

Potential Issues for Five-Year Review of the MTCA Cleanup Regulation

Introduction and Purpose

The purpose of this paper is to compile a list of technical and policy issues The Department of Ecology (Ecology) is considering as part of its evaluation of whether, and how, to modify the MTCA Cleanup Regulation during the upcoming five-year rule review.

Ecology is asking the Science Advisory Board (SAB or Board) to review this issue paper and provide advice on:

- Are there other issues Ecology should consider as part of its five-year review?
- What issues does the Board consider the highest priority for Ecology to consider?
- What sources of information are Board members aware of that would help with Ecology's evaluation of these issues?

Background

WAC 173-340-702 (11) states the Department of Ecology will review and, as appropriate, update WAC 173-340-700 through 173-340-760 at least once every five years.

Ecology plans to start the five-year rule review process in 2007. As part of this review, Ecology plans to hold several scoping meetings to get recommendations on issues and rule provisions.

Ecology will review the public comments and then decide whether to begin a process to amend the MTCA rule and what issues will be addressed during the rulemaking process. When selecting issues, Ecology will consider the following:

- Are the rule revisions needed to promote more effective cleanup actions?
- Is the issue a frequently-encountered issue that impacts cleanup actions at a large number of sites?
- Are the rule revisions needed to incorporate new scientific or regulatory information?
- What issues are most important to individuals and organizations that have provided scoping comments?
- What level of resources will be needed to address the issue?
- Are rule revisions the most appropriate mechanism for addressing the issue?

Range of Potential Issues Identified During Rule Implementation

The MTCA Cleanup Regulation was amended in 2001. Since that time, Ecology staff, cleanup proponents, the MTCA Science Advisory Board, and others have identified a wide range of issues that could be addressed during the five-year rule review.

- General Issues: There are several broad issues or questions that apply to the rule in general. These include:

- Are there parts of the rule that are particularly confusing and could benefit from simplification or reorganization?
- Do the methods for establishing cleanup levels provide a reasonable level of protection given the uncertainty and variability in exposure and toxicity?
- Issues Associated with Areawide Soil Contamination: The Area-wide Soil Contamination Task Force completed their report and recommendations in June 2003. The Task Force recommended that Ecology revise the MTCA Cleanup Regulation to support implementation of the Task Force recommendations. The Toxics Cleanup Program agreed to evaluate the need for rule revisions. Issues include:
 - Should the rule be revised to clarify when owners/operators of individual properties located within larger areas of contaminations must report information on arsenic and lead contamination?
 - Should the rule be revised to clarify when Ecology will list individual properties located within larger areas of contaminations?
 - Should the rule be revised to clarify how and when Ecology will exercise enforcement discretion at individual properties located within larger areas of contamination?
- Issues Associated with Identifying, Evaluating and Regulating Hazardous Substances based on Carcinogenic Effects: The MTCA rule includes a definition of “carcinogen” and procedures for calculating cancer slope factors that are based on the 1986 EPA cancer guidelines. On March 29, 2005, EPA issued two new guidance documents. The first document, *Guidelines for Carcinogen Risk Assessment*, replaces the 1986 cancer risk guidelines. The 2005 guidelines include a new set of weight of evidence descriptors that replace the previous system (A, B1, B2, C and D) and new procedures for calculating cancer slope factors. The second document, *Supplementary Guidance for Assessing Susceptibility from Early Life Stage Exposure to Carcinogens*, provides guidance on assessing early life exposure¹ to carcinogens. There are several issues associated with the identification, evaluation and regulation of hazardous substances based on carcinogenicity.
 - Should the definition for “carcinogen” be revised and updated based on the 2005 EPA cancer guidelines?
 - Should the procedures² for calculating cancer slope factors be revised and updated based on the 2005 EPA cancer guidelines?

¹ Generally, cancer risks from childhood exposures to chemicals are evaluated based on methods that evaluate the chemical exposure to adults. This approach assumes chemicals are equally potent for inducing cancer risks from exposures in both early life and later life stages. For a selected group of chemicals with a mutagenic mode of action, available studies indicate higher cancer risks resulting from a given exposure occurring early in life when compared with the same amount of exposure during adulthood.

² The current rule specifies procedures for calculating a cancer slope factor that includes the use of the linearized multistage model. It is not clear whether the current level of detail is necessary given that Ecology has never developed a cancer slope factor using the linearized multi-stage model.

- Should the rule be revised to incorporate procedures that account for the potential for early-life exposure making a greater contribution to cancers appearing later in life?
- Issues Associated with Identifying, Evaluating and Regulating Hazardous Substances based on Non-Cancer Health Effects: The MTCA rule establishes procedures for establishing cleanup levels based on non-cancer effects using chemical specific reference doses and default exposure parameters. Cleanup levels are based on a hazard quotient of one (1). The rule establishes a hierarchy of reference dose values from EPA databases and procedures for calculating reference doses for situations where EPA has not developed a reference dose. There are several issues associated with the evaluation and regulation of hazardous substances based on non-cancer health effects:
 - Should the rule be revised to incorporate procedures for establishing reference doses or equivalent toxicity measures for chemicals where it is not possible to identify population thresholds for adverse effects?
 - Should the rule be revised to identify that the Benchmark Dose (BMD) methodology may be used to establish reference doses by applying uncertainty factors and modifying factors to the benchmark dose?
 - Should the rule be revised to allow for the use of a hazard quotient (or relative source contribution) less than one when there are significant non-site related background exposures?
 - Should the rule be revised to identify additional information sources or databases for toxicity values (for example, CalEPA and Oak Ridge National Laboratory)?
- Issues Associated with Establishing Ground Water Cleanup Levels: The MTCA rule includes default exposure scenarios and equations for establishing cleanup levels for ground water that is a current or potential source of drinking water. However, the rule does not provide similar methods for establishing cleanup levels for non-potable ground water. Potential rulemaking issues include:
 - Should the rule be amended to incorporate EPA's approach for accounting for concurrent exposure through drinking water and vapors (versus MTCA's current approach of using an inhalation correction factor of 2 for all volatile chemicals)?
 - Should the rule be amended to provide default methods for developing cleanup levels for non-potable ground water?
- Issues Associated with Establishing Surface Water Cleanup Levels Based on Bioaccumulation of Contaminants in Fish and Shellfish Tissue: The MTCA rule provides for the use of a bioaccumulation factor when establishing surface water cleanup levels. Potential rulemaking issues include:
 - Use of Bioaccumulation Factors: The MTCA rule specifies that bioconcentration factors (BCFs) used to prepare water quality criteria under Section 304 of the Clean Water Act shall be used when establishing cleanup levels and remediation levels based on preventing consumption of contaminated fish and shellfish. Many

regulatory agencies now use bioaccumulation factors (BAFs) when evaluating the health risks associated with accumulation of contaminants in fish tissue. BAFs take into account fish uptake via the gills and trophic transfer.

- Should the rule be updated to require or allow the use of BAFs to establish surface water cleanup levels?
- Should the rule be updated to reference other sources of BAF values?
- Fish Consumption Rates: The MTCA rule includes a default fish consumption rate that is used to calculate surface water cleanup levels. The MTCA default value is based on surveys of recreational fishers performed in the 1980's. More recent studies indicate that the MTCA default value may not provide an adequate basis for evaluating the health risks for high exposure groups (for example Native American populations, subsistence fishing, and Asian Pacific Islanders).
 - Should the rule be revised to provide a procedure or process for basing requirements on high fish-consuming populations?
- Issues Associated with Methods for Establishing Soil Cleanup Levels: The MTCA rule includes equations for calculating soil cleanup levels for unrestricted and industrial land uses. The standard equations for calculating Method B and C soil cleanup levels are based on incidental soil ingestion. Concurrent exposure resulting from dermal contact is only considered under modified Method B/C or for petroleum contamination. The rule also includes (1) narrative standards for other pathways (e.g. accumulation of hazardous substances grown in contaminated soils, vapor intrusion) and (2) procedures for establishing cleanup levels to prevent ground water contamination and adverse effects on plants and wildlife. Potential rulemaking issues include:
 - Should the rule be revised to incorporate life-stage exposure pathways and parameters corresponding to critical windows of susceptibility for the developing fetus, infants and young children?
 - Should the rule be revised to include exposure parameters based on acute exposures?
 - Should the rule be revised to update the exposure scenarios and/or exposure parameters based on new scientific information or regulatory guidance?
 - Should the standard methods for establishing soil cleanup levels based on direct contact be revised to reflect concurrent exposure via incidental soil ingestion and dermal contact?
 - Should the rule be revised to provide methods and requirements for establishing cleanup levels based on preventing exposures resulting from the accumulation of hazardous substances grown in contaminated soils?
 - Should the rule be revised to provide specific methods and requirements for establishing cleanup levels based on preventing the migration of volatile hazardous substances into buildings?

- Issues Associated with Compliance Methods for Soil and Ground Water Cleanup Standards: The MTCA rule includes a three-part decision rule³ for demonstrating compliance with soil and ground water cleanup standards. There are several potential rulemaking issues:
 - Use of 2 mm Size Fraction: Soil particle size may influence contaminant concentrations and potential exposures to contaminants because the surface area of the particles increases with decreasing soil particle size. While the 2 mm particle size is a convenient size, some regulatory agencies use other particle sizes. For example, EPA's lead models are based on soil passing a #60 sieve (0.25 mm). **Should the rule be revised to require the use of a different size fraction to evaluate compliance with soil cleanup standards for lead and/or other hazardous substances?**
 - Flexibility in Use of the 2 Times and 10% Rules: MTCA's three part decision rule for compliance operates in tandem where failure of one element of the decision rule translates to failure for compliance. This can result in standards that are difficult to meet at some sites. **Should the rule be amended to provide the flexibility to use a factor greater than two (2) or 10% when evaluating individual sample results?**
 - Use of Land's Method: The Land's method specified in WAC 173-340-740 (7) (d) (i) (A) is the default statistical procedure to determine compliance for lognormally distributed data for calculating the 95% confidence limit on the true mean soil concentrations. This method has been criticized by some as being inappropriate for evaluation of data at contaminated sites. There are alternative statistical methods available to calculate the 95% confidence limit on mean soil concentrations. **Should the rule be amended to use a different default statistical method?**
 - Exposure and Decision Units Defined: MTCA does not define exposure or decision units relative to the scale or size of the site or level of protectiveness. The definition of an exposure or decision unit is statistically important when composite sampling and analysis is conducted over a very large site to determine the upper confidence limit on the mean soil concentrations. Composite sampling will artificially reduce the upper confidence limit on the mean. In consideration of compliance for calculating an upper confidence limit on the mean soil concentrations, should MTCA be modified to clarify the definition of exposure or decision units relative to the scale or size of site?
- Issues Associated with the Evaluation of the Vapor Intrusion Pathway: The science for modeling and measuring vapor migration has evolved considerably over the last several years. This work indicates that the intrusion of contaminated vapors from

³ The MTCA rule establishes a three-part decision rule for evaluating compliance with cleanup standards for soil [WAC 173-340-740 (7) (e)] and groundwater [WAC 173-340-720 (8) (e)]. The three part decision rule includes:

- The upper 95% confidence limit on the true mean (average) must be less than the cleanup level;
- No sample concentration can be more than twice the cleanup level; and
- Less than 10% of the samples can exceed the cleanup level.

ground water or soil into buildings may be a significant pathway of exposure to hazardous volatile organic chemicals. Currently, The MTCA rule requires evaluation of the vapor exposure pathway for soils in only very limited circumstances. Ecology is in the process of preparing guidance for evaluation of the vapor intrusion pathway. **Several technical and policy issues may come out of that guidance development process that may lead to consideration of rule amendments.**

- Issues Associated with the Sediment Cleanup Standards: WAC 173-340-760 states that "...[i]n addition to complying with the requirements in this chapter, sediment cleanup actions conducted under this chapter must comply with the requirements of chapter 173-204 WAC..." There are several potential rulemaking issues associated with the integration and coordination of requirements in the SMS and MTCA rules:
 - Should the rule be revised to clarify how the MTCA human health risk policies (including consideration of multiple hazardous substances and multiple exposure pathways) apply to sediment cleanup actions?
 - Should the rule be revised to clarify the relationships between cleanup standards established under WAC 173-204-560, Method B and C cleanup levels and remediation levels established pursuant to WAC 173-340-355?
 - Should the rule be revised to clarify the relationship between the cleanup action requirements in WAC 173-340-360 and sediment cleanup action requirements in WAC 173-204-570?
- Updates for Method A Cleanup Levels: The MTCA rule includes several tables that provide cleanup levels. Potential issues related to these tables include:
 - Should the Method A soil cleanup level for lead (250 mg/kg for unrestricted site use) be reevaluated in light of new scientific information that indicates that exposures below 10 ug/dL pose a significant threat to young children?
 - Should the Method A industrial soil cleanup level for lead (1000 mg/kg) be reevaluated in light of new scientific information on relationships between adult lead exposure and several adverse health effects (for example, cardiovascular, neurological, reproductive effects, and adverse effects on the developing fetus)?
 - Some of the Method A table cleanup levels represent urban - area background concentrations (such as arsenic) rather than natural background concentrations. When Method A table cleanup levels defer to background concentrations, should MTCA Method A tables be modified to represent natural background concentrations rather than urban area background?
 - Should the Method A soil cleanup levels for trichloroethylene be reevaluated based on the vapor intrusion pathway?
- Terrestrial Ecological Cleanup Levels: The 2001 MTCA rule amendments provided a new process for evaluating the impact of contamination on terrestrial plants and animals. Potential issues related to these provisions include:
 - Should the Ecological Screening values in Tables 749-2 and 749-3 be reevaluated based on EPA Ecological Soil Screening Levels?

- Remedy Selection: The MTCA rule requires remedies be evaluated for protectiveness of human health provides limited guidance in how to conduct such an evaluation and consideration of land use when developing cleanup alternatives.
 - Should the rule amendments specify more specific procedures for evaluating the protectiveness of remedies?

References

Environmental Protection Agency. 2005a. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum. Washington DC. EPA/630/P-03/001F.

Environmental Protection Agency. 2005b. Supplementary Guidance for Assessing Susceptibility from Early Life Stage Exposure to Carcinogens. Risk Assessment Forum. Washington DC. EPA/630/R-03/001F.