identify practical implications of draft approach using the chemicals of concern identified in Appendix B of the draft vapor intrusion guidance document;
  - Discuss with Vapor Work Group as review Appendix B of the draft vapor intrusion guidance;
  - Distribute to MTCA/SMS Advisory Group for review and discussion during May and June.

3. Early Life Stage Considerations (Multiple Rule Sections)

- Numerous studies over the last 20 years indicate that exposures to carcinogens early in life have a much greater impact on lifetime cancer risks than exposures later in life. EPA and California EPA have developed scientific procedures and policies to account for this increased susceptibility.
- Ecology has prepared several documents to support discussions with the Science Panel. The Science Panel completed their review of this issue at the March 25th meeting and reached several conclusions:
  - The panel reviewed the EPA guidance on early life stage considerations and concluded that the guidance is consistent with current scientific information. They recommended that Ecology consider this information when revising the MTCA rule.
  - The panel recommended that Ecology consider early life susceptibility when establishing cleanup levels for all carcinogens (not just those that act through a mutagenic mode of action). They noted that there are numerous definitions/technical challenges associated with determining whether a chemical acts through a mutagenic mode of action.
  - The panel concluded that the methodologies in the USEPA and California EPA guidance documents are consistent with current scientific information.
- Ecology presented this issue at the March 22nd MTCA/SMS Advisory Group meeting (using BaP to illustrate the method). Key points include:
  - Members expressed a wide range of preferences ranging from no adjustments, adjustments for carcinogens acting through a mutagenic mode of action (EPA) and adjustments for all carcinogens (California EPA).
  - Several members expressed concerns about workability. Members suggested that Ecology fully evaluate the implications of this approach (including discussions with Ecology site managers).
  - One member said Ecology should revisit the 2007 policies dealing with PAH mixtures. He noted that the rationale for Ecology's 2007 policy on PAH mixtures was based (in part) on the fact that the MTCA cleanup level equations did not take into account early life stage susceptibility.
  - One member submitted well-thought-out comments on this issue. Key points include: (1) Expanding the use of this approach to non-mutagenic carcinogens would be contrary to EPA guidance and, given the substantial cost impact of such a change, does not appear to be justified; (2) The toxicity factors for BaP and other carcinogens already include a number of health protective factors. The MTCA rule also includes a number of health protective policies. Additional generic factors do not appear to be justified given the high degree of conservatism already built-in to the toxicity factors/MTCA rule. (3) The EPA weighting factors used in the BaP example do not appear to be based on toxicological characteristics of PAHs; (4) Many of the studies used to support this approach involved exposures that are much higher than environmental exposures. Extrapolation is uncertain at best; (5) Deriving cleanup levels that are substantially below background does not appear to be useful; and (6) Ecology should consider EPA's draft guidance for characterizing PAH mixtures.
- Next steps:
  - Review/follow-up on advisory group comments (Still time to submit comments);
  - Evaluate implementation impacts (# exceedances, impacts on sites, periodic reviews, etc);
  - Discuss options with Ecology site managers and TCP Management Team;
  - Prepare risk management recommendations for MTCA/SMS Advisory Group review.

4. Concurrent Soil Exposure Pathways (WAC 173-340-740 and -745)

- The current MTCA rule provides a difficult to implement option for considering dermal exposure. Ecology is evaluating this issue as we look at ways to simplify/clarify MTCA rule provisions.
- Ecology has prepared several documents to support discussions with the Science Panel and MTCA/SMS Advisory Group.
    - The Science Panel discussed this issue at meetings held in June and November 2009. No further discussion planned. In general, the Science Panel concluded that Ecology's exposure calculations are consistent with current scientific information.
    - The MTCA/SMS Advisory Group discussed this issue in relation to potential revisions to cleanup levels for benzo[a]pyrene. Members expressed a range of opinions (always consider dermal contact, never consider dermal contact, consider dermal contact for selected chemicals). Some members noted the large uncertainty and limited dermal absorption information. Several members also recommended that Ecology consider the cumulative impact of this potential change and other potential changes being considered by the Department.
- Next steps:
    - Prepare draft rule revisions taking into account advisory group comments, current rule framework and impacts of other potential rule revisions.

5. Lead Cleanup Levels (WAC 173-340-708, -720, -740, and -745)

- The current MTCA Method A soil cleanup standard for lead is 250 mg/kg. This standard is applicable to all types of land uses including current and potential future residential properties, schools, parks and other areas where young children may be present on a regular basis.
- Ecology believes that it is appropriate to review the MTCA standard in light of scientific information published since the 2001 rule revisions. In particular, there have been several studies completed since 2001 that have reported adverse health effects at blood lead levels below 10 ug/dL (the basis for the current MTCA standard). In 2004, the MTCA Science Advisory Board recommended that Ecology review whether the underlying basis for the lead cleanup level remains consistent with the MTCA statutory directives.
- Ecology distributed policy options to MTCA/ SMS Advisory Group in March 2010. In that paper, Ecology outlined several scientific and policy reasons to support a revised standard between 100 - 150 mg/kg. The MTCA/SMS Advisory Group discussed this issue at the March 22nd meeting. Subsequent to that meeting, two members provided well-thought-out comments on this issue. Comments include:
    - The IEUBK model has a strong scientific and regulatory foundation. Ecology should revise the rule to allow the IEUBK model to be used to establish site-specific cleanup levels.
    - Use of an incremental exposure model is consistent with MTCA approach for other substances. Ecology should also consider new information on lead exposure
    - There was a wide range of opinion on the target blood lead level. Some recommended that Ecology use a lower target blood lead concentration to update the MTCA standards. Recommendations range from 1 ug/dL to 5 ug/dL. . Others thought it was premature to use a lower target blood lead concentration to establish MTCA cleanup levels. Federal guideline remains 10 ug/dL and there is no consensus on alternative value. MTCA standard remains one of the most stringent state standards.
    - It makes sense to use a 10% probability of exceedance if Ecology elects to use a lower target blood lead concentration. This is similar to the approach used by the Office of Environmental Health Hazard Assessment (OEHHA) when developing the California soil screening values.
    - California soil value is a screening value – not a cleanup level. Wisconsin has adopted a soil cleanup level of 250 mg/kg for non-industrial sites (50 mg/kg value has limited applicability).
    - Evaluation of implementation impacts of new standard is good first step. Ecology needs to refine this analysis since all lead sites do not have arsenic issues.
- Next steps:
    - Modify MTCA rule to allow use of IEUBK model to establish site-specific cleanup levels;
    - Complete sensitivity analyses;
    - Review MTCA/SMS Advisory Group comments on policy options (there is still time to submit comments);
    - Refine/expand analysis of implementation impacts with focus on lead-only situations (e.g., roadside leads, implications for areas near buildings with lead-based paint, shooting ranges);
    - Develop revised proposal for review by MTCA/SMS Advisory Group (May or June meeting);
    - Review by Science Panel (late summer/fall).

6. EPA Inhalation Risk Assessment Guidelines (WAC 173-340-708 and -750)

- 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*[2] (referred to as Part A). The current MTCA equation for air cleanup levels based on carcinogenic effects is summarized in Figure 1 below. The MTCA rule includes similar procedures for calculating air cleanup levels based on non-cancer effects.
- EPA published revisions to the Superfund procedures for evaluating health risks resulting from inhalation exposure in early 2009. The updated guidance (*Risk Assessment Guidance for Superfund: Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*[3]) is attached to this review (See Attachment 1). Part F is designed to promote consistent implementation of EPA's procedures for assessing inhalation risks[4]. Key differences between the MTCA rule and the updated EPA guidance include the following:
  - 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.
  - EPA recommends that risk assessors not use inhalation toxicity values generated using simple route-to-route extrapolation.
- Ecology discussed the EPA guidance and implications for the MTCA rule at the March 25th Science Panel meeting. There was general agreement that the EPA guidance document is consistent with current scientific information and provides a sound basis for rule revisions.
- Ecology is considering revisions to the MTCA cleanup rule based on the EPA inhalation risk assessment guidance (Part F). These revisions will be discussed with Vapor Work Group and include:
  - Modify the equations used to calculate air cleanup levels. Draft revisions for Equation 750-2 (cancer risks) are shown below. Similar revisions would be made to Equation 750-1 (non-cancer risks).
  - Add new definitions for inhalation unit risk factor and reference concentration. Ecology plans to use the EPA definitions provided in the Part F guidance.

Draft Revision to Equation 750-2 Based on EPA Inhalation Risk Guidance

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

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)

[2] EPA. 1989. Risk Assessment Guidance for Superfund. Volume I. Part A. Office of Emergency and Remedial Response, Washington D.C. EPA-540/1-89/-002.
[3] EPA. 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.
[4] EPA.1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry

7. Updates to Method A Ground Water Cleanup Levels (WAC 173-340-720)

- Ecology has completed a preliminary review of the Method A Tables. Ecology needs to work through issues 1-6 and 9 before developing draft revisions to the Method A values. .

8. Updates to Method A Soil Cleanup Levels (WAC 173-340-740 and -745)

- Ecology has completed a preliminary review of the Method A Tables. Ecology needs to work through issues 1-7 before developing draft revisions to the Method A values. .

9. Vapor Work Group

- Ecology has formed a six-member Vapor Work Group. Members include:
  - Marcia Bailey (EPA)
  - Patty Boyden (Port of Vancouver)
  - Mike Ehlebracht (Hart Crowser)
  - Priscilla Tomlinson (Integral Consulting)
  - Barbara Trejo (Department of Health)
  - Chris Waldron (Pioneer Technologies Corporation)
- The first meeting will be held on May 13th at the Ecology Headquarters Building (2-4 pm). We are structuring the process around 3-4 meetings. Ecology/work group members will provide status reports to MTCA/SMS Advisory Group.
- Topics to be addressed by the Vapor Work Group include:
  - Guidance Document– Help Ecology resolve remaining issues associated with finalizing the guidance document.
  - Guidance – Appendix B - Screening Levels – Help Ecology resolve several issues including application of current EPA Inhalation Risk Guidance, use of non-IRIS toxicity values and definition of carcinogen).
  - Rule Revisions – Work with Ecology to develop new and modified rule provisions. Revisions may include new sections + revisions needed to support VI decision-making, This may include revisions to Definitions (Section 200), Human Health Risk Assessment Procedures (Section 708) and Cleanup Standards to Protect Air Quality (Section 750).