Background Document

For The
Proposed Amendments to the
Model Toxics Control Act
Cleanup Regulation
Chapter 173-340 WAC

Washington State Department of Ecology
Toxics Cleanup Program

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List of Abbreviations and Acronyms

General

ARARs	Applicable or Relevant and Appropriate Requirements
ASTSWMO	Association of State & Territorial Solid Waste Management Officials
B(a)P	Benzo[a]pyrene
Cal EPA	California Environmental Protection Agency
CLARC	Cleanup Levels and Risk Calculation Guidance Document
CDDs	Polychlorinated dibenzo-p-dioxins
CDFs	Polychlorinated dibenzofurans
Ecology	Washington Department of Ecology
EPA	United States Environmental Protection Agency
HpCB	Heptachlorobiphenol
HpCDD	Heptachlorodibenzo-p-dioxin
HpCDF	Heptachlorodibenzofuran
HxCB	Hexachlorobiphenyl
HxCDD	Hexachlorodibenzo-p-dioxin
HxCDF	Hexachlordibenzofuran
IRIS	Integrated Risk Information System
MTCA	Model Toxics Control Act
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
PeCB	Pentachlorobiphenyl
PeCDD	Pentachlorodibenzo-p-dioxin
PeCDF	Pentachlorodibenzofuran
PEF	Potency Equivalency Factor
OCDD	Octachlorodibenzo-p-dioxin
ODCF	Octoachlorodibenzofuran
RPF	Relative Potency Factor
TCDD	2, 3, 7, 8-Tetrachlorodibenzo-p-dioxin
TeCB	Tetrachlorobiphenyl
TCP	Toxics Cleanup Program
TEC	Toxicity Equivalent Concentration
TEF	Toxicity Equivalency Factor
TEQ	Total toxicity equivalent concentration or total toxicity equivalence
WAC	Washington Administrative Code
WHO	World Health Organization
10^{-6}; 1 X 10^{-6}	One in one million risk level
10^{-5}; 1 X 10^{-5}	One in one hundred thousand risk level

Weight and Concentration Units

kg	Kilogram
g	Gram, one thousandth of a kilogram, 1 X 10^{-3} kg
mg	Milligram, one-millionth of a kilogram, 1 X 10^{-6} kg
µg	Microgram, one-billionth of a kilogram, 1 X 10^{-9} kg
ng	Nanogram, one-trillionth of a kilogram, 1 X 10^{-12} kg
pg	Picogram, one-quadrillionth of a kilogram, 1 X 10^{-15} kg

ppm	Parts per million (mg/kg; mg/L)
ppb	Parts per billion (µg/kg; µg/L)
ppt	Parts per trillion (ng/kg; ng/L)
ppq	Parts per quadrillion (pg/kg; pg/L)

1 Introduction

1.1 Overview

The Department of Ecology (Ecology) is proposing to amend the Model Toxics Control Act (MTCA) Cleanup Regulation (Chapter 173-340 WAC). This rulemaking will update and clarify the policies and procedures for establishing cleanup levels for mixtures of polychlorinated dibenzo-p-dioxins/ polychlorinated dibenzofurans, polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs).

The MTCA Cleanup Regulation currently specifies that cleanup proponents may use an Environmental Protection Agency (EPA) methodology to characterize mixtures of dioxins and furans. In 2001, Ecology published guidance explaining how to use the EPA methodology to establish cleanup levels for dioxin and furan mixtures. A recent lawsuit raised issues related to the applicability of this guidance under the regulation. At the same time, several environmental groups petitioned Ecology to incorporate the guidance into the rule. In response to these events, Ecology decided to explicitly define in the rule how the federal methodology should be used within the MTCA regulatory framework.

Ecology has prepared this document to assist public review and discussion of the MTCA rule revisions being considered by the Toxics Cleanup Program (TCP). Specifically, the document is designed to achieve two main purposes:

- Describe the revisions that Ecology plans to make to the MTCA Cleanup Regulation.
- Describe the key rulemaking issues that Ecology considered when preparing the proposed rule revisions, options for resolving those issues and Ecology's rationale for choosing particular options when preparing the draft rule revisions.

1.2 Reasons for the Rulemaking

The Model Toxics Control Act was passed by Washington voters in November 1988. The law establishes the basic authorities and requirements for cleaning up contaminated sites. Ecology originally adopted cleanup standards in February 1991. Ecology completed significant changes to the cleanup standards in February 2001.

Under the revised rule, a person undertaking a cleanup action may use the Environmental Protection Agency's toxicity equivalency factor (TEF) values and methodology when assessing dioxin and furan mixtures. In November 2001, Ecology published a guidance document, the Cleanup Levels and Risk Calculations (CLARC), that explains how to use the TEF methodology when establishing cleanup levels.

In November 2005, the Rayonier Corporation filed a lawsuit challenging Ecology's use of the guidance document at the Port Angeles mill site. Rayonier's argument was the MTCA rule requires Ecology to establish cleanup levels for each dioxin congener. This was based on using a cancer risk level of one-in-one million (or 10^{-6}), as opposed to applying 10^{-6} risk level to the whole mixture.

In April 2006, Ecology settled the lawsuit and agreed that Rayonier's approach was also a plausible interpretation of the current MTCA rule. Ecology agreed to settle the lawsuit. Since neither the current MTCA rule nor the federal guidance referenced in the MTCA rule clearly requires the procedures in the CLARC guidance.

Along with settlement discussions, several environmental groups presented a rulemaking petition to Ecology in March 2006. These groups requested that Ecology amend the rule to clarify that policies and procedures in the Ecology guidance be used when establishing cleanup levels for dioxins/furans and other similar mixtures.

Ecology reviewed the rulemaking petition and decided to begin a focused rulemaking process to address the issues raised in the lawsuit and rulemaking petition. Specifically, Ecology decided to define in the rule how the federal methodology should be used within the MTCA regulatory framework. Furthermore, Ecology decided that amending the MTCA rule to explicitly define key policy choices is preferable to repeatedly resolving those policies on a site-specific basis.

1.3 Rulemaking Process

Ecology began the rulemaking process on June 7, 2006. This process began with filing the CR-101 with the Office of the Code Reviser. Later that month, Ecology prepared draft rule language that was distributed to interested parties for review and comment. Ecology held several meetings to discuss the draft rule language and key rulemaking issues.

Ecology received many comments on the draft rule language. Ecology also held four meetings with the MTCA Science Advisory Board to discuss key rulemaking issues. Ecology has modified the June draft rule language based on the comments received from the public and the MTCA Science Advisory Board.

Ecology published the proposed rule for formal public comment on April 4, 2007. Public hearings will be held in May. Ecology will then review the public comments and make a final decision on the rule amendments.

1.4 Relationship to Five-Year Rule Review

Ecology's actions to clarify the methods and procedures for evaluating mixtures of dioxins/furans, PAHs, and PCBs is the first phase of a two-phase rulemaking process. In the second phase of the process, Ecology will conduct the five-year review process specified in the MTCA rule. WAC 173-340-702 (11) states Ecology will review and, as appropriate, update WAC 173-340-700 through 173-340-760 at least once every five years.

Ecology plans to initiate the five-year rule review process in 2007 following the completion of this focused rulemaking. As part of the review process, Ecology plans to hold several scoping meetings to obtain recommendations on issues and/or rule provisions. Ecology will review the public comments and then decide (1) whether to begin a second rulemaking phase and (2) what issues will be addressed during the second rulemaking phase.

1.5 Organization of the Document

The remaining parts of this document are organized into the following sections:

- **Section 2 – Background Information:** This section provides a brief summary of the MTCA Cleanup Regulation and the TEF methodology and describes how the TEF methodology has been used to establish cleanup levels.
- **Section 3 - Description of the Proposed Rule Revisions**: This section summarizes the rule revisions that Ecology is considering during the rulemaking process. This section also provides a comparison of cleanup levels under the current and proposed rule language.
- **Section 4 – Rulemaking Issues:** This section provides a discussion of ten key policy and technical issues central to this rulemaking effort. The section is divided into ten subsections (one issue per subsection) that include:
    - A brief description of the issue.
    - The options for resolving the issue.
    - Ecology's preferred option and the rationale for choosing that option.
- **Section 5 – References**
- **Section 6 – Representative Structural Formulas**

2 Background Information

2.1 Statutory Background

The Model Toxics Control Act (Initiative 97), Chapter 70.105D RCW, was passed by the voters of the State of Washington in November 1988 and became effective March 1, 1989. The law establishes the basic authorities and requirements for cleaning up contaminated sites in a manner that will protect human health and the environment.

As a general declaration of policy, MTCA, chapter 70.105D RCW, states that:

> Each person has a fundamental and inalienable right to a healthful environment, and each person has a responsibility to preserve and enhance that right. The beneficial stewardship of the land, air, and waters of the state is a solemn obligation of the present generation for the benefit of future generations.

The statute also states that:

> A healthful environment is now threatened by the irresponsible use and disposal of hazardous substances. There are hundreds of hazardous waste sites in this state, and more will be created if current waste practices continue. Hazardous waste sites threaten the state's water resources, including those used for public drinking water. Many of our municipal landfills are current or potential hazardous waste sites and present serious threats to human health and the environment. (RCW 70.105D.010(1))

The main purpose of MTCA is to prevent or remedy these threats to human health and the environment.[1] To achieve these statutory goals, MTCA establishes a wide range of duties and responsibilities for Ecology. The law directs Ecology "to immediately implement all provisions of this chapter to the maximum extent practicable, including investigative and remedial actions where appropriate." (RCW 70.105D.030(2)). In particular, MTCA requires Ecology to adopt, and thereafter enforce, rules under chapter 34.05 RCW. Ecology must:

> Publish and periodically update minimum cleanup standards for remedial actions 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[.][2]

2.2 MTCA Cleanup Standards – The Current Rule

Ecology originally adopted cleanup standards in 1991 ("MTCA Cleanup Regulations" or MTCA Rule"). Ecology completed significant changes to the cleanup standards in February 2001. Under the current MTCA rules, there are three methods (Methods A, B and C) for establishing cleanup levels.

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[1] MTCA's general declaration of policy states "[t]he main purpose of [the law]is to raise sufficient funds to clean up all hazardous waste sites and to prevent the creation of future hazards due to improper disposal of toxic wastes into the state's land and waters." (RCW 70.105D.010(2))

[2] The federal cleanup law referenced in MTCA is the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA) 42 U.S.C. 9601 et seq.

- ***Method A*** can be used to establish cleanup levels at relatively small sites that involve few contaminants. Under Method A, cleanup levels must be at least as stringent as the following:
  - Applicable & Relevant & Appropriate Requirements (ARARs). MTCA requires that cleanup levels must be at least as stringent as requirements in other applicable state and federal laws and regulations. For example, Method A cleanup levels must be at least as strict as any applicable surface water quality standards in the National Toxics Rule.
  - Method A Tables. Cleanup levels are listed in Tables 720-1, 740-1, and 745-1. These tables provide values for carcinogenic PAHs and PCBs but not for dioxins and furans.
  - Plants and Wildlife. Concentrations that result in no significant adverse effects on the protection and propagation of terrestrial ecological receptors using the procedures in WAC 173-340-7490 through WAC 173-340-7493, unless it is demonstrated under those sections that establishing a soil concentration is unnecessary.

- ***Method B*** can be used to establish cleanup levels at any site. Under Method B, cleanup levels must be at least as stringent as the following:
  - Applicable & Relevant & Appropriate Requirement (ARARs). Standards in applicable state and federal laws. MTCA requires that cleanup levels must be at least as stringent as requirements in other applicable state and federal laws and regulations. For example, Method B cleanup levels must be at least as strict as any applicable surface water quality standards in the National Toxics Rule.
  - Risk-Based Cleanup Levels. Cleanup levels calculated using the methods in WAC 173-340-720 through 173-340-750.
    - Individual Hazardous Substances. The cancer risk for individual substances cannot exceed one in one million (10^{-6}). The non-cancer risk for individual substances cannot exceed a hazard quotient of one.
    - Total Site Risk. The total site risk for carcinogens cannot exceed one-in-one hundred thousand (10^{-5}). Non-cancer total site risk cannot exceed a hazard quotient of one. The MTCA rules require that the cleanup levels established for individual substances be adjusted downward if the total risk posed by the entire mixture exceeds either of these limits. Total site risk includes consideration of multiple hazardous substances and multiple pathways of exposure.
  - Plants and Wildlife. Concentrations that are estimated to result in no adverse effects on the protection and propagation of aquatic life and no significant adverse effects on terrestrial ecological receptors using the procedures in WAC 173-340-7490 through WAC 173-340-7493.

- ***Method C*** can be used to establish cleanup levels in limited situations—typically for soil cleanup levels for industrial land uses. Method C cleanup levels must be at least as stringent as the following:
  - Applicable & Relevant & Appropriate Requirements (ARARs). MTCA requires that cleanup levels must be at least as stringent as requirements in other applicable state and federal laws and regulations. For example, Method C cleanup levels must be at least as strict as any applicable surface water quality standards in the National Toxics Rule.

- Risk-Based Cleanup Levels. Cleanup levels calculated using the methods in WAC 173-340-720 through 173-340-750.
  - Individual Hazardous Substances. The cancer risk for individual substances cannot exceed one in one hundred thousand (10^{-5}). The non-cancer risk for individual substances cannot exceed a hazard quotient of one.
  - Total Site Risk. The total site risk for carcinogens cannot exceed one-in-one hundred thousand (10^{-5}). Non-cancer total site risk cannot exceed a hazard index of one (1). The MTCA rules require that the cleanup levels established for individual substances be adjusted downward if the total risk posed by the entire mixture exceeds either of these limits. Total site risk includes consideration of multiple hazardous substances and multiple pathways of exposure.
- Plants and Wildlife. Concentrations that are estimated to result in no significant adverse effects on the protection and propagation of aquatic life, and no significant adverse effects on wildlife using the procedures in WAC 173-340-7490 through WAC 173-340-7493.

2.3 Toxicity Equivalency Factors (TEFs)3

People and other organisms are exposed to a wide range of complex environmental mixtures. However, toxicological information is available for only a limited number of individual chemicals in those mixtures. This makes it very difficult to for scientists to characterize the toxicity of the whole mixture. Over the last 20 years, scientists have developed several approaches for evaluating and characterizing the toxicity of mixtures.

One of the most frequently-used approaches is the “Toxicity Equivalency Factor” or “TEF” methodology (see Figure 1). Under this approach, the toxicity of one member of the chemical group is selected as the index chemical. The remaining members of the chemical group are assigned TEF values which provide an order of magnitude estimate of toxicity or cancer potency relative to an index chemical. The toxicity of each member of the chemical group is evaluated by multiplying the concentration of that member by its TEF value. The product is called the toxicity equivalent concentration. The whole mixture can be characterized by as the sum of these toxicity equivalent concentrations. This is often referred to as the total toxicity equivalent concentration (TTEC) or the total toxic equivalence (TEQ) of the chemical mixture. In this way, the health risks posed by the whole mixture can be assessed using the TEQ and the toxicological information for the index chemical.

[3] For the purposes of this document, the toxicity equivalency factor (TEF), potency equivalency factor (PEF), and relative equivalency factor (REF) are all referred to as “toxicity equivalency factor” or “TEF”

Figure 1: Characterizing Dioxin and Furan Mixtures

$$\text{Total Toxicity Equivalence (TEQ)} = \sum C_n * TEF_n$$

Where:

TEQ = Total Toxicity Equivalence

TEF_n = Toxic equivalency factor of the individual congener associated with its respective mixture

C_n = Concentration of the individual congener in the mixture

Dioxins and furans are generally present in the environment as a complex mixture of chemical "congeners" that differ in terms of the number and location of chlorine atoms. 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD = index chemical) is the most toxic and best-studied of the 210 polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran congeners (CDDs and CDFs). EPA first adopted the TEF methodology as an interim procedure for evaluating the toxicity and risks associated with exposures to dioxin and furan mixtures (EPA, 1987, 1989). The majority of state, federal and international environmental agencies currently use the TEF values developed by the World Health Organization (Van den Berg, et al., 1998) when evaluating the health risks posed by dioxin/furan mixtures.

Polycyclic aromatic hydrocarbons (PAHs) are a group of chemicals formed during the incomplete burning of organic materials such as wood, garbage, oil, coal, gas and tobacco. There are more than 100 different PAHs. EPA (1993) published provisional guidance for evaluating the carcinogenic risks associated with PAH mixtures using a relative potency factor (RPF) approach. The EPA (1993) approach uses benzo(a)pyrene [BaP] as the index chemical (i.e., having a relative potency of 1.0) and includes RPF values for seven (7) carcinogenic PAHs. The California Environmental Protection Agency (Cal EPA, 1994) expanded upon the EPA approach when it developed Potency Equivalency Factors (PEFs) for use in evaluating PAH mixtures. The Cal EPA approach also uses BaP as the index chemical and includes PEFs for twenty-two (22) carcinogenic PAHs[4].

In February 2001, Ecology revised WAC 173-340-708(8) by adding new provisions applicable to mixtures of chlorinated dibenzo-p-dioxins, chlorinated dibenzofurans, and polycyclic aromatic hydrocarbons:

- Chlorinated Dioxins/Furans. WAC 173-340-708(8)(d) states that cleanup proponents may use EPA's TEF values and methodology when assessing the potential carcinogenic risk of mixtures of chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans. Under the EPA methodology, 2,3,7,8 TCDD is the index chemical. The total toxicity equivalent concentration of the mixture is represented by the sum of the products of the TEF and the concentration of the respective dioxin or furan congener.

[4] In 2001, Ecology amended the MTCA rule to explicitly authorize use of the Cal EPA (1994) methodology to evaluate the toxicity and assess the risks from exposure to carcinogenic PAH mixtures.

- Polycyclic Aromatic Hydrocarbons (PAHs). WAC 173-340-708(8)(d) states that cleanup proponents may use the Relative Potency Factors (RPFs) and methodology developed by the California EPA (Cal-EPA) when assessing the potential carcinogenic risk of mixtures of cPAH. Under the Cal-EPA methodology, benzo[a]pyrene (B[a]P) is the index chemical. The total toxicity equivalent concentration of the mixture is represented by the sum of the products of the TEF and the respective cPAH compound concentrations.

2.4 Two Approaches Have Been Used to Set Cleanup Levels with the TEF Methodology

The current MTCA rule does not clearly specify how the TEF methodology must be used when calculating cleanup levels for mixtures of dioxins/furans and PAHs. Two approaches have been used to establish cleanup levels using the EPA TEF methodology under the MTCA rule:

- Cleanup Levels Established for the Whole Mixture. In November 2001, Ecology published guidance[5] on how to use the TEF methodology when establishing and evaluating compliance with MTCA cleanup levels. The guidance includes the following approach:
    - Analyze a sample from the medium of concern to determine the congeners (or cPAH) and the concentration of each congener (or cPAH);
    - Multiply each congener (or cPAH) concentration identified in the sample by the applicable toxicity equivalency factor to obtain a toxicity equivalent concentration; and
    - Add the products of the concentration of each congener (or cPAH) and its TEF to obtain the total equivalency of the mixture (TEQ) or total toxicity equivalent concentration.
    - Compare the calculated value[6] to the applicable cleanup level for the reference chemical (either 2,3,7,8 TCDD or benzo[a]pyrene).

  Under this approach, the mixture is characterized by a single value (the total toxicity equivalent concentration). Cleanup levels for the mixture are then established using a cancer risk level of one-in-one million (10^{-6}). Under this approach, the mixture is treated like it is a single hazardous substance.

- Cleanup Levels Established for Individual Congeners or PAH Compounds. In November 2005, Rayonier Properties, LLC argued that the MTCA rule requires Ecology to establish cleanup levels for dioxin mixtures using a cancer risk level of 10^{-5} (as opposed to applying 10^{-6} risk level to the whole mixture). Under this approach, cleanup levels for individual congeners would be established using a cancer risk level of 10^{-6}. Ecology agreed that Rayonier's approach was one plausible interpretation of the MTCA rule in terms of using the TEF methodology to establish cleanup levels. Under this approach:
    - Analyze a sample from the medium of concern to determine the congeners (or cPAH) and the concentration of each congener (or cPAH).

[5] Cleanup Levels and Risk Calculation (CLARC) Guidance

[6] NOTE: If statistics are being used to determine compliance, then the upper bound estimate of the mean of multiple samples would be compared to the cleanup level (or remediation level). If the total toxicity equivalent concentration for the sample (or upper bound of multiple samples) exceeds the Method B/C cleanup level (or remediation level) for the index chemical, then the cleanup level has not been met.

- Divide the cleanup level for the reference chemical (TCDD or benzo[a]pyrene) by the applicable toxicity equivalency factor to obtain a cleanup level for each congener or cPAH compound.
- Compare the measured concentration[7] of each congener (or cPAH) to the applicable cleanup level for the particular congener or cPAH.

The total site risk (accounting for all congeners, cPAHs, other hazardous substances and multiple exposure pathways) cannot exceed a cancer risk of 10^{-5}.

[7] NOTE: If statistics are being used to determine compliance, then the upper bound estimate of the mean of multiple samples would be compared to the cleanup level (or remediation level). If the total toxicity equivalent concentration for the sample (or upper bound of multiple samples) exceeds the Method B/C cleanup level (or remediation level) for the index chemical, then the cleanup level has not been met.

3 Description of the Proposed Rule

Ecology initiated the rulemaking process on June 7, 2006, by filing the CR-101 with the Office of the Code Reviser. Later that month, Ecology prepared draft rule language that was distributed to interested parties for review and comment.

Ecology received many comments on the draft rule language. Ecology also held four meetings with the MTCA Science Advisory Board to discuss key rulemaking issues. Ecology has modified the June draft rule language based on the comments received from the public and the MTCA Science Advisory Board.

3.1 Proposed Rule Revisions

Ecology is proposing to revise and update the policies and procedures for establishing cleanup levels for certain types of chemical mixtures. Key elements of the proposed rule amendments include the following:

- Risk Policies Applicable to Dioxins/Furans, PAHs and PCBs. Ecology proposes amending WAC 173-340-708(8) to revise and update the risk policies for mixtures of dioxins/furans, carcinogenic PAHs and PCBs. Ecology proposes to:
  - Require that cleanup levels for mixtures of dioxins and furans be based on a cancer risk of one-in-a-million (10^{-6}).
  - Require that cleanup levels for mixtures of carcinogenic PAHs be based on a cancer risk of one-in-a-million (10^{-6}).
  - Require that cleanup levels for PCB mixtures continue to be based on a cancer risk of one-in-a-million (10^{-6}).
- Toxic Equivalency Factors (TEF) Used to Characterize Mixtures. Ecology proposes amending the rule to require people to use the most current TEF values:
  - TEFs for dioxins/furans and PCBs recommended by the World Health Organization (Van den Berg, et al. 2006).
  - Updated potency equivalency factors (PEFs) for carcinogenic PAHs adopted by the California Environmental Protection Agency (California EPA, 2005).
- Default Parameters Used to Calculate Cleanup Levels. Ecology proposesmodifying the Gastrointestinal Absorption Fraction used to establish soil cleanup levels for dioxin and furan mixtures.
- Evaluating Cross-Media Impacts. Ecology proposes amending WAC 173-340-708(8) requiring cleanup proponents to consider the physical-chemical properties of individual PAH compounds or dioxin-congeners when evaluating cross-media impacts.

3.2 Comparison of Current and Proposed Cleanup Levels

The proposed rule revisions will result in changes to the procedures for calculating cleanup levels. This section also provides a comparison of cleanup levels under the current and proposed rule language. When making these comparisons, Ecology has used the Rayonier Settlement approach to describe the baseline regulatory requirements. Ecology chose this approach because neither the current MTCA rule, nor the federal guidance referenced in the MTCA rule, explicitly requires the procedures in the Cleanup Levels and Risk Calculations (CLARC) guidance.

- Cleanup Levels for Dioxins and Furans: Ecology expects the proposed rule revisions will have the following impacts on cleanup levels for dioxins and furans:

    - **Ground Water and Surface Water Cleanup Levels.** Ecology has concluded that the proposed rule revisions will not affect dioxin cleanup levels for ground and surface waters. Ground water cleanup levels established under WAC 173-340-720 will continue to be based on the Maximum Contaminant Limit (MCL) for dioxin in the state and federal drinking water regulations. Surface water cleanup levels established under WAC 173-340-730 will continue to be based on the National Toxics Rule and Section 304 water quality criteria documents.

    - **Method B Soil Cleanup Levels Based on Non-Cancer Risks.** The proposed rule revisions will not change the methods and policies for establishing Method B soil cleanup based on non-cancer human health risks.

    - **Method B Soil Cleanup Levels Based on Cancer Risks.** Ecology has concluded that the proposed rule revisions will result in changes to dioxin soil cleanup levels based on human cancer risks. When setting cleanup levels based on cancer risk, the proposed rule revisions will result in Method B soil cleanup levels for dioxin mixtures that are 30 to 50% lower (more stringent) than cleanup levels that would be established under the current rule (See Table 1). When estimating the baseline cleanup levels for dioxin/furan mixtures (16-24 ppt) in Table 1, Ecology considered both the regulatory limits for individual congeners (10^{-6}) and the whole mixture (10^{-5}). After reviewing data from Washington cleanup sites, Ecology concluded that requirements for individual congeners will result in cleanup levels that are more stringent than simply applying a cleanup level of 67 ppt for the whole mixture. Specifically, Ecology believes that dioxin/furan mixtures with TEQ values between 16 and 24 ppt will fail to meet the requirement that individual congener concentrations not exceed 6.7 ppt. This conclusion is based on data showing that one congener usually contributes 25-35% of the toxicity of the whole mixture.

    - **Industrial Soil Cleanup Levels.** Ecology has concluded that the proposed rule revisions will result in changes to industrial soil cleanup levels based on human health risks. In general, the levels established under the proposed rule revisions will be 60-70% higher (less stringent) than those established under the current rule.

    - **Soil Cleanup Levels Based on Ecological Protection.** The proposed rule revisions will not change the methods and policies for establishing soil cleanup levels based on ecological protection.

Table 1: Comparison of Soil Cleanup Levels for Dioxins/Furans		
	Regulatory Baseline	Proposed Rule
Unrestricted – Human Health*		
2,3,7,8 TCDD	6.7 ppt	11 ppt
Dioxin/Furan Mixtures (TEQ)	16 – 24 ppt**	11 ppt
Industrial – Human Health*		
2,3,7,8 TCDD	875	1,460 ppt
Dioxin/Furan Mixtures (TEQ)	875	1,460 ppt
Ecological Screening		
Dioxins	2 – 5 ppt	2 – 5 ppt
Chlorinated Dibenzofurans	2 – 3 ppt	2 – 3 ppt

*Assumes direct contact via soil ingestion is the controlling exposure pathway and a gastrointestinal absorption fraction of 0.6.
** Based on median cleanup level at dioxin/furan contaminated sites in Washington State

- **Cleanup Standards to Protect Air Quality**:[8] Soil cleanup levels must be set at levels that prevent unacceptable risks due to inhalation of windblown soil particulates. The proposed rule revisions would result in changes to the Method B air cleanup levels based on carcinogenic risk. However, inhalation of windblown soil particulates is generally a minor exposure pathway relative to incidental soil ingestion and Ecology does not typically evaluate this pathway. Consequently, Ecology has concluded that the changes to Method B air cleanup levels will not significantly impact soil cleanup levels. Ecology also believes that the changes in Method B air cleanup standards will not significantly impact requirements for remedial actions. The proposed rule revisions might also result in revisions to emission limits for remedial actions that result in air emissions. However, Ecology believes that emission limits for such actions will continue to be established based on requirements in Chapter 173-460 WAC (Controls for New Sources of Toxic Air Pollutants).

- **Sediment Cleanup Standards**. Ecology uses the general policies and procedures in WAC 173-340-700 through -710 when establishing site-specific requirements for contaminated sediment sites. It is not clear how the proposed revisions would actually impact sediment cleanup standards and cleanup actions.[9] However, Ecology believes that the issue of how to establish MTCA sediment cleanup standards must be addressed as part of a larger set of regulatory questions on the relationships between requirements in the Sediment Management Standards (SMS) rule and the MTCA rule. Ecology is currently working with other sediment management agencies (e.g. EPA, Corp of Engineers, Department of Natural Resources, etc.) and interested parties to review a number of issues associated with dioxin-contaminated sediments in Puget Sound. Ecology has decided to wait until that process is completed before developing rule amendments (if any) to address sediment cleanup requirements.

[8] This section would be applicable at sites with dioxin and furan contamination if it was necessary to establish (1) a soil cleanup level that addresses inhalation of windblown soil particulates or (2) emission limits for remedial actions.
[9] Ecology believes that the proposed rule revisions would not have significant impacts on sediment cleanup standards and actions because: (1) cleanup requirements take into account background concentrations that are often higher than site-specific risk-based standards; (2) cleanup screening levels (CSLs) under the SMS rule are comparable to Method C cleanup levels under the MTCA rule and these cleanup levels are not impacted by the proposed rule revisions; (3) current sediment guidance and applicable water quality standards are based on similar methods and policies; and (4) there are a number of other site-specific and regulatory factors (biota sediment accumulation factor, fish and shell consumption rates, net environmental protection, costs, technical feasibility etc.) that influence sediment cleanup standards and cleanup actions.

- Cleanup Levels for Carcinogenic PAHs. Ecology expects that the proposed rule revisions will have the following impacts on cleanup levels for carcinogenic PAHs:
  - **Ground Water and Surface Water Cleanup Levels.** Ecology has concluded that the proposed rule revisions will not significantly change ground water and surface water cleanup levels for carcinogenic PAH mixtures. Ground water cleanup levels established under WAC 173-340-720 will continue to be based upon the Method A cleanup level or the Maximum Contaminant Limit (MCL) for benzo[a]pyrene in the state and federal drinking water regulations. Surface water cleanup levels established under WAC 173-340-730 will continue to be based on the National Toxics Rule.
  - **Method A Soil Cleanup Levels.** The proposed rule revisions will not change the Method A soil cleanup levels for carcinogenic PAH (cPAH) mixtures for unrestricted land use (0.1 mg/kg) and industrial land use (2 mg/kg). Because the TEF for dibenz(a,h)anthracene is somewhat less stringent under the proposed rule amendment, this could result in slightly higher cPAH mixture concentrations being able to demonstrate compliance with the Method A soil cleanup levels.
  - **Method B Soil Cleanup Levels Based on Non-Cancer Risks.** The proposed rule revisions will not change the methods and policies for establishing Method B soil cleanup levels based on non-cancer human health risks. The hazard quotient used to calculate cleanup levels for individual hazardous substances is the same as the hazard index used when evaluating total site risks.
  - **Method B Soil Cleanup Levels Based on Cancer Risks.** Ecology has concluded that the proposed rule revisions will result in changes to Method B soil cleanup levels for cPAHs that are based on cancer human health risk (See Table 2). The proposed rule revisions will not change the Method B cleanup level for benzo(a)pyrene (B(a)P) which is the reference chemical in the TEF approach. However, the proposed rule revisions will result in Method B soil cleanup levels for mixtures that are 25 to 50% lower (more stringent) than cleanup levels that would be established under the current rule. As with dioxins and furans, the relatively small difference is due to the fact that benzo[a]pyrene typically contributes 60-80% of the TEQ for the whole mixture.[10]
  - **Industrial Soil Cleanup Levels.** At industrial sites, the cancer risk target for the individual PAHs (10^{-5}) is the same as the cancer risk target for total site risk (10^{-5}). Consequently, the proposed rule revisions will not change Method C industrial soil cleanup levels that are based on cancer risk.[11]
  - **Soil Cleanup Levels Based on Ecological Protection.** The proposed rule revisions will not change the methods and policies for establishing soil cleanup levels based on ecological protection.

Table 2: Comparison of Soil Cleanup Levels for Carcinogenic PAHs		
	Regulatory Baseline	Proposed Rule

[10] Because the TEF for dibenz(a,h)anthracene is somewhat less stringent under the proposed rule amendment, this could result in slightly higher cPAH mixture concentrations being able to demonstrate compliance with the Method B soil cleanup levels.

[11] Because the TEF for dibenz(a,h)anthracene is somewhat less stringent under the proposed rule amendment, this could result in slightly higher cPAH mixture concentrations being able to demonstrate compliance with Method C cleanup levels.

Unrestricted – Human Health*		
Method A (BaP and cPAH)	0.1 mg/kg	0.1 mg/kg
Method B (BaP)	0.14 mg/kg	0.14 mg/kg
Method B (cPAHs)	0.16 – 0.26 mg/kg**	0.14 mg/kg
Industrial – Human Health***		
Method A (BaP and cPAH)	2 mg/kg)	2 mg/kg
Method C (BaP)	18 mg/kg (2 mg/kg)	18 mg/kg (2 mg/kg)
Method C (cPAHs)	18 mg/kg (2 mg/kg)	18 mg/kg (2 mg/kg)
Ecological Screening		
BaP (unrestricted site use)	12-30 mg/kg	12-30 mg/kg
BaP (industrial and commercial)	12 – 300 mg/kg	12 – 300 mg/kg
*Assumes direct contact via soil ingestion is the controlling exposure pathway. ** Based on the median cleanup level at cPAH contaminated sites in Washington State. ***The cleanup level for the direct contact pathway is the first number. If the leaching pathway is a concern at the site, the cleanup level will be 2 ppm (based on the 3 phase model in WAC 173-340-747 using the standard assumptions for soil above the water table.		

- **Cleanup Standards to Protect Air Quality**:[12] Soil cleanup levels must be set at levels that prevent unacceptable risks due to inhalation of windblown soil particulates. The proposed rule revisions would result in changes to the Method B air cleanup levels based on carcinogenic risk. However, inhalation of windblown soil particulates is generally a minor exposure pathway relative to incidental soil ingestion and Ecology does not typically evaluate this pathway. Consequently, Ecology has concluded that the changes to Method B air cleanup levels will not significantly impact soil cleanup levels. Ecology also believes that the changes in Method B air cleanup standards will not significantly impact requirements for remedial actions. The proposed rule revisions might also result in revisions to emission limits for remedial actions that result in air emissions. However, Ecology believes that emission limits for such actions will continue to be established based on requirements in Chapter 173-460 WAC (Controls for New Sources of Toxic Air Pollutants).

- **Sediment Cleanup Standards**. Ecology uses the general policies and procedures in WAC 173-340-700 through -710 when establishing site-specific requirements for contaminated sediment sites. It is not clear how the proposed revisions would actually impact sediment cleanup standards and cleanup actions.[13] However, Ecology believes that the issue of how to establish MTCA sediment cleanup standards must be addressed as part of a larger set of regulatory questions on the relationships between requirements in the Sediment Management Standards (SMS) rule and the MTCA rule. Ecology is currently working with other sediment management agencies (e.g. EPA, Corp of Engineers, Department of Natural Resources, etc.) and interested parties to review a number of issues associated with dioxin-contaminated sediments in Puget Sound.

[12] This section would be applicable at sites with dioxin and furan contamination if it was necessary to establish (1) a soil cleanup level that addresses inhalation of windblown soil particulates or (2) emission limits for remedial actions.
[13] Ecology believes that the proposed rule revisions would not have significant impacts on sediment cleanup standards and actions for PAH contaminated sediments because: (1) With some exceptions, most organisms metabolize PAH compounds which limits bioaccumulation; (2) cleanup screening levels (CSLs) under the SMS rule are comparable to Method C cleanup levels under the MTCA rule and these cleanup levels are not impacted by the proposed rule revisions; and (3) there are a number of other site-specific and regulatory factors (biota sediment accumulation factor, fish and shell consumption rates, net environmental protection, costs, technical feasibility etc.) that influence sediment cleanup standards and cleanup actions.

Ecology has decided to wait until that process is completed before developing rule amendments (if any) to address sediment cleanup requirements.

- Cleanup Levels for PCB Mixtures. Ecology has concluded that the proposed rule revisions will not result in significant changes to cleanup standards for PCBs because the use of the TEF methodology is optional.
  - **Ground Water and Surface Water Cleanup Levels.** The proposed rule revisions will not affect PCB cleanup levels for ground and surface waters. Ground water cleanup levels established under WAC 173-340-720 will continue to be based on the Maximum Contaminant Limit (MCL) for PCBs in the state and federal drinking water regulations. Surface water cleanup levels established under WAC 173-340-730 will continue to be based on the National Toxics Rule and Section 304 water quality criteria documents.
  - **Method A Soil Cleanup Levels.** The proposed rule revisions will not change the Method A soil cleanup levels for PCB mixtures for unrestricted land use (1 mg/kg) and industrial land use (10 mg/kg).
  - **Method B Soil Cleanup Levels Based on Non-Cancer Risks.** The proposed rule revisions will not change the methods and policies for establishing Method B soil cleanup based on non-cancer human health risks.
  - **Method B Soil Cleanup Levels Based on Cancer Risks.** Ecology has concluded that the proposed rule revisions will not result in significant changes to PCB soil cleanup levels based on human health risks because the use of the TEF methodology is optional.
  - **Industrial Soil Cleanup Levels.** The proposed rule revisions will not result in changes to industrial soil cleanup levels based on human health risks.
  - **Soil Cleanup Levels Based on Ecological Protection.** The proposed rule revisions will not change the methods and policies for establishing soil cleanup levels based on ecological protection.

Table 3: Comparison of Soil Cleanup Levels for PCB Mixtures

	Regulatory Baseline	Proposed Rule
Unrestricted – Human Health		
Method A (total PCBs)	1 mg/kg	1 mg/kg
Method B (total PCBs)*	0.2 - 1 mg/kg	0.2 - 1 mg/kg
Industrial – Human Health		
Method A (total PCBs)	10 mg/kg	10 mg/kg
Method C (total PCBs)*	0.2 - 10 mg/kg	0.2 - 10 mg/kg
Ecological Screening		
PCB Mixtures (unrestricted site use)	0.65 – 2 mg/kg	0.65 – 2 mg/kg
PCB Mixtures (industrial & commercial)	0.65 – 2 mg/kg	0.65 – 2 mg/kg

*Lowest value is for protection of ground water using the 3 phase model in WAC 173-340-747 and standard assumptions for soil above the water table; highest value is based on the ARAR.

  - **Cleanup Levels to Protect Air Quality.** Ecology has concluded that the proposed rule revisions will not result in significant changes to cleanup requirements based on protecting air quality because the use of the TEF methodology is optional.

- **Sediment Cleanup Standards.** Ecology has concluded that the proposed rule revisions will not result in significant changes to sediment cleanup standards because the use of the TEF methodology is optional.

3.3 Potential Impacts of Rule Revisions on Cleanup Actions

Ecology evaluated whether the proposed rule amendments are likely to result in significant changes to the cleanup actions implemented at these types of facilities. In performing this evaluation, Ecology considered the nature and extent of contamination typically found at these types of cleanup sites, the types of cleanup actions conducted at these types of facilities and the MTCA rule requirements that determine site cleanup requirements.

- Sites with Elevated Levels of Dioxin and Furans. Ecology does not expect that the proposed rule revisions will result in significant changes to the cleanup actions implemented at most sites with dioxin and furan contamination. Ecology reached this conclusion based on the following considerations:
  - Small differences in cleanup levels are unlikely to alter cleanup actions where capping/ containment is an important element of the cleanup action (such as landfills, wood treating).
  - The proposed rule revisions are unlikely to result in meaningful differences in soil removal volumes because (1) there is very little difference in cleanup levels under the current rule and the proposed rule revisions because one congener generally contributes 25-35% of the TEQ for the whole mixture and Ecology is proposing to modify the default absorption value and (2) soil removal at the types of sites listed in Table 2 is generally limited to highly contaminated soils with residual contamination being contained on-site.
  - Cleanup requirements at many of these types of sites will continue to be driven by cleanup levels for other contaminants (e.g. total petroleum hydrocarbons, metals).
  - Industrial properties may need to remediate a smaller area of soil under the proposed rule.
  - Ecology believes that the proposed rule revisions may increase the acreage defined as being impacted by air deposition. However, Ecology expects that the incremental increases in acreage (relative to the current MTCA rule) will be small[14] because (1) aerial deposition of dioxin mixtures is not an issue at most cleanup sites, (2) there is very little difference in cleanup levels selected under the current rule and the proposed rule revisions because one congener generally contributes @25-35% of the TEQ for the whole mixture and (3) Ecology is proposing to modify the default GI absorption fraction.

- Sites with Elevated Levels of Carcinogenic PAHs. Carcinogenic PAHs are primarily found at MTCA sites due to use of heavy fuel oils, lubricating oils and wood preservatives. Ecology does not expect that the proposed rule revisions will result in significant changes to the cleanup actions implemented at sites with elevated levels of PAHs because:
  - Ecology expects that many of these types of sites will continue to use Method A to establish cleanup levels. Ecology is not proposing to revise the Method A cleanup levels.

[14] Ecology has compared the sampling results obtained from 20 locations in Port Angeles. Twelve locations exceed cleanup levels using Option 1, four locations exceed cleanup levels using Option 2 and four locations exceed cleanup levels using the proposed rule revision.

- Cleanup requirements at many of these types of sites will continue to be driven by cleanup levels for other contaminants (such as total petroleum hydrocarbons, metals).
- Ecology does not expect that the proposed rule revisions will result in meaningful differences in soil removal volumes because (1) there is very little difference in cleanup levels selected under the two rulemaking options because benzo[a]pyrene generally contributes 60-80% of the TEQ for the whole mixture and (2) it is difficult to make fine distinctions in soil contamination levels during soil removal (such as removal via backhoe).
- Ecology does not expect that the small differences in cleanup levels selected under the two rulemaking options will alter cleanup actions where capping /containment is an important element of the cleanup action (such as landfills, wood treating).

- <u>Sites with Elevated Levels of PCBs</u>. Ecology does not expect that the proposed rule revisions will result in significant changes to cleanup actions at sites with elevated levels of PCBs because the use of the TEF methodology is optional.

4 Rulemaking Issues

Ecology staff and management considered a wide range of issues when preparing the draft rule revisions. Figure 2 identifies ten issues that are central to this rulemaking. This section is divided into ten subsections (one issue per subsection). Each subsection includes (1) a brief description of the issue; (2) the options for resolving the issue; and (3) Ecology's proposed option and the rationale for choosing that option.

Figure 2
Key Rulemaking Issues

Dioxin/Furan Mixtures

Issue #1	Should Ecology revise the MTCA rule to require people to use the toxic equivalency factors (TEFs) developed by the World Health Organization when evaluating the human health risks of dioxin/furan mixtures?
Issue #2	Should Ecology revise the MTCA rule to require that Method B cleanup levels for dioxin/furan mixtures be based on a cancer risk of one-in-one million?
Issue #3	Should Ecology revise the default assumptions in the MTCA rule to take into account the relative bioavailability of soil-bound dioxins and furans?

PAH Mixtures

Issue #4	Should Ecology revise the MTCA rule to require people to use the latest relative potency factors developed by the California Environmental Protection Agency when evaluating the human health risks of PAH mixtures?
Issue #5	When characterizing the carcinogenic risks of PAH mixtures, should Ecology continue to focus its' evaluation on the seven PAH compounds identified in the current MTCA rule?
Issue #6	Should Ecology revise the MTCA rule to require that Method B cleanup levels for carcinogenic PAH mixtures be based on a cancer risk of one-in-one million?

PCB Mixtures

Issue #7	Should Ecology revise the MTCA rule to explicitly allow or require people to use of the TEF values and methodology developed by the World Health Organization when evaluating the human health risks of PCB mixtures?
Issue #8	Should Ecology continue to require that cleanup levels for PCB mixtures be based on a cancer risk of one-in-one million?
Issue #9	How should Ecology take into account non-dioxin-like health effects when using the TEF methodology to assess PCB mixtures?

General Issues

Issue #10	How should Ecology apply the TEF methodology when evaluating cross-media impacts?

Choice of TEF Values for Dioxin/Furan Mixtures

Issue #1

Should Ecology revise the MTCA rule to require people to use the toxic equivalency factors (TEFs) developed by the World Health Organization when evaluating the human health risks of dioxin/furan mixtures?

Background

Polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran congeners (dioxins and furans) are generally present in the environment as a complex mixture of chemical "congeners" that differ in terms of the number and location of chlorine atoms. 2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD) is the most toxic and best-studied of the 210 dioxin and furan congeners. Because of the need to evaluate the risks associated with the whole mixture, scientists have developed the "Toxicity Equivalency Factor" or "TEF" methodology. Under this approach, each congener is assigned a TEF, which is some fraction of the toxicity of TCDD. The total toxic equivalency (TEQ) of a mixture is the sum of the products of the concentration of each congener in the contaminated medium and the TEF value for that congener.

The TEF methodology has evolved over the last twenty years as a result of scientific reviews and evaluations conducted by several organizations. EPA first adopted the TEF methodology as an interim procedure for evaluating the toxicity and risks associated with exposures to dioxin and furan mixtures (EPA, 1987). EPA subsequently updated its TEF values based on international consensus regarding the interpretation of relevant toxicological information for dioxin and furan mixtures (EPA, 1989). The MTCA rule (WAC 173-340-708(8)) references the 1989 EPA document and specifies that those TEFs may be used when assessing the potential carcinogenic risk of dioxin/furan mixtures.

The World Health Organization (WHO) and International Programme on Chemical Safety (IPCS) initiated a joint project in 1997 to review available toxicity data for dioxin-like compounds. The expert panel completed its evaluation and published recommended TEF values (Van den Berg, et al., 1998). These values are generally referred to as the WHO-98 TEFs. Table 4 compares the WHO-98 TEF values with the earlier EPA values. The majority of state, federal and international environmental agencies currently use the WHO-98 values when evaluating the health risks posed by dioxin/furan mixtures. For example, EPA used the WHO-1998 TEF values when preparing the dioxin reassessment report (EPA, 2003c).

The World Health Organization convened a meeting of scientific experts in June 2005 to review the WHO-98 TEF values and other related issues. The scientific experts participating in that meeting recommended changes to the TEF values for 4 of the 17 dioxin and furan congeners (See Table 4). The results of that meeting are summarized in Van den Berg et al. (2006).

In 2004, EPA asked the National Academy of Sciences to review the agency's dioxin reassessment report. The NAS report was recently published and the committee concluded that the "...the toxic equivalency factor methodology provides a reasonable, scientifically justifiable, and widely accepted method to assess the relative potency of DLCs[15]..." (NAS, 2006, p. 6)[16].

Table 4
Toxicity Equivalency Factors (TEFs) For Chlorinated Dioxins and Furans

Congener	EPA 1987[17]	EPA 1989 (Current MTCA Rule)	NATO 1989[18]	WHO 1998[19]	WHO 2005 TEFs[20]
TEFs for Chlorinated Dibenzo-p-Dioxins					
2,3,7,8-TCDD	1	1	1	1	1
1, 2,3,7,8-PeCDD	0.5	0.5	0.5	1	1
1, 2,3,4,7,8-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,6,7,8-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,7,8,9-HxCDD	0.04	0.1	0.1	0.1	0.1
1,2,3,4,6,7,8-HpCDD	0.001	0.01	0.1	0.01	0.01
1,2,3,4,6,7,8,9-OCDD	0	0.001	0.001	0.0001	0.0003
TEFs for Chlorinated Dibenzofurans					
2,3,7,8-TCDF	0.1	0.1	0.1	0.1	0.1
1,2,3,7,8-PeCDF	0.1	0.05	0.05	0.05	0.03
2,3,4,7,8-PeCDF	0.1	0.5	0.5	0.5	0.3
1,2,3,4,7,8-HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,6,7,8-HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,7,8,9-HxCDF	0.01	0.1	0.1	0.1	0.1
2,3,4,6,7,8- HxCDF	0.01	0.1	0.1	0.1	0.1
1,2,3,4,6,7,8-HpCDF	0.001	0.01	0.01	0.01	0.01
1,2,3,4,7,8,9- HpCDF	0.001	0.01	0.01	0.01	0.01
1,2,3,4,6,7,8,9-OCDF	0	0.001	0.001	0.0001	0.0003

MTCA Rulemaking Options

Ecology has considered three options for this rulemaking issue:

1. EPA-89 Values. Under this option, Ecology would continue to use the TEF values from the 1989 EPA Guidance Document when evaluating the human health risks associated with mixtures of dioxins and furans.
2. WHO-1998 Values. Under this option, Ecology would revise the MTCA rule to specify that the WHO-98 TEF values should be used when evaluating the human health risks associated with mixtures of dioxins and furans.
3. WHO-2005 Values. Under this option, Ecology would revise the MTCA to specify that the WHO-2005 TEF values (Van den Berg et al. 2006[21]) should be used when evaluating the human health risks associated with mixtures of dioxins and furans.

[15] DLC = Dioxin-Like Compounds.
[16] The NAS committee also recommended that EPA acknowledge the need for better uncertainty analysis of the toxicity values and should include an initial uncertainty analysis of overall toxicity in the final EPA report.
[17] U.S. EPA's 1989. Update to the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-dioxins and-dibenzofurans (CDDs and CDFs), EPA/625/3-89/016, March 1989.
[18] NATO/CCMS. (1988) Scientific basis for the development of the International Toxicity Equivalency Factor (I-TEF) method of risk assessment for complex mixtures of dioxins and related compounds. Report No. 178, Dec. 1988.
[19] Van den Berg, M; Birnbaum, L; Bosveld, ATC; et al. (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106(12):775-792.
[20] Van den Berg et al. (2006).

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to require that the WHO-2005 TEF values should be used when evaluating the human health risks of mixtures of dioxins and furans (Option 3). Ecology's rationale for using more the current TEF values includes the following:

- The TEF methodology has a strong biological basis. The TEF methodology is a relative potency approach that is grounded in the concept that dioxin/furan mixtures act through a common mechanism of action that involves binding to the Ah receptor (aryl hydrocarbon hydroxylase receptor). The methodology is based on the assumption that the total dose can be represented by the sum of the doses for individual chemicals in the whole mixture. This assumption (dose additivity) has been evaluated for a number of toxic endpoints. Of particular relevance to the current rulemaking process, Walker et al. (2005) evaluated the dose-additive carcinogenicity of a mixture of dioxin-like compounds and found that (1) the dose-response for the mixture could be predicted from a combination of the potency-adjusted doses of the individual congeners; (2) the WHO-98 TEF values adequately predicted the increased incidence of liver tumors associated with exposure to a mixture of dioxin-like compounds; and (3) the shapes of the dose-response curves were the same in the studies of three individual congeners and the mixture.

- The WHO-2005 TEF values are based on current scientific information. The WHO-2005 TEF values reflect the current scientific consensus on the relative toxicity of dioxin-like compounds. These values were developed after a rigorous scientific review performed by international experts. These values are consistent with earlier scientific reviews by the EPA Risk Assessment Forum (EPA, 2000), EPA's Science Advisory Board (EPA, 2001) and the National Research Council (NAS, 2003; NAS, 2006). The NAS panel (2006) specifically recommended that EPA consider the results of the WHO/IPCS review when revising the dioxin reassessment report. In addition, the MTCA Science Advisory Board recently concluded:

  The Board stated that the 2005 TEF values for dioxin and furans recommended by the WHO are consistent with current scientific information. As noted above, the Board stated that it was fortuitous that the WHO had recently completed a review and evaluation of available scientific information which resulted in updated TEF values for dioxins and furans (Attachment to March 19, 2007 Meeting Summary).

- The WHO expert panel considered the scientific uncertainties associated with current information when revising the TEF values. Ecology recognizes that there are uncertainties in the TEF values and the application of this approach to predict health risks and calculate cleanup levels. However, a scientific panel convened by EPA and the Department of Interior concluded that "...the uncertainties associated with using RePs or TEFs are not thought to be larger than other sources of uncertainty within the risk assessment process (e.g. dose-response assessment, exposure assessment and risk characterization)..."(EPA, 2001b). The EPA Science Advisory Board also noted that five of the 29 dioxin-like compounds (17 PCDDs/PCDFs and 12 dioxin-like PCB congeners) considered by EPA account for over 70% of the TEQ in the human diet. The Board noted that the variability in relative potency

[21] The scientific experts expressed continued support for the TEF approach. However, they identified changes to the TEF values for four of the seventeen dioxin and furan congeners: 2,3,4,7,8-pentachlorodibenzofuran (TEF revised from 0.5 to 0.3); 1,2,3,7,8-pentachlorodibenzofuran (TEF revised from 0.05 to 0.03); and octachlorodibenzo-p-dioxin and octachlorodibenzofuran (TEF revised from 0.0001 to 0.00003)

factors for these five congeners is much lower than the variability in TEFs for congeners that are minor contributors to human exposure (EPA, 2001a). Hawes et al. (2006) reached similar conclusions.

- Ecology's proposal to use the WHO-2005 TEF values is consistent with approaches being used by Ecology and other environmental agencies. Ecology believes that the use of the most current TEF values published by the World Health Organization is consistent with the current MTCA rule and reflects a logical update based on more recent scientific information. Numerous agencies currently use the WHO-98 TEF values when evaluating the health risks associated with dioxin and furan mixtures. For example:
    - The Water Quality Program used the WHO-98 TEFs when establishing the Total Maximum Daily Load (TMDL) for Lake Chelan (Ecology, 2005).
    - The Environmental Assessment Program used the WHO-98 TEFs to prepare the 2004 303(d) list of impaired waterbodies (Ecology, 2004).
    - The Solid Waste and Financial Assistance Program used the WHO-98 TEFs when preparing the initial list of persistent, bioaccumulative toxins (PBTs).
    - EPA used the WHO-98 TEF values when preparing the 2003 dioxin reassessment report.
    - The EPA Superfund program recommends that the WHO-98 TEF values be used when evaluating the health risks posed by dioxin/furan mixtures.
    - EPA used the WHO-98 TEF values when establishing reporting requirements for dioxin and dioxin-like compounds under Section 313 of the Emergency Planning and Community Right-to-Know Act.
    - ATSDR used the WHO-98 TEF values to establish a Minimal Risk Level (MRL) for dioxin-like compounds.
    - Several state health and environmental agencies currently use the WHO-98 TEF values to evaluate dioxin and furan mixtures (See Table 8, p. 34).

- Ecology does not believe that the use of the WHO-2005 TEF values will significantly increase or decrease the stringency of cleanup requirements established under MTCA. As indicated in Table 4, the two approaches include identical TEF values for 12 of the 17 dioxin and furan congeners. Of the remaining five congeners, the WHO-2005 TEF values are lower than the 1989 EPA TEF values for four congeners (1,2,3,7,8-PeCDF, 2,3,4,7,8-PeCDF, OCDD and OCDF); the WHO-2005 TEF value for PeCDF is higher. While these differences may affect conclusions on individual samples, Ecology does not believe that the use of the WHO-98 TEF or the WHO-2005 values will significantly alter cleanup requirements on a statewide basis (relative to the current rule language).

Cleanup Levels for Dioxin/Furan Mixtures

Issue #2

Should Ecology revise the MTCA rule to require that Method B[22] cleanup levels for dioxin/furan mixtures be based on a cancer risk of one-in-one million?

Background

Ecology amended the MTCA rule in February 2001. Under the rule amendments, a person undertaking a cleanup action may use the Environmental Protection Agency's (EPA, 1989) interim methodology and the toxicity equivalency factor (TEF) values when assessing dioxin and furan mixtures.

The existing MTCA rule does not clearly specify how the TEF methodology must be used when calculating Method B cleanup levels for mixtures of dioxins/furans and PAHs. Two approaches have been used to establish cleanup levels using the EPA TEF methodology:

- Cleanup Levels for the Whole Mixture Based on a Cancer Risk Level of One-in-One Million**.** In November 2001, Ecology published guidance[23] on how to use the TEF methodology when establishing and evaluating compliance with MTCA cleanup levels. The guidance directed people to (1) use the TEF methodology to calculate a total toxic equivalency concentration and (2) compare the calculated value to the applicable cleanup level for the reference chemical (either 2,3,7,8 TCDD or benzo[a]pyrene). Under this approach, the mixture is characterized by a single value (the total toxicity equivalent concentration). Method B cleanup levels for the mixture are then established using a cancer risk level of one-in-one million (10^{-6}).

- Cleanup Levels for Individual Congeners Based on Cancer Risk Level of One-in-One Million**.** In November 2005, Rayonier Properties, LLC argued that the MTCA rule requires Ecology to establish cleanup levels for dioxin mixtures using a cancer risk level of 10^{-5} (as opposed to applying 10^{-6} risk level to the whole mixture). Under this approach, cleanup levels for individual congeners would be established using a cancer risk level of 10^{-6}. Ecology agreed that Rayonier's approach was a reasonable interpretation of the current MTCA rule and, consequently, represents a plausible approach for using the TEF methodology to implement the current MTCA rule. Under this approach, the TEF methodology is used to calculate a cleanup level for each congener. The total site risk (taking into account all congeners, other hazardous substances, and multiple exposure pathways) cannot exceed a cancer risk of one-in-a-hundred thousand (10^{-5})

MTCA Rulemaking Options

Ecology has considered three options for resolving this issue:

[22] Under Method C, the cancer risk target for the individual PAHs (10^{-5}) is the same as the cancer risk target for total site risk (10^{-5}). Consequently, Method C cleanup levels based on cancer risk are not affected by the decision on whether to apply a 10-6 risk level to individual congeners or the whole mixture.

[23] Cleanup Levels and Risk Calculation (CLARC) Guidance

1. Cleanup Levels for Individual Congeners Based on a Cancer Risk Level of One-in-One Million. This is the approach specified in the Rayonier Settlement Agreement. Under this option, Method B cleanup levels for other dioxin and furan congeners would be established by dividing the TCDD cleanup level by the applicable congener-specific TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (10^{-5}), when more than 10 dioxin and furan congeners are present at a site (a likely occurrence), the cleanup levels for TCDD and other individual congeners would need to be adjusted downward to insure this overall site risk limit is not exceeded. If there are multiple pathways of exposure, a further downward adjustment for individual congeners would need to also be made.

2. Cleanup Levels for Dioxin/Furan Mixtures Based on a Cancer Risk Level of One-in-One Million. This is the approach specified in the Cleanup Levels and Risk Calculation (CLARC) Guidance. Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 17 dioxin/furan congeners identified in Table 4) for environmental samples that would then be compared to TCDD cleanup level.

3. Cleanup Levels for Mixtures of All Dioxin-like Compounds (Dioxins, Furans and Dioxin-like PCBs) Based on a Cancer Risk Level of One-in-One Million. Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). This option differs from option #2 because the TEF methodology would be used to calculate a TEQ based on a larger number of congeners. Under this option, the TEQ is calculated using information on the 17 dioxin/furan congeners identified in Table 4 and the 12 PCB congeners identified in Table 9. The resulting TEQ value is then compared to the TCDD cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to state that dioxin and furan mixtures will be considered a single hazardous substance for assessing carcinogenic risk under MTCA. Under this approach, Method B cleanup levels for mixtures of dioxins and furans must be based on a cancer risk of one-in-one million (10^{-6}) (Option #2). Ecology's rationale for selecting this option includes the following:

- Dioxin/furan mixtures differ from the majority of mixtures found at MTCA sites. Most MTCA sites include mixtures of hazardous substances. However, the mixtures addressed in this rulemaking differ from most other types of mixtures in that (1) the congeners in the mixture always occur together and (2) scientists have concluded that the 17 dioxin/furan congeners identified in the rule act through common biological mechanisms and essentially behave like one chemical in the human body.[24]

- Ecology believes the proposed approach is an appropriate policy choice for regulating dioxins and furans within the overall MTCA decision-making framework. Ecology believes that it is appropriate to establish cleanup levels for dioxins and furan mixtures using a cancer risk level of one-in-one million because:

[24] The TEF approach is based on the concept that the various congeners of dioxin/furan essentially act as one chemical, affecting the Ah receptor (aryl hydrocarbon hydroxylase receptor).

- The proposed approach provides a margin of safety that minimizes the potential for health risks from exposure pathways that are not explicitly addressed in the MTCA rule. Ecology made a number of simplifying assumptions regarding exposure pathways when developing the MTCA rule. For example, soil cleanup levels are based on an evaluation of the direct contact pathway (e.g. soil ingestion and dermal contact) and migration from soil to ground water. For the majority of hazardous substances, this approach addresses the main human exposure pathways. However, dioxins and furans differ from many other hazardous substances because they are able to bioaccumulate in the terrestrial food chain (soil>plants>animals>humans). EPA (2003) has estimated that soil-related food chain exposure may equal or exceed exposures resulting from soil ingestion.
- The proposed approach provides a margin of safety that minimizes the potential that soil cleanup levels based on carcinogenic risks will result in unacceptable non-cancer health risks. Exposures to dioxins/furans have been shown to increase the risks of developing a wide range of non-cancer health problems including hepatic, immunological, dermal, endocrine effects, neurological effects and reproductive and development effects. The MTCA rule includes procedures for establishing cleanup levels based on non-cancer health effects. However, dioxins and furans differ from other hazardous substances because (1) EPA has not officially established a reference dose and (2) EPA has concluded that a reference dose for non-cancer effects may be below current background levels of exposure. Consequently, the proposed approach provides a margin of safety to address the data gaps for non-cancer health effects.

- <u>The proposed approach simplifies the procedures for establishing MTCA cleanup levels</u>. The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}. Treating dioxin and furan mixtures as a single hazardous substance minimizes the need to make such adjustments. This simplifies the process for establishing cleanup levels

- <u>The proposed approach is consistent with the policy choices underlying cleanup levels for PCB mixtures</u>. EPA (2003) has concluded that chlorinated dioxins and furans mixtures and PCB mixtures share many similar exposure and toxicity characteristics. The proposed approach for dioxins and furans is consistent with the policy choices underlying cleanup levels for PCB mixtures in the current MTCA rule. For example, the Method A soil cleanup levels for PCB mixtures in the current MTCA rule were established for the whole mixture using a cancer risk level of one-in-one million.

- <u>The proposed approach is consistent with approaches used by other Ecology programs</u>. The proposed approach is consistent with approaches used by other Ecology programs when evaluating the health risks associated with dioxin and furan mixtures. These requirements are often ARARs that establish minimum cleanup standards under MTCA. For example:
  - The Water Quality Program used the WHO-98 TEFs when establishing the TMDL for Lake Chelan. In that evaluation, Ecology used congener-specific data to calculate TEQs which were compared with the National Toxics Rule (NTR) criterion for TCDD[25].

[25] The NTR criterion for TCDD is based on a 10^{-6} cancer risk level.

- The Environmental Assessment Program identified impaired water bodies by comparing the TEQs for dioxins/furans to the NTR criteria for TCDD. (Ecology, 2004).
- The Hazardous Waste & Toxics Reduction Program specifies that fertilizers must contain no more than eight parts per trillion of dioxin, measured as toxic equivalent (TEQ).
- The Air Quality Program uses the TEF methodology to calculate TEQs for potential emissions from proposed new sources of dioxins/furans. The TEQ values are compared to a screening level for dioxin/furans that is expressed in terms of TCDD. The screening level is based on an incremental cancer risk of one-in-one million (WAC 173-460-060).

- The proposed approach is consistent with how EPA and other federal and international agencies have regulated and/or evaluated dioxin mixtures. EPA and other federal environmental agencies have established a wide range of regulatory requirements for dioxins and furans. Ecology recognizes that these requirements reflect a wide range of policy choices on acceptable cancer or non-cancer risks – many of which differ from the policy choices reflected in the MTCA rule. However, most agencies have established requirements for the whole mixture – not individual congeners. Essentially, these agencies have treated mixtures of dioxins and furans in the same way they treat other hazardous substances like arsenic and trichloroethylene. Consequently, Ecology believes the proposed approach for regulating dioxins and furans under MTCA is consistent with the approaches used by other federal and international agencies. For example:
  - EPA (1998) published a guidance memo for cleanup of dioxin-contaminated properties. The guidance specifies that compliance should be evaluated by comparing the 1 ppb cleanup standard to TEQs calculated from information on 17 dioxin/furan congeners.
  - EPA has published human health water quality criteria for TCDD in the NTR (EPA, 1992) and the California Toxics Rule (EPA, 2000). In promulgating the California Toxics Rule, EPA stated that water quality-based effluent limits for dioxin or dioxin-like compounds should be expressed using a TEQ approach (65 FR 31682 at 31695).
  - EPA established emission limits for medical waste incinerators that include limitations expressed in terms of either (1) allowable levels of total chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans or (2) allowable TEQs. The proposed rule for primary manganese refining facilities also includes emission limits for dioxin/furan mixtures expressed in terms of ng of toxic equivalents (TEQ) per dry standard cubic meter.
  - ATSDR (1998) established a Minimal Risk Level (MRL) for dioxin and dioxin-like compounds at a concentration of 1 pg TEQ/kg-day.
  - The WHO has established a tolerable daily intake of 1-4 pg TEQ/kg-day.
  - The FDA uses the TEF methodology and TEQs to monitor food and animal feed with the goal of reducing dietary exposure to dioxin-like compounds (FDA, 2005).

- The proposed approach is consistent with how many other state agencies have regulated dioxin and furan mixtures within their regulatory frameworks. The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) recently completed a survey of state screening levels and action levels (ASTSWMO, 2006). They found that "...[t]he cancer risk basis of the standards and guidelines reported by States ranged from a stringent one-in-ten million (1E-07) to one-in-ten thousand (1E-04). The majority of standards utilize the more typical one-in-one million (1E-06) risk level criteria...." Ecology reviewed the web pages of several environmental agencies in other states to determine whether agencies were treating dioxin/furan mixtures as a single hazardous substance (Option 2) or a mixture of multiple hazardous substances (Option 1). While it is sometimes difficult to interpret some of the regulatory provisions, the results[26] indicate that many (but not all) states use approaches that are consistent with Option 2 (i.e. establish cleanup levels and/or criteria for TCDD and then use the TEQ for the mixture to evaluate compliance with those cleanup levels and/or criteria). One exception is the Oregon Superfund program which uses an approach similar to Option 1.

Table 5: Comparison of Approaches Used By Other State Environmental Agencies When Evaluating Dioxin/Furan Mixtures

State	Environmental Program	TEF Values	Regulatory Approach	Risk Level applicable to mixture
Florida[27]	Superfund	WHO-98	Mixture	10^{-6}
Minnesota[28]	Pollution Control Agency	WHO-98	Mixture	10^{-5} (includes PCBs)
New York[29]	Water Quality	EPA-89	Mixture	10^{-5}
Oregon[30]	Waste Mgt & Cleanup	WHO-98	Congener & Mixture	10^{-5}
Oregon[31]	Water Quality	WHO-98	Mixture	10^{-6}
Texas[32]	Superfund	WHO-98	Mixture	10^{-5} (includes PCBS)
Wisconsin[33]	Superfund	EPA-89	Mixture	10^{-6}

- <u>The proposed approach reflects public concerns about exposure to toxic chemicals</u>. Public concerns about health threats posed by toxic chemicals have grown over the last decade as new information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of toxic chemicals in Puget Sound and other parts of the state. Options 2 and 3 reflect risk policy choices that are consistent with public concerns and the high priority assigned to these initiatives.

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[26] Ecology has not surveyed all 50 states and, consequently, recognizes that the results may not reflect the full range of approaches used by different state agencies and/or the variability among programs within a single state agency
[27] FloridaTechnical Report: Development of Cleanup Target Levels (CTLs) For Chapter 62-777, Florida AdministrativeCode, Prepared for the Division of Waste Management Florida Department of Environmental Protection By Center for Environmental & Human Toxicology, University of Florida, Gainesville, Florida, February, 2005, Table 19, Page 61;
[28] Minnesota Pollution Control Agency, Site Remediation Section. Draft Guideline: Risk-Based Guidance for the Soil-Human Health Pathway Vol. 2 Technical Support Document Section 8.2.4. Calculation Spreadsheet: Tier 1 SRV Spreadsheet; Risk-tier1srv.xls, 01/06
[29] New York State Department of Environmental Conservation Rules and Regulations, 6NYCRR Part 703, Surface Water and Groundwater Quality Standards and Groundwater Effluent Limitations, Table 1
[30] Oregon Department of Environmental Quality, Waste Management & Cleanup Division. Policy on Toxicity Equivalency Factors. And Electronic Correspondence with Oregon DEQ M. Paulsen to McCormack, March 2006.
[31] Oregon Department of Environmental Quality, Toxic Compounds Criteria, 1999-2003 Water Quality Standards Review Draft Issue Paper, Section 2.3.
[32] Texas Commission on Environmental Quality, Texas Risk Reduction Program, Development of Protective Concentration Levels. Rule §350.76 Approaches for Specific Chemicals of Concern to Determine Human Health Protective Concentration Levels.
[33] Wisconsin Department of Natural Resources.

Relative Bioavailability of Dioxin/Furan Mixtures in Soils (Ingestion Pathway)

Issue #3

Should Ecology revise the default assumptions[34] in the MTCA rule to take into account the relative bioavailability of soil-bound dioxins and furans?

Background

The Model Toxics Control Act (MTCA) Cleanup Regulation provides methods to establish residential (unrestricted land use) and industrial (restricted land use) soil cleanup levels (WAC 173-340-740 through -745). The gastrointestinal (GI) absorption fraction is one of several factors considered when establishing soil cleanup levels. The MTCA rule establishes a default GI absorption fraction of 1.0. This value is based on the assumption that soil-bound dioxin and furans are absorbed to the same extent as dioxin and furans administered in the studies used to establish the cancer slope factor and/or reference dose.

The Department received a wide range of comments on the June 2006 draft rule language. Several organizations expressed the opinion that the default assumption was overly-conservative and recommended that Ecology revise the rule to incorporate a default value that is less than 1.0. In contrast, other organizations expressed the opinion that the default GI absorption fraction of 1.0 should be maintained under this rule revision.

Ecology held four meetings with the MTCA Science Advisory Board between September 2006 and March 2007. During that series of meetings, Ecology presented several options for addressing this issue that were reviewed by the Board.

MTCA Rulemaking Options

Ecology has considered four options for resolving this issue:

1. Default GI Absorption Fraction = 1.0: Under this option, Ecology would maintain the current MTCA rule language that establishes a GI absorption fraction of 1.0 for dioxin/furan mixtures. Method B soil cleanup levels for TCDD would continue to be established at a soil concentration of 6.7 ppt. Industrial soil cleanup levels would continue be established at a soil concentration of 875 ppt.
2. Default GI Absorption Fraction = 0.4: Under this option, Ecology would revise the MTCA rule to establish a default GI absorption fraction of 0.4 for mixtures of dioxins/furans. This value is based on the information in the EPA dioxin reassessment report. Under this option, Method B soil cleanup levels for TCDD would be established at a soil concentration of 17 ppt. Industrial soil cleanup levels would be established at a soil concentration of 2,200 ppt.
3. Default GI Absorption Fraction = 0.7 (tetra- and penta-congeners) and 0.4 (hexa-, hepta- and octa-congeners): Under this option, Ecology would revise the MTCA Cleanup Regulation to

[34] WAC 173-340-200 states that "Gastrointestinal absorption fraction" means the fraction of a substance transported across the gastrointestinal lining and taken up systematically into the body.

specify a default GI absorption fraction of 0.7 for tetra- and penta-congeners and 0.4 for hexa-, hepta- and octa- congeners. Method B soil cleanup levels would be established at a soil concentration of 11-17 ppt (cleanup levels would vary depending on the composition of the mixture). Industrial soil cleanup levels would be established at soil concentrations of 1,300 to 2,200 ppt (cleanup levels would vary depending upon the composition of the mixture).

4. Default GI Absorption Fraction = 0.6: Under this option, Ecology would revise the MTCA rule to establish a default GI absorption fraction of 0.6 for mixtures of dioxins/furans. Under this option, Method B soil cleanup levels for TCDD would be established at a soil concentration of 11 ppt. Industrial soil cleanup levels would be established at a soil concentration of 1,460 ppt.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-740 and -745 to establish a default GI absorption fraction of 0.6 (Option #4). Ecology's rationale for selecting this option includes the following:

- The proposed approach has a strong underlying scientific basis. The National Academy of Sciences, the World Health Organization and the Environmental Protection Agency have each concluded that soil-bound dioxins and furans are generally less bioavailable than dioxins and furans in food and water. The World Health Organization (Van den Berg et al. 2006) has also stated that the reduced bioavailability needs to be taken into account when applying TEF values to abiotic media such as soils. The MTCA Science Advisory Board has also said that it is reasonable to conclude that soil-bound dioxins and furans are less bioavailable that dioxins and furans in foods and drinking water.

- The proposed approach takes into account the results from available scientific studies performed to evaluate the relative bioavailability of TCDD. Ecology compiled and reviewed studies performed to evaluate the bioavailability of soil-bound dioxins and furans. The vast majority of studies have evaluated the bioavailability of 2,3,7,8 TCDD. There is high degree of variability in study results that reflect differences in study designs, soil types and evaluation endpoints (See Summary Tables at the end of this document). The MTCA Science Advisory Board concluded that a 0.5 absorption value for soil-bound dioxin and furans is consistent with current scientific information and represents a central tendency value. However, the Board also noted that this value should not be interpreted to be an upper bound value and absorption fractions for sensitive population groups or individuals would likely be higher. NOTE: When the 0.5 value is adjusted for the absorption in the studies the cancer slope factor for dioxin is based on (0.8), the result is a GI absorption fraction of 0.6.

- The proposed approach takes into account (on a qualitative basis) the congener-specific differences in the relative bioavailability of soil-bound dioxins and furans. Several scientific committees have concluded that more-chlorinated congeners are less bioavailable than less-chlorinated congeners such as 2,3,7,8 TCDD. Consequently, default values based solely on studies with TCDD may overestimate the bioavailability of mixtures that include a wide range of congeners. Ecology considered an option (option #3) that includes two default values (0.7 value for the dioxin and furan congeners with four and five chlorine atoms and 0.4 for higher-chlorinated congeners. The MTCA Science Advisory Board disagreed with this approach. They concluded that there is sufficient information to suggest that there may be congener-specific differences in bioavailability. However, the Board also concluded that the information is too uncertain and variable to assign a congener-specific point estimate based on the degree of chlorination for the different dioxin/furan congeners and that assigning congener-specific values confers a level of precision not warranted by the current scientific information.

- The proposed approach is consistent with EPA Dioxin Reassessment and default values established by state agencies that have evaluated this issue. EPA used a relative bioavailability of 0.4 when evaluating the risks of soil-bound dioxins. Michigan and Minnesota use relative bioavailability values between 0.5 and 0.6 when establishing soil cleanup levels. However, most states appear to be using a default value of 1.0.

- Ecology believes the revised approach will continue to result in soil cleanup levels that are protective. Ecology establishes soil cleanup levels based on reasonable maximum exposures. The "reasonable maximum exposure" is defined as "…the highest exposure that can reasonably expected to occur for humans or other living organisms at a site under current and potential future site use." In calculating reasonable maximum exposures, EPA and Ecology generally use a combination of upper-bound and average values for the individual exposure parameters. Ecology agrees with the Science Advisory Board that this value represents a central tendency value. However, Ecology believes the revised approach will continue to result in protective soil cleanup levels given the other parameters and assumptions used to calculate MTCA cleanup levels. Soil cleanup levels established using the revised approach (11 ppt) fall at the lower (more protective) end of soil cleanup levels and screening values used by EPA and other states.

Choice of TEF Values for cPAH Mixtures

Issue #4

Should Ecology revise the MTCA rule to require people to use the latest relative potency factors developed by the California Environmental Protection Agency when evaluating the human health risks of PAH mixtures?

Background

Polycyclic Aromatic Hydrocarbons (PAHs) are a group of chemicals formed during the incomplete burning of organic materials such as wood, garbage, oil, coal, gas and tobacco. There are more than 100 different PAHs.

EPA (1993) published provisional guidance for evaluating the carcinogenic risks associated with PAH mixtures using a relative potency factor (RPF) approach. The EPA (1993) approach uses benzo(a)pyrene [BaP] as the index chemical (i.e., having a relative potency of 1.0) and includes RPF values for seven (7) carcinogenic PAHs.

The California Environmental Protection Agency (Cal EPA, 1994) expanded upon the EPA approach when it developed Potency Equivalency Factors (PEFs) for use in evaluating PAH mixtures. The Cal EPA 1994 approach also uses BaP as the index chemical and includes PEFs for twenty-two (22) carcinogenic PAHs. In 2001, Ecology amended the MTCA rule to explicitly authorize cleanup proponents to use the Cal EPA (1994) methodology to evaluate the toxicity and assess the risks from exposure to carcinogenic PAH mixtures.

The California EPA recently completed a review of the 1994 PEF values. Based on that review, Cal EPA published an update list of PEF values (Cal EPA, 2005). The Cal EPA (2005) approach continues to use BaP as the index chemical and includes PEFs for twenty-five (25) carcinogenic PAHs. Table 6 summarizes the PAH compounds and RPF/PEF values in the three approaches (i.e. EPA, 1993; Cal EPA, 1994; and Cal EPA, 2005).

MTCA Rulemaking Options

Ecology has considered two options for resolving this rulemaking issue:

1. Cal-EPA 1994 Values: Under this option, Ecology would continue to use the PEF values from the 1994 California Environmental Protection Agency's guidance document;
2. Cal-EPA 2005 Values: Under this option, Ecology would revise the MTCA rule to specify that the updated PEF values (Cal EPA 2005) should be used when assessing PAH mixtures.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to specify that the PEF values and methodology described in Cal EPA (2005) should be used when assessing the human health risks of PAH mixtures (Option #2). Ecology's rationale for selecting this option includes the following:

- The California EPA methodology has a strong scientific and biological basis. Polycyclic aromatic hydrocarbons are a well defined group of chemicals consisting of three or more fused aromatic rings. PAHs are ubiquitous multi-media contaminants commonly found as complex environmental mixtures. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of action for all cPAHs (EPA, 1993; Naz, 1999). When preparing the 2001 rule amendments, Ecology concluded that Cal-EPA (1994) values had broader applicability than the EPA (1993) values:

  > *EPA's TEFs are all based on dermal studies which is good for internal relative ranking but may not be good for applying to ingestion or inhalation exposures. In fact, EPA explicitly cautions against applying their TEFs to inhalation exposures. Instead, EPA proposes that their TEFs be applied only to ingestion exposure and is silent on the issue of dermal exposure (which is surprising, since their TEFs are based on mouse skin painting). In contrast, CalEPA TEFs are based on a variety of exposure routes, including a drinking water study for dibenzo(a,h)anthracene (Snell and Stewart, 1962), an intrapulmonary study for benzo(k)fluoranthene (Deutsch-Wenzel et al, 1983), and a skin painting study for chrysene (Wynder and Hoffman, 1959). In general, CalEPA TEFs were based on tumor data from relevant exposure routes (i.e., intrapulmonary and intratracheal administration, since CalEPA TEFs were targeted at air contaminants), tumor data from other exposure routes, genotoxicity data, and structure-activity relationships (SARs), in that order. Because CalEPA TEFs were based on a broader array of carcinogenic endpoints, these appear to have more general applicability (e.g., for route to route extrapolation) than EPA's approach based on a single endpoint. (Ecology SAB Briefing Memorandum, 1998)*

- The California EPA methodology and values are based on current scientific information. Cal EPA (2005) considered the most recent scientific information evaluating individual tumorigenic responses for 25 cPAHs when updating the 1994 values.

- The MTCA Science Advisory Board has concluded that the California EPA methodology and values are consistent with current scientific information. The MTCA Science Advisory Board reviewed and endorsed Ecology's use of the original Cal-EPA values during the 2001 rulemaking process. Ecology believes that the use of the updated Cal-EPA values is a logical extension of the initial decision to use the original Cal-EPA values. After reviewing Ecology's current rule proposal, the MTCA Science Advisory Board concluded:

  > *The Board stated that the 2005 PEF values for carcinogenic PAHs recommended by the California Environmental Protection Agency are consistent with current scientific information. As with dioxins and furans, the Board stated that it was fortuitous that the California EPA had recently completed a review and evaluation of available scientific information and published updated PEF values for carcinogenic PAHs. The Board noted that CalEPA considered a wide range of studies when establishing PEF values. The Board also observed that the California document describing the methodology provides information that is useful for Ecology as it proceeds with the MTCA rule update. (Attachment to March 19, 2007 Meeting Summary)*

- The 2005 PEF values are similar to the PEF values specified in the current MTCA rule. The updated Cal-EPA values are similar to PEF values in 1994 Cal-EPA guidance materials. As indicated in Table 6, the 1994 and 2005 Cal-EPA approaches include identical PEF values for six of the seven cPAHs typically assessed at cleanup sites. The exception is dibenzo(a,h)anthacene which has a smaller PEF in the updated guidance. While this difference may impact conclusions on individual samples, Ecology does not believe that the use of the more current PEF values will significantly alter the stringency of cleanup requirements on a statewide basis.

- The 2005 PEF values are consistent with values used by EPA and other state agencies to characterize PAH mixtures. EPA and most other state environmental agencies use some type of relative potency approach to characterize PAH mixtures. However, EPA and most states use the methodology and values specified in an EPA guidance document (EPA 1993). The Cal-EPA approach is conceptually similar to the EPA approach. Scientists at EPA-Region 10 agree that the current California EPA's PEFs provide a scientifically valid way to evaluate the health risks associated with exposures to PAH mixtures.

Table 6: Comparison of Relative Potency Factors (RPFs) and Potency Equivalency Factors (PEFs) for Polycyclic Aromatic Hydrocarbons

Polycyclic Aromatic Hydrocarbon	Relative Potency Factors (RPF) (EPA, 1993[35])	Potency Equivalency Factors (PEF) (Cal-EPA, 1994[36]) (Current MTCA)	Potency Equivalency Factors (PEFs) (Cal-EPA, 2005[37]) (Planned Revisions)
Benzo(a)pyrene	1	1	1
Benz(a)anthracene	0.1	0.1	0.1
Benz(b)fluoranthene	0.1	0.1	0.1
Benz(j)fluoranthene	------------------	0.1	0.1
Benz(k)fluoranthene	0.01	0.1	0.1
Dibenz(a,j)acridine	------------------	0.1	0.1
Dibenz(a,h)acridine	------------------	0.1	0.1
7H-dibenzo(c,g)carbazole	------------------	1.0	1.0
Dibenzo(a,e)pyrene	------------------	1.0	1.0
Dibenzo(a,h)pyrene	------------------	10	10
Dibenzo(a,i)pyrene	------------------	10	10
Dibenzo(a,l)pyrene	------------------	10	10
Indeno(1,2,3-cd)pyrene	0.1	0.1	0.1
5-methylchrysene	------------------	1.0	1.0
1-nitropyrene	------------------	0.1	0.1
4-nitropyrene	------------------	0.1	0.1
1,6-dinotropyrene	------------------	10	10
1,8-dinotropyrene	------------------	1.0	1.0
6-nitrochrysene	------------------	10	10
2-nitrofluorene	------------------	0.01	0.01
Chrysene	0.001	0.01	0.01
Dibenz(a,h)anthracene	1	0.4	0.1
7,12-dimethylbenzanthracene	------------------	-------------------	10
3-methylcholanthrene	------------------	-------------------	1
5-nitroacenaphthene	------------------	-------------------	0.01

[35] U.S. EPA, 1993. Provisional Guidance for Quantitative risk Assessment of Polycyclic Aromatic Hydrocarbons. July 1993. EPA/600/R-93/089.

[36] Cal-EPA, 1994. Benzo(a)pyrene as a toxic air contaminant. Part B: Health Assessment, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Berkeley, California

[37] Cal-EPA, 2005. Air Toxics Hot Spots Program Risk Assessment Guidelines, Part II Technical Support Document for Describing Available Cancer Potency Factors. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. May 2005. Pages B-77 to B-97.

Range of PAH Compounds Used to Characterize cPAH Mixtures

Issue #5

When evaluating the carcinogenic risks of cPAH mixtures, should Ecology continue to focus on the seven PAH compounds identified in the current MTCA rule?

Background

EPA (1993) published provisional guidance for evaluating the carcinogenic risks associated with PAH mixtures using a relative potency factor (RPF) approach. The EPA (1993) approach uses benzo(a)pyrene [BaP] as the index chemical (i.e., having a relative potency of 1.0) and includes RPF values for seven (7) carcinogenic PAHs (See Table 7).

Cal EPA (1994) expanded upon the EPA approach when it developed Potency Equivalency Factors (PEFs) for use in evaluating PAH mixtures. The Cal EPA approach also uses BaP as the index chemical and includes PEFs for twenty-two (22) carcinogenic PAHs. The updated Cal-EPA guidance document (Cal EPA, 2005) includes PEFs for twenty-five (25) carcinogenic PAHs.

WAC 173-340-708(8)(e) specifies that, at a minimum, seven cPAH[38] compounds (benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene) must be evaluated when using the TEF approach to characterize cPAH mixtures. However, the rule also states that Ecology may require other compounds from the Cal-EPA list to be evaluated at individual sites. To date, Ecology has not required other cPAH compounds to be evaluated at individual sites.

Table 7: cPAH Compounds Included in California EPA 2005 Guidance

cPAHs Listed in MTCA Rule	TEF	Other cPAHs on Cal-EPA List	TEF
benzo[a]pyrene	1	benzo(j)fluoranthene	0.1
benzo[a]anthracene	0.1	dibenz[a,j]acridine	0.1
benzo[b]fluoranthene	0.1	dibenz[a,h]acridine	0.1
benzo[k]fluoranthene	0.1	7H-dibenzo[c,g]carbazole	1
chrysene	0.01	dibenzo[a,e]pyrene	1
dibenz[a,h]anthracene	0.1	dibenzo[a,h]pyrene	10
indeno[1,2,3-cd]pyrene	0.1	dibenzo[a,i]pyrene	10
		dibenzo[a,l]pyrene	10
		5-methylchrysene	1
		1-nitropyrene	0.1
		4-nitropyrene	0.1
		1,6-dinitropyrene	10
		1,8-dinitropyrene	1
		6-nitrochrysene	10
		2-nitrofluorene	0.01
		7,12-dimethylbenzanthracene[a]	10
		3-methylcholanthrene	1
		5-nitroacenaphthene	0.01

[38] WAC 173-340-200 includes the following definition: "PAHs (carcinogenic)" or "cPAHs" means those polycyclic aromatic hydrocarbons substances, PAHs, identified as A (known human) or B (probable human) carcinogens by the United States Environmental Protection Agency. These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene."

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. Characterize PAH Mixtures Using Information on Seven PAH Compounds: Under this option, Ecology would revise WAC 173-340-708(8)(e)(ii) to state that PAH mixtures must be characterized using the seven PAH compounds listed in the definition of "carcinogenic PAHs".
2. Characterize PAH Mixtures Using Information on Seven PAH Compounds with the Option to Consider Other Carcinogenic PAHs: Under this option, Ecology would continue to use the current rule language which states that, at a minimum, analyses and TEF calculations must be based on the seven PAH compounds identified in the definition of "PAH (carcinogenic)" with Ecology retaining the discretion to require an evaluation of additional compounds at individual sites.
3. Characterize PAH Mixtures Using Information on Twenty-Five PAH Compounds: Under this option, Ecology would revise WAC 173-340-708(8)(e)(ii) to state that PAH mixtures must be characterized using the twenty-five PAH compounds listed in the California EPA guidance.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to continue to use the current language in WAC 173-340-708(8). Under the current rule, analyses and TEF calculations must be based on the seven PAH compounds identified in the definition of "PAH (carcinogenic)" with Ecology retaining the discretion to require an evaluation of additional compounds at individual sites (Option 2). Ecology's rationale for selecting this option includes the following:

- Scientific and regulatory agencies have identified a number of other PAH compounds as known or potential human carcinogens. Polycyclic aromatic hydrocarbons are a well-defined group of chemicals consisting of three or more fused aromatic rings. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of actions for all cPAHs (EPA, 1993; Naz, 1999). EPA has identified seven (7) PAH[39] compounds as A (known human) or B (probable human) carcinogens[40]. The National Toxicology Program (NTP, 2005) has identified 15 PAH compounds as "reasonably anticipated to be a human carcinogen". Cal EPA considered the most recent scientific information evaluating individual tumorigenic responses for 25 cPAHs when updating the PEF values for cPAHs (Cal EPA, 2005).
- Ecology has not considered other PAH compounds beyond the seven cPAH compounds specified in the current rule when evaluating health risks associated with PAH mixtures: WAC 173-340-708(8)(e) specifies that, at a minimum, seven cPAH[41] compounds must be

[39] These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene.
[40] On March 29, 2005, EPA issued "Guidelines for Carcinogen Risk Assessment" which replaced the 1986 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).
[41] WAC 173-340-200 includes the following definition: "PAHs (carcinogenic)" or "cPAHs" means those polycyclic aromatic hydrocarbons substances, PAHs, identified as A (known human) or B (probable human) carcinogens by the United States Environmental Protection Agency. These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene."

evaluated when using the TEF approach to characterize cPAH mixtures. However, the rule also states that Ecology may require other compounds from the Cal-EPA list to be evaluated at individual sites. To date, Ecology has not required cleanup proponents to evaluate other cPAH compounds when performing remedial investigations.

- Most environmental programs use information on seven PAH compounds when evaluating the health risks posed by PAH mixtures. Ecology reviewed the methods and procedures used by other environmental programs to characterize PAH mixtures. Several Ecology programs[42] [43]consider more than the seven PAH compounds identified in EPA (1993) when evaluating PAH mixtures. However, it appears that most state and federal environmental agencies focus on the seven PAH compounds when evaluating carcinogenic risks. For example:
  - The Air Quality Program focuses on the seven cPAH compounds identified in EPA (1993) when evaluating new source emissions under Chapter 173-460 WAC (Controls For New Sources Of Toxic Air Pollutants).
  - EPA's Superfund Program generally uses the methods and procedures described in EPA (1993) when evaluating health risks associated with cPAH mixtures.
  - Ecology reviewed the methods and procedures used by several other state superfund programs. Based on that review, most states appear to be using the EPA (1993) methodology and focus their evaluation on the seven cPAHs identified in the EPA document (See Table 8).
- Standard analytical methods are not available and/or routinely used for many of the cPAH compounds included on the Cal-EPA list. Standard analytical methods typically do not analyze for the levels of many of the cPAH compounds included on the Cal-EPA list. As additional information becomes available on the presence of these cPAH compounds and the risk posed by these additional compounds, additional cPAH compounds can be addressed by retaining the current rule language.

[42] The Hazardous Waste Program. Polycyclic aromatic hydrocarbons are designated dangerous wastes based on persistence criteria consistent with WAC 173-303-100 (6). For the purposes of Chapter 173-303 WAC, the PAHs of concern for designation include a large suite of PAHs. A person whose waste contains PAHs as defined in WAC 173-303-040, must determine the total PAH concentration by summing the concentration percentages of each of the polycylic aromatic hydrocarbons for which they know the concentrations (Ecology, 1998b). The equivalent concentration percentage is the sum of all the concentration percentages for a particular toxic category, such as halogenated organic compounds or PAHs.

[43] Ecology considers 16 PAH compounds when evaluating compliance with the Sediment Management Standards (Chapter 173-204 WAC). PAH concentrations are reported on a weight-weight basis (ug/kg wet weight or mg/kg dry weight) for each individual low and high molecular weight PAH and then added together to reflect the total concentration for low and high molecular weight PAHs. Low molecular weight PAHs (LPAH) include naphthalene, 2-methylnaphthalene, acenaphthylene, acenaphthene, fluorene, phenanthrene and anthracene. High molecular weight PAHs (HPAH) include fluroanthene, pyrene, benzo(a)anthracene, chrysene, bewnzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, indeno(1,2,3-cd)pyrene, dibenzo(a,H)anthracene, and benzo(ghi)perylene.

Cleanup Levels for cPAH Mixtures

Issue #6

Should Ecology revise the MTCA rule to require that Method B cleanup levels for carcinogenic PAH mixtures be based on a cancer risk of one-in-one million?

Background

Ecology amended the MTCA Cleanup Regulation in February 2001. Under the rule amendments, a person undertaking a cleanup action may use the California EPA (1994) methodology and potency equivalence factors (PEFs) when assessing PAH mixtures.

The existing MTCA rule does not clearly specify how the TEF methodology must be used when calculating cleanup levels for PAH mixtures. Two approaches have been used to establish cleanup levels using the TEF methodology:

Ecology amended the MTCA rule in February 2001. Under the rule amendments, a person undertaking a cleanup action may use the Environmental Protection Agency's (EPA, 1989) interim methodology and the toxicity equivalency factor (TEF) values when assessing dioxin and furan mixtures.

The existing MTCA rule does not clearly specify how the TEF methodology must be used when calculating Method B cleanup levels for mixtures of dioxins/furans and PAHs. Two approaches have been used to establish cleanup levels using the EPA TEF methodology:

- Cleanup Levels for the Whole PAH Mixture Based on a Cancer Risk Level of One-in-One Million. In November 2001, Ecology published guidance[44] on how to use the TEF methodology when establishing and evaluating compliance with MTCA cleanup levels. The guidance directed people to (1) use the TEF methodology to calculate a total toxic equivalency concentration and (2) compare the calculated value to the applicable cleanup level for the reference chemical (either 2,3,7,8 TCDD or benzo[a]pyrene). Under this approach, the mixture is characterized by a single value (the total toxicity equivalent concentration). Method B cleanup levels for the mixture are then established using a cancer risk level of one-in-one million (10^{-6}).

- Cleanup Levels for Individual Congeners Based on Cancer Risk Level of One-in-One Million. In November 2005, Rayonier Properties, LLC argued that the MTCA rule requires Ecology to establish cleanup levels for dioxin mixtures using a cancer risk level of 10^{-5} (as opposed to applying 10^{-6} risk level to the whole mixture). Under this approach, cleanup levels for individual congeners would be established using a cancer risk level of 10^{-6}. Ecology agreed that Rayonier's approach was a reasonable interpretation of the current MTCA rule and, consequently, represents a plausible approach for using the TEF methodology to implement the current MTCA rule. Under this approach, the TEF methodology is used to calculate a cleanup level for each congener. This approach could also be used for PAH mixtures. Under this approach, the total site risk (taking into account all

[44] Cleanup Levels and Risk Calculation (CLARC) Guidance

cPAHs, other hazardous substances, and multiple exposure pathways) cannot exceed a cancer risk of one-in-a-hundred thousand (10^{-5})

MTCA Rulemaking Options

Ecology has considered two options for resolving this issue:

1. Cleanup Levels for each cPAH are Based on a Cancer Risk Level of One-in-One Million. This approach is similar to the approach for dioxin cleanup levels specified in the Rayonier Settlement Agreement. Under this option, Method B cleanup levels would be established for B(a)P based on an incremental cancer risk of one-in-one million (10^{-6}). Cleanup levels for other PAH compounds would be established by dividing the B(a)P cleanup level by the applicable TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (10^{-5}), when more than 10 carcinogens (PAHs or hazardous substances) are present at a site, the cleanup levels for B(a)P and other carcinogenic PAHs would need to be adjusted downward to insure this overall risk limitation is not exceeded. If there are multiple pathways of exposure, a further downward adjustment for carcinogenic PAHs would also need to be made.
2. Cleanup Levels for PAH Mixtures are Based on a Cancer Risk Level of One-in-One Million. This is the approach specified in the Cleanup Levels and Risk Calculation (CLARC) Guidance. Under this option, Method B cleanup levels would be established for B(a)P based on an incremental cancer risk of one-in-one million (10^{-6}). The PEF values in Cal-EPA (2005) would be used to calculate a TEQ (based on the 7 PAH compounds identified in the first column of Table 7) for environmental samples that would then be compared to the B(a)P cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to state that cPAH mixtures will be considered a single hazardous substance for assessing carcinogenic risk under MTCA. Under this approach, Method B cleanup levels for mixtures of cPAHs must be based on a cancer risk of one-in-one million (10^{-6}) (Option #2). Ecology's rationale for selecting this option includes the following:

- PAH mixtures differ from the majority of mixtures found at MTCA sites. Most MTCA sites include mixtures of hazardous substances. However, the mixtures addressed in this rulemaking differ from most other types of mixtures in that (1) the different PAH compounds generally occur together and (2) scientists have concluded that the PAH compounds identified in the rule act through common biological mechanisms and essentially behave like one chemical in the human body[45].
- Ecology believes that the proposed approach provides a margin of safety that minimizes the potential for health risks from PAH compounds that are not routinely considered when establishing cleanup levels for PAH mixtures: WAC 173-340-708(8)(e) specifies that, at a

[45] Polycyclic aromatic hydrocarbons are a well defined group of chemicals consisting of three or more fused aromatic rings. The carcinogenicity of PAHs is due to the generation of biologically active metabolites which covalently bind to DNA and is considered a common mode of actions for all cPAHs (EPA, 1993; Naz, 1999). The TEF methodology is, in part, based on cPAHs collectively producing a similar biological responses – essentially acting as one chemical through a common mode of action.

minimum, seven cPAH[46] compounds (benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene) must be evaluated when using the TEF approach to characterize cPAH mixtures. However, scientific and regulatory agencies have identified a number of other PAH compounds as known or potential human carcinogens. For example, the National Toxicology Program (NTP, 2005) has identified 15 PAH compounds as "reasonably anticipated to be a human carcinogen". The California Environmental Protection Agency has established potency equivalency factors for twenty-five carcinogenic PAHs (Cal EPA, 2005). Under the proposed approach, the seven PAHs identified in the MTCA rule serve as surrogates or indicators for the broader suite of 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 PAHs. Recent studies indicate that exposure to carcinogens during childhood can increase the risk of developing cancer later in life. In March 2005, EPA published the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (EPA, 2005b) that describes approaches for using this information when assessing health risks. In that document, EPA identified benzo[a]pyrene, dimethylbenz[a]anthracene and dibenzo[a,h]anthracene as chemicals that have a mutagenic mode of action for carcinogenicity. In June 2006, EPA published guidance for implementing the Supplemental Guidance. EPA (2006) recommended that risk assessors use the age-dependent adjustment factors in the Supplemental Guidance when using the cancer slope factors for these compounds. The use of these factors is a broader issue that Ecology plans to consider during the five-year process.

- The proposed approach simplifies the approach for establishing MTCA cleanup levels: The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}Treating PAH mixtures as a single hazardous substance minimizes the need to make such adjustments. This simplifies the process for establishing cleanup levels. —

- The proposed approach is consistent with the policies and procedures used to establish the Method A cleanup levels in the current MTCA rule: Option 2 is also consistent with the policies and procedures underlying the Method A soil cleanup levels[47]. This approach was extensively discussed with the TPH Policy Oversight Group during the 2001 MTCA rule making and developed based on those discussions.

- The proposed approach is consistent with the policies and procedures used by several other Ecology programs: Several other Ecology programs have adopted approaches that are similar to Option 2. For example:
  - The Air Quality Program treats PAH mixtures as a single toxic air pollutant when evaluating potential emissions from proposed new sources. Under this regulation, PAH emissions are compared to screening levels for mixtures of PAHs that are expressed in

[46] WAC 173-340-200 includes the following definition: "PAHs (carcinogenic)" or "cPAHs" means those polycyclic aromatic hydrocarbons substances, PAHs, identified as A (known human) or B (probable human) carcinogens by the United States Environmental Protection Agency. These include benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, benzo(a)pyrene, chrysene, dibenzo(a,h)anthracene, and indeno(1,2,3-cd) pyrene."

[47] When developing the Method A values, cPAH mixtures were treated as a single hazardous substance and the Method A soil cleanup level was calculated using a target cancer risk of one-in-one million (10^{-6})

terms of B(a)P[48]. The screening levels are based on an incremental cancer risk of one-in-one million (WAC 173-460-060).

- o The Water Quality Program has established a ground water criterion for both PAHs and BaP (Chapter 173-200 WAC).

However, Ecology recognizes that not all programs use the same approach to evaluate/ regulate PAH mixtures. For example, the National Toxics Rule establishes surface water standards based on protection of human health and includes individual criteria for seven PAH compounds. Compliance is evaluated separately for each PAH compound.

- The proposed approach reflects public concerns about exposure to toxic chemicals: Public concerns about health threats posed toxic chemicals have grown over the last decade as new information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of bioaccumulative chemicals in Puget Sound and other parts of the state. Selection of an option that relaxes cleanup requirements for chemical mixtures (Option 1) would be inconsistent with these Ecology initiatives.

- The proposed approach is consistent with approaches used by some EPA programs: There is also a great deal of variability in the approaches used by federal programs to evaluate/ regulate PAH mixtures. EPA has established a maximum contaminant level (MCL) for BaP and compliance is evaluated based on BaP measurements in drinking water. However, several federal programs implement approaches that are similar to Option 2. For example:

  - o The EPA Superfund program continues to use the methods and procedures described in EPA (1993) and has reaffirmed the use of TEF methodology for cPAHs considered as a single hazardous substance for the whole mixture by summing the carcinogenic potential of individual PAHs relative to an index compound (e.g., benzo(a)pyrene)[49].
  - o EPA established emission limits for polycyclic organic matter, PAHs, as part of its list of 189 hazardous air pollutants using TEF methodology to evaluate the potential health risks from exposures to airborne particulate mater contaminated with PAHs.

- The proposed approach falls within the range of approaches use by other state environmental agencies. The Association of State and Territorial Solid Waste Management Officials (ASTSWMO) recently completed a survey of state screening levels and action levels (ASTSWMO, 2006). They found that "...[t]he cancer risk basis of the standards and guidelines reported by States ranged from a stringent one-in-ten million (1E-07) to one-in-ten thousand (1E-04). The majority of standards utilize the more typical one-in-one million (1E-06) risk level criteria...." Ecology reviewed the web pages of several environmental agencies in other states to determine whether agencies were treating PAH mixtures as a single hazardous substance (Option 2) or a mixture of multiple hazardous substances (Option 1). The results are shown in Table 8 on the following page. Ecology identified two states that treat PAH mixtures as single hazardous substances when establishing those requirements. However,

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[48] For mixtures of PAHs, WAC 173-460-050 states "The owner or operator of a source that may emit a mixture of polyaromatic hydrocarbon emissions shall quantify the following PAHs and shall consider them together as one TAP equivalent in potency to benzo(a)pyrene: benzo(a)anthracene, benzo(b)fluoranthene, benzo(k)fluoranthene, chrysene, dibenzo(a,h,)anthracene, indenol(1,2,3-cd)pyrene, benzo(a)pyrene." [WAC 173-460-050 (4) (iii) (c)].

[49] Lynn Flowers, Abstract:Toxicology of Polycyclic Aromatic Hydrocarbon (PAH) Mixtures. IRIS Staff, US Environmental Protection Agency. Presentation from Spring 2005 Society of Toxicology Meeting.

the majority of states surveyed by Ecology consider each PAH compound as an individual hazardous substance (Option 1).[50]

Table 8: Approaches Used By Other State Environmental Agencies When Evaluating PAH Mixtures

State	State Programs	TEF Value	Each PAH = Single Substance (Option 1)	Mixture = Single Substance (Option 2)	Cancer Risk Level Applied to PAHs
Florida[51]	Waste Management Div.	EPA 1993	X		$1x10^{-6}$
New Jersey[52]	Site Remediation Program	EPA 1993	X		$1x10^{-6}$
Idaho[53]	Waste Mngmt & Remed.	EPA 1993	X		$1x10^{-6}$
Louisiana[54]	Remediation Service Div.	EPA 1993	X		$1x10^{-6}$
Massachusetts[55]	MA Dept. of Env. Prot.	EPA 1993	X		$1x10^{-6}$
Minnesota[56]	Pollution Control Agency	Cal-EPA		X	$1x10^{-5}$ (mixture)
Oregon[57]	Oregon DEQ	EPA 1993	X		$1x10^{-6}$
Texas[58]	Remediation Division	EPA 1993	X		$1x10^{-5}$
Wisconsin[59]	Dept. of Nat. Resources	EPA 1993	X	X[60]	$7x10^{-7}$ (mixture)

[50] Ecology has not surveyed all 50 states and, consequently, recognizes that the results may not reflect the full range of approaches used by different state agencies and/or the variability among environmental programs within a single state agency.

[51] Technical Report: Development of Cleanup Target Levels (CTLs) For Chapter 62-777, F.A.C., Prepared for the Division of Waste Management Florida Department of Environmental Protection By Center for Environmental & Human Toxicology, Univ. of Florida, Gainesville, FL, Feb., 2005, Table 19, Page 61; and Table 1: page 4 of 41

[52] Site remediation Program; contact Linda Cullen (609-984-9778

[53] Idaho Risk Evaluation Manual, Final, July 2004; RBCA Tier 2 Software version 1.0, user's guide and Risk-based Corrective Action for Tier 2 Evaluation.

[54] LDEQ RECAP 2003; APPENDIX D: GUIDELINES FOR ASSESSING POLYCYCLIC AROMATIC HYDROCARBONS POLYCHLORINATED DIBENZODIOXINS/POLYCHLORINATED DIBENZOFURANS

[55] Massachusetts Department of Environmental Protection. Polycyclic Aromatic Hydrocarbons (PAHs). Guidance for Disposal Site Risk Characterization.

[56] Minnesota Department of Health. Risk Assessment Rules/Guidance. Polycyclic Aromatic Hydrocarbons:Methods for Estimating Health Risks from Carcinogenic PAHs. And Risk-Based Guidance for The Soil-Human Health Pathway. Volume 2. Technical support document Minnesota Pollution control Agency. Site Remediation Section, January 1999, page 53. Calculation Spreadsheet: Tier 1 SRV Spreadsheet; Risk-tier1srv.xls, 01/06.

[57] Oregon Department of Environmental Quality. E-Mail From M. Poulsen (OR DEQ) to Dr. M. Bailey (EPA, Region X) March 30, 2006; and email from Michael Anderson . OR DEQ) to Ecology Staff on June 27, 2006.

[58] Texas Natural Resource Conservation Commission; Chapter 350 – Texas Risk Reduction Program; SUBCHAPTER D : DEVELOPMENT OF PROTECTIVE CONCENTRATION LEVELS; §§350.71 - 350.79; September 23, 1999 page 89; and TNRCC Regulatory Guidance Remediation Division: RG-366/TRRP-18; Risk Levels, Hazard Indices, and Cumulative Adjustment; August 2002

[59] Wisconsin Department of Natural Resources. Soil Cleanup Levels for Polycyclic Aromatic Hydrocarbons (PAHs) Interim Guidance. Publication RR-519-97, April 1997.

[60] The Wisconsin DNR Interim Guidance specifies that cleanup proponents may develop soil cleanup levels based on BaP equivalent concentrations as an alternative to applying generic residual contamination levels (RCLs).

Use of the TEF Methodology for PCBs Mixtures

Issue #7

Should Ecology revise the MTCA rule to explicitly allow or require people to use the TEF values and methodology developed by the World Health Organization when assessing the human health risks of PCB mixtures?

Background

Polychlorinated biphenyls (PCBs) are a group of synthetic organic chemicals that include 209 individual chlorinated biphenyl compounds (known as congeners). Commercial mixtures of PCBs were manufactured in the United States from @ 1930 to 1977 under the trademark "**Aroclor**" followed by a four digit number; usually the first two digits indicate the parent biphenyl molecule and the last two digits indicate the percent chlorine by weight[61]. PCBs were used as coolants and lubricants in electrical equipment, such as capacitors and transformers, because of their inflammability, chemical stability, and insulating properties. There are no known natural sources of PCBs.

There are two general approaches for evaluating health risks associated with environmental concentrations of PCBs:

- Total PCB Concentrations. Under the MTCA Cleanup Regulation, excess cancer risks, cleanup levels and remediation levels for PCB mixtures are currently calculated using the cancer slope factor for PCBs published in the Integrated Risk Information System (IRIS) database. Compliance is evaluated using measurements of total PCB concentrations in environmental media using standard methods (e.g. EPA Methods 8080 and 8081) that involve the use of gas chromatography/electron capture detection systems. Specifically, total PCB concentrations are estimated by comparing the chromatographic pattern of peaks in the environmental sample with the pattern or number of peaks in a commercial Arochlor sample.

- Congener-specific analyses. PCB mixtures may include up to 209 individual congeners which differ in terms of the number and location of chlorine atoms. Over the last 30 years, the standard approach for estimating PCB environmental concentrations has begun to shift from the analysis of commercial mixtures to congener-based analyses. There is a now sizable body of scientific information supporting the use of TEFs to characterize PCB mixtures.

The TEF methodology for coplanar PCBs has evolved over the last fifteen years (see Table 12). EPA (1991)[62] concluded that selected PCBs may share a common mode of action with TCDD. Ahlborg et al. (1994)[63] concluded that TEFs are applicable to certain PCBs that display dioxin-

[61] For example, Aroclor 1260 contains 12 carbon atoms (parent biphenyl molecule) and approximately 60 percent chlorine by weight. Aroclor 1016 is an exception to this nomenclature scheme, as it contains 12 carbon atoms and contains over 41 percent chlorine by weight.
[62] U.S. EPA. 1991. Workshop report on toxicity equivalency factors for polychlorinated biphenyl congeners. Risk Assessment Forum. EPA/625/3-91/020. The purpose of the 1991 EPA workshop was to examine the existing toxicity and exposure database on PCBs to ascertain the feasibility of developing toxicity equivalency factors for dioxin-like PCB congeners.
[63] Ahlborg UG, Becking GC, Birnbaum LS, Brouwer A, Derks HJGM, Feeley M, Golor G, Hanberg A, Larsen JC, Liem AKD, et al. 1994. Toxic equivalency factors for dioxin-like PCBs; report on a WHO-ECEH and IPCS

like properties because they share a common mode of action with TCDD. In 1998, the World Health Organization (WHO)[64] generated a database consisting of approximately 1,200 peer-reviewed publications evaluating the toxicity of PCBs. Based on that review, the WHO proposed TEF values for 12 dioxin-like PCBs (Van den Berg et al., 1998)[65]. Several state and federal agencies currently use the WHO-98 values to characterize the health risks of PCB mixtures.

The WHO convened a meeting of scientific experts in June 2005 to review the WHO-98 TEF values and other related issues. The scientific experts participating in that meeting recommended changes to the TEF values for nine of the twelve dioxin-like PCB congeners (See Table 9). The results of that meeting are summarized in Van den Berg et al. (2006).

Table 9: Toxicity Equivalency Factors (TEFs) For Polychlorinated Biphenyls (PCBs)

IUPAC #	Structure	WHO/94[66]	WHO/98[67]	WHO/05
77	3,3',4,4'-TCB	0.0005	0.0001	0.0001
81	3,4,4',5-TCB	-------	0.0001	0.0003
105	2,3,3',4,4'-PeCB	0.0001	0.0001	0.00003
114	2,3,4,4',5-PeCB	0.0005	0.0005	0.00003
118	2,3,4,4',5-PeCB	0.0001	0.0001	0.00003
123	2,3,4,4',5-PeCB	0.0001	0.0001	0.00003
126	3,3',4,4',5- PeCB	0.1	0.1	0.1
156	2,3,3',4,4',5-HxCB	0.0005	0.0005	0.00003
157	2,3,3',4,4',5-HxCB	0.0005	0.0005	0.00003
167	2,3,4,4',5,5'- HxCB	0.00001	0.00001	0.00003
169	3,3',4,4',5,5'- HxCB	0.01	0.01	0.03
170	2,2',3,3',4,4',5-HpCB	0.0001	-------	-------
180	2,2',3,4,4',5,5'-HpCB	0.00001	-------	-------
189	2,3,3',4,4',5,5'-HpCB	0.0001	0.0001	0.00003

In 2004, EPA asked the National Academy of Sciences to review the agency's Dioxin Reassessment Report. The NAS report was recently published in 2006 and the committee concluded that the "...the toxic equivalency factor methodology provides a reasonable, scientifically justifiable, and widely accepted method to assess the relative potency of DLCs..." (NAS, 2006, p. 6)[68].

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. Require Evaluation of Dioxin-Like PCB Congeners. Under this option, Ecology would revise the MTCA Cleanup Regulation to require that excess cancer risks, cleanup levels and

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consultation. Chemosphere 28 (6): 1049-1067. The results of the 1991 EPA workshop were published in this peer-reviewed technical publication

64 European Center for Environmental Health and the International Program on Chemical Safety

65 Van den Berg M, Birnbaum L, Bosveld, ATC, Brunstrom B, Cook P, Feeley M, Giesy JP, Hanberg A, Hasegawa R, Kennedy SW, et al. (1998). Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environmental Health Perspectives 106(12):775-792. This peer-reviewed publication is the technical standard for using WHO-recommended TEFs for polychlorinated dibenzo-*p*-dioxins and dibenzofurans and dioxin-like PCBs.

66 Ahlborg, U; Becking, GC; Birnbaum, LS; et al. (1994) Toxic equivalency factors for dioxin-like PCBs: report on a WHO-ECEH and IPCS consultation, Dec. 1993. Chemosphere 28(6):1049-1067.

67 Van den Berg, M; Birnbaum, L; Bosveld, ATC; et al. (1998) Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environ Health Perspect 106(12):775-792.

68 The NAS committee also recommended that EPA acknowledge the need for better uncertainty analysis of the toxicity values and should include an initial uncertainty analysis of overall toxicity in the final EPA report.

remediation levels for PCB mixtures be calculated using the WHO-2005 TEF values and methodology recommended by the World Health Organization (Van den Berg et al. 2006).

2. Provide Option to Evaluate Dioxin-Like PCB Congeners. Under this option, Ecology would revise the MTCA Cleanup Regulation to provide the option for calculating excess cancer risks, cleanup levels and remediation levels for PCB mixtures using the WHO-2005 TEF values and methodology recommended by the World Health Organization (Van den Berg et al. 2006).

3. Defer Issue to Future Rulemaking Process. Under this option, Ecology would defer this issue to a subsequent rulemaking and continue to calculate excess cancer risk, cleanup levels and remediation levels using information on total PCB concentrations and the cancer slope factor for PCB mixtures published in the Integrated Risk Information System (IRIS) database.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to provide the option for cleanup for Ecology and others to use the WHO-2005 TEF values and methodology when calculating excess cancer risk, cleanup levels and remediation levels for PCB mixtures (Option 2). Ecology's rationale for selecting this option includes the following:

- Application of the TEF methodology to coplanar PCBs has a sound biological basis. The TEF approach for dioxin-like PCBs is based on the concept that the various congeners of dioxin-like PCBs essentially act as one chemical, affecting the Ah receptor (aryl hydrocarbon hydroxylase receptor).

- The TEF values for dioxin-like PCB congeners have a sound scientific basis. The WHO-98 TEF values are based on a rigorous scientific review and professional consensus. More recent scientific reviews conducted by the EPA Risk Assessment Forum (EPA, 2000), EPA's Science Advisory Board (EPA, 1995; EPA, 2001), the World Health Organization (Van den Berg et. al., 1998) and the National Research Council (NAS, 2003; NRC, 2001) have re-affirmed the scientific basis for these values. In addition, the MTCA Science Advisory Board recently concluded:

  > *The Board stated that the 2005 TEF values for dioxin-like PCBs recommended by the WHO are consistent with current scientific information. As noted above, the Board stated that it was fortuitous that the WHO had recently completed a review and evaluation of available scientific information which resulted in updated TEF values for dioxins and furans.*

- The TEF methodology is an effective tool for assessing environmental risks. The TEF methodology is a tool that allows the assessor to evaluate the toxicity of a complex environmental mixture in the absence of complete knowledge of the toxicity for all of the components of the mixture. EPA has used the TEF methodology to evaluate the risks of PCB contamination in and around the Hudson River, the Housatonic River, and in the EPA's Great Lakes Initiative. The National Research Council (2001) concluded that congener-specific analyses often provide a better basis for assessing environmental risks because:

  - After release into the environment, PCB mixtures change through partitioning, transformation, and bioaccumulation, differing considerably from commercial mixtures.
  - There is a selective retention of persistent PCB congeners through the food chain (enrichment) that confers greater exposure and potential risks.

    - Persistent congeners can retain biological activity long after exposure stops.
    - Half-life estimates for a PCB mixture can underestimate its long – term persistence, because half-lives of its components differ widely.
    - Environmental PCBs occur as mixtures, there are no cancer studies of PCB mixtures found in the environment. Studies are available for some commercial Aroclor mixtures, though similarity to an environmental mixture can be uncertain. This uncertainty results because mixtures are partitioned, transformed, and bioaccumulated in the environment. Testing an Aroclor mixture in the laboratory may not be a valid surrogate for assessing an Aroclor mixture that has been in the environment.

- Ecology and other environmental agencies are currently using congener-specific analyses to evaluate the health risks of PCB mixtures. Ecology has reviewed the methods and procedures used by other environmental programs to characterize PCB mixtures. Several agencies currently use the WHO-98 TEF values and methodology to evaluate health risks and establish regulatory requirements for PCB mixtures. For example:
    - When preparing the 303(d) list of impaired water bodies, the Environmental Assessment Program calculated TEQs for dioxins/furans and PCBs in fish tissue and surface water in freshwater environments using the WHO-98 TEF values. The Water Quality Program used this evaluation to identify impaired waterbodies by comparing the total TEQs for dioxins/furans and PCBs relative to the water quality criterion for 2, 3, 7, 8-TCDD (Ecology, 2004).
    - EPA's Superfund Program uses the methods and procedures described in IRIS for evaluating mixtures of PCBs[69]. The EPA Superfund program also recommends that the risk of dioxin-like congeners be considered (using WHO-98 values) when evaluating the health risks posed by PCB mixtures (EPA 2000 and 2003b).
    - Several environmental agencies in other states currently use the WHO-98 TEF values for dioxin-like PCBs when evaluating excess cancer risks and establishing regulatory requirements. States using the WHO-98 TEF values for dioxin-like PCBs include California[70], Louisiana[71], Massachusetts[72], Minnesota[73], Oregon[74] and Texas[75].

- There are several practical considerations that may limit the use of congener-specific analyses at individual sites. Ecology believes that congener-specific analysis provide a sound approach for evaluating PCB mixtures. However, there are several practical considerations that may limit the use of this approach at individual sites. Consequently, Ecology decided to revise the rule to provide the flexibility for cleanup proponents to continue to use the current rule provisions. These considerations include:

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[69] EPA includes the following statement in the IRIS database entry for PCBs: When congener concentrations are available, the slope-factor approach can be supplemented by analysis of dioxin TEQs to evaluate dioxin-like toxicity. Risks from dioxin-like congeners (evaluated using dioxin TEQs) would be added to risks from the rest of the mixture (evaluated using slope factors applied to total PCBs reduced by the amount of dioxin-like congeners).
[70] California EPA, 2005
[71] ATSDR Health Consultation, Review of 2002 Eunice City Lake Fish Investigation Eunice, Louisiana. July 27, 2005
[72] Housatonic Superfund Site Risk Assessment
[73] Minnesota Department of Health. Risk Assessment Rules/Guidance. Polycyclic Aromatic Hydrocarbons:Methods for Estimating Health Risks from Carcinogenic PAHs.
[74] Oregon Department of Environmental Quality. E-Mail From M. Poulsen (OR DEQ) to Dr. M. Bailey (EPA, Region 10) March 30, 2006.
[75] Texas Administrative Code, Title 30, Part 1, Chapter 350 subchapter D, Rule 350.76, (e)(1)(A)

- **Analytical Costs**. Congener-specific analyses are more expensive than total PCB analyses and, consequently, may not be appropriate for smaller cleanup sites.
- **Applicable Requirements**. MTCA cleanup levels must be at least as stringent as requirements in other applicable laws and regulations. Several existing regulatory requirements are based on total PCB measurements. Consequently, cleanup proponents may be required to measure total PCB concentrations.
- **Uncertainties on the Completeness of Assessment**. PCB toxicity includes both dioxin-like and non-dioxin-like modes of action that contribute to the overall toxicity of PCB mixtures. Dioxin equivalence evaluates the toxicity of only the dioxin-like PCB portion of the PCB mixtures. Non-dioxin-like toxicity, in turn, includes both cancer and non-cancer effects due to different modes of action.

Cleanup Levels for PCB Mixtures

Issue #8

Should Ecology continue to require that cleanup levels for PCB mixtures be based on a cancer risk of one-in-one million?

Background

Under the current MTCA rule, cleanup levels for PCB mixtures are established using the appropriate cancer slope factor for PCB's published in the Integrated Risk Information System (IRIS) database. Compliance with PCB cleanup levels is evaluated using measurements of total PCBs in soil or other environmental media (the sum of all Aroclors). Under this approach, PCB mixtures are treated as a single hazardous substance when establishing cleanup levels.

Application of the TEF approach to PCB congeners raises questions in terms of how this information will be used when establishing cleanup levels. These questions are similar to those identified for dioxin and furan mixtures (See Issue #2). Specifically, Ecology will need to decide whether to either (1) continue to treat PCB mixtures as a single hazardous substance (using a total toxic equivalence concentration to characterize the mixture) or (2) treat each congener as an individual hazardous substance.

MTCA Rulemaking Options

Ecology has considered three options for resolving this issue:

1. <u>Cleanup Levels for Individual Dioxin-Like PCB Congeners Based on a Cancer Risk of One-in-One Million</u>: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one-in-one million (10^{-6}). Cleanup levels for dioxin-like PCB congeners would be established by dividing the TCDD cleanup level by the applicable congener-specific TEF. Because there is an overall limit on cancer risk under MTCA of one-in-one hundred thousand (10^{-5}), the cleanup levels for individual congeners might need to be adjusted downward to insure this overall risk limitation is not exceeded.
2. <u>Cleanup Levels for PCB Mixtures Based on a Cancer Risk of One-in-One Million</u>: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). The TEF methodology would be used to calculate a TEQ (based on the 12 dioxin-like PCB congeners identified in Table 9) for environmental samples that would then be compared to the TCDD cleanup level.
3. <u>Cleanup Levels for Mixtures of All Dioxin-like Compounds (Dioxins, Furans and Dioxin-like PCBs) Based on a Cancer Risk Level of One-in-One Million</u>: Under this option, Method B cleanup levels would be established for TCDD based on an incremental cancer risk of one in one million (10^{-6}). This option differs from option #2 because the TEF methodology would be used to calculate a TEQ based on a larger number of congeners. Under this option, the TEQ is calculated using information on the 17 dioxin/furan congeners identified in Table 4 and the 12 PCB congeners identified in Table 9. The resulting TEQ value is then compared to the TCDD cleanup level.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to clarify that PCB mixtures will continue to be considered a single hazardous substance for assessing carcinogenic risk under MTCA. Under this approach, Method B cleanup levels for PCB mixtures must be based on a cancer risk of one-in-one million (10^{-6}) (Option #2). Ecology's rationale for selecting this option includes the following:

- The proposed approach is consistent with the current MTCA rule requirements for PCB mixtures. Option 2 is consistent with the approach used for PCB mixtures in the current MTCA rule. PCB mixtures have been historically treated as a single hazardous substance when developing Method B and C cleanup levels or determining compliance with the Method A cleanup levels.
- The proposed approach is consistent with requirements established by other Ecology programs that are ARARs for MTCA sites. MTCA cleanup levels must be at least as stringent as legally applicable and relevant and appropriate requirements (ARARs) established under other state and federal environmental laws. Option 2 is consistent with approaches used by other Ecology programs to develop requirements that are applicable to MTCA cleanup sites. For example:
  - The Water Quality Program uses surface water human health criterion for marine and freshwaters identified in the National Toxics Rule for PCBs as a single numeric criterion for all PCBs. The EPA's National Recommended Water Quality Criteria for 2002 reaffirms the consideration of PCBs as a single hazardous substance stating: The polychlorinated biphenyl (PCB) numeric criterion for the protection of human health applies to total PCBs which is the sum of all homolog, all isomer, all congener, or all Aroclor analyses. Consequently, this option is consistent with the minimum cleanup standard for surface waters in Washington.
  - The Environmental Assessment Program calculated TEQs for dioxins/furans and PCBs in fish tissue and surface water in freshwater environments using the WHO-98 TEF values. Ecology identified impaired waterbodies by comparing the total TEQs for dioxins/furans and PCBs relative to the NTR criterion for TCDD and total PCBs (64 FRN 61195) with a designated 10^{-6} risk level (Ecology, 2004).
  - The Air Quality Program specifies risk-based acceptable source impact levels for Class A toxic air pollutants using unit risk factors published in EPA's Integrated Risk Information System (IRIS). When performing these evaluations, PCB mixtures are treated as a single hazardous substance in the same way as other toxic air pollutants such as arsenic or trichloroethylene.
- The proposed approach simplifies the procedures for establishing MTCA cleanup levels. The MTCA Cleanup Regulation specifies that Method B and C cleanup levels established for individual hazardous substances based on a particular pathway (e.g. soil ingestion) must be adjusted downward to take into account exposure to multiple hazardous substances and/or multiple exposure pathways in situation where total excess cancer risk would exceed 10^{-5}. Treating PCB mixtures as a single hazardous substance minimizes the need for such adjustments. This simplifies the process for establishing cleanup levels.
- The proposed approach is consistent with Ecology's initiatives on toxic chemicals. Public concerns about health threats posed toxic chemicals have grown over the last decade as new

information on toxicity and body burdens have become available. Ecology has undertaken several initiatives to reduce and cleanup sources of bioaccumulative chemicals in Puget Sound and other parts of the state. Selection of an option that relaxes cleanup requirements for chemical mixtures (Option 1) would be inconsistent with these Ecology initiatives.

- The proposed approach is consistent with approaches being used by other environmental programs. Ecology has reviewed the methods and procedures used by other environmental programs to characterize PCB mixtures. These programs differ in terms of analytical parameters (e.g. total PCB analysis vs dioxin-like PCB congener analysis), regulatory focus (e.g. site cleanup, water quality, etc.) and risk policies. However, the vast majority of programs reviewed by Ecology treat PCB mixtures as a single hazardous substance when establishing regulatory requirements. For example:
    - EPA has established a maximum contaminant level for PCBs under the Safe Drinking Water Act. The MCL establishes a single numeric standard (0.0005 mg/L) for total PCBs. The Washington Board of Health has adopted an identical drinking water standard for PCBs (WAC 246-290-310).
    - The EPA Superfund Program uses the methods and procedures described in IRIS for evaluating mixtures of PCBs. PCB mixtures are treated as a single hazardous substance.
    - The Agency for Toxic Substances and Disease Registry (ATSDR) uses the TEF methodology to evaluate the toxicity and assess the risks of PCB mixtures. For example, ATSDR evaluated the health risks associated with eating PCB contaminated fish in Eunice City Lake in Louisiana. In that evaluation, ATSDR calculated TEQs using the WHO-98 TEFs for the 12 dioxin-like PCB congeners. The TEQs for each fish species were then compared to the EPA Region III risk-based concentration (RBC) for TCDD levels in fish tissue. The Region III RBC for TCDD in fish tissue is based on an excess cancer risk of one-in-one million (10^{-6}).
    - The Food & Drug Administration (FDA) uses the TEF methodology and toxicity equivalent factors to monitor food and animal feed with the goal of reducing dietary exposure to dioxin-like compounds (FDA, 2005).
    - Ecology reviewed the methods and procedures used by several other state environmental programs. Most states have established cleanup levels for total PCBs that treat the mixture as a single hazardous substance. Several states also use the WHO-98 TEF values and methodology to evaluate dioxin-like PCBs. Many of these states treat mixtures of dioxin-like PCBs as if the mixture (characterized by the TEQ) was a single hazardous substance. Some states (e.g. Texas) calculate TEQs that reflect the sum of dioxins, furans and dioxin-like PCBs.

Consideration of Non-Dioxin Health Effects Associated With PCB Mixtures

Issue #9

How should Ecology take into account non-dioxin-like health effects when using the TEF methodology to assess the potential carcinogenic risk of PCB mixtures under MTCA?

Background

Under the MTCA Cleanup Regulation, excess cancer risks, cleanup levels and remediation for PCB mixtures are currently established using information on the total PCB concentrations at a site and the cancer slope factor for PCBs published in the Integrated Risk Information System (IRIS) database.

However, there is a sizable body of scientific information supporting the use of a TEF methodology to characterize PCB mixtures. EPA (1991)[76] concluded that selected PCBs may share a common mode of action with 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). Ahlborg et al. (1994)[77] toxicity equivalency factors (TEFs) are considered to be applicable to PCBs for the health endpoint of cancer through the common mode of action shared with TCDD.

In 1998, the WHO generated a database consisting of approximately 1,200 peer-reviewed publications evaluating the toxicity of PCBs. The WHO proposed TEF values for 12 dioxin-like PCBs based on their evaluation of this database. The proposed WHO-98 TEF values for polychlorinated biphenyls were published by Van den Berg et al. (1998)[78] and have been recognized by national and international regulatory agencies (Cal EPA, 2005).

MTCA Rulemaking Options

Ecology has considered three options for resolving this rulemaking issue:

1. <u>Limit evaluation of PCB congeners to those with dioxin-like effects</u>: Under this option, the 12 dioxin-like congeners identified by the World Health Organization would be used to characterize the health risks for the whole mixture;
2. <u>Separately evaluate dioxin-like health effects and non-dioxin health effects</u>: Under this option, Method B cleanup levels would be based on the endpoint resulting in the most stringent cleanup level.

[76] U.S. EPA. 1991. Workshop report on toxicity equivalency factors for polychlorinated biphenyl congeners. Risk Assessment Forum. EPA/625/3-91/020. The purpose of the 1991 EPA workshop was to examine the existing toxicity and exposure database on PCBs to ascertain the feasibility of developing toxicity equivalency factors for dioxin-like PCB congeners.

[77] Ahlborg UG, Becking GC, Birnbaum LS, Brouwer A, Derks HJGM, Feeley M, Golor G, Hanberg A, Larsen JC, Liem AKD, et al. 1994. Toxic equivalency factors for dioxin-like PCBs; report on a WHO-ECEH and IPCS consultation. Chemosphere 28 (6): 1049-1067. The results of the 1991 EPA workshop were published in this peer-reviewed technical publication.

[78] Van den Berg M, Birnbaum L, Bosveld, ATC, Brunstrom B, Cook P, Feeley M, Giesy JP, Hanberg A, Hasegawa R, Kennedy SW, et al. (1998). Toxic equivalency factors (TEFs) for PCBs, PCDDs, PCDFs for humans and wildlife. Environmental Health Perspectives 106(12):775-792. This peer-reviewed publication is the technical standard for using WHO-recommended TEFs for polychlorinated dibenzo-*p*-dioxins and dibenzofurans and dioxin-like PCBs.

3. Perform an integrated evaluation of dioxin-like health effects and non-dioxin-like health effects: Under this option, Method B cleanup levels would be established at concentrations where the cancer risk from all congeners does not exceed an incremental cancer risk of one-in-one million (10^{-6}).

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to specify that an integrated evaluation of dioxin-like and non-dioxin-like health effects may be required by Ecology on a site-specific basis when using toxicity equivalency factors to evaluate dioxin-like PCBs. Ecology's rationale for selecting this option includes the following:

- PCB toxicity includes both dioxin-like and non-dioxin-like modes of action that contribute to the overall toxicity of PCB mixtures. The TEF methodology considers the toxicity of only the dioxin-like PCB portion of the PCB mixtures. Non-dioxin-like toxicity includes both cancer and non-cancer effects due to different modes of action. Although evaluation methods of PCB effects continue to evolve, dioxin-like toxicity (as evaluated with TEF methodology) is an important component of PCB toxicity that requires consideration.
- An integrated evaluation is consistent with current EPA Guidance . An integrated evaluation of dioxin-like and non-dioxin-like health effects for PCBs would follow the general guidance provided by EPA's Integrated Risk Information System:

  > When congener concentrations are available, the slope-factor approach can be supplemented by analysis of dioxin TEQs to evaluate dioxin-like toxicity. Risks from dioxin-like congeners (evaluated using dioxin TEQs) would be added to risks from the rest of the mixture (evaluated using slope factors applied to total PCBs reduced by the amount of dioxin-like congeners).

- Specific procedures for performing an integrated evaluation are not available: Specific procedures for an integrated evaluation of dioxin-like and non dioxin-like health effects have not been developed beyond that provided in EPA's Integrated Risk Information System. Additional experience needs to be accumulated before establishing a specific approach in rule.

Use of TEF Values When Evaluating Cross-Media Transfer

Issue #10

How should Ecology apply the TEF methodology when evaluating cross-media impacts?

Background

Mixtures of polychlorinated dibenzo-p-dioxins and dibenzofurans, polychlorinated biphenyls, and polycyclic aromatic hydrocarbons exist in the environment as complex chemical mixtures. The Department of Ecology has determined these mixtures are persistent, bioaccumulative toxins (WAC 173-333-100). This means these complex environmental mixtures remain in the environment for long periods of time with the potential to transfer from one medium to another and accumulate in the food chain.

Models are typically used to predict how these chemical mixtures migrate from one medium to another (such as leaching from soil to groundwater) and bioaccumulate (concentrate in fish from water or sediment). The transport and partitioning of these complex environmental mixtures are determined, in part, by physicochemical properties such as water solubility, vapor pressure, Henry's law constant, and octanol-water partition coefficient. This "cross media" transport of these mixtures is complicated by the fact that these mixtures are made up of congeners or different PAHs each with different physicochemical properties. And the composition of the mixtures changes over time (weathering) through partitioning, chemical transformation, and preferential bioaccumulation. Environmental partitioning of a chemical refers to the processes by which mixtures, or components of the mixture, separate into air, water, sediment, and soil.

MTCA Rulemaking Options

Ecology has considered two options for resolving this rulemaking issue:

1. Index Chemical: Under this option, cleanup proponents would use the chemical properties of the index chemical (that is, TCDD, BaP) when modeling the fate and transport of dioxin/furan, PAH and PCB mixtures.
2. Congener-Specific Analysis: Under this option, cleanup proponents would use congener- and PAH-specific properties, when available, when modeling the fate and transport of dioxin/furan, PAH and PCB mixtures.

Ecology's Rulemaking Proposal and Rationale

Ecology is proposing to revise WAC 173-340-708(8) to require that congener- and PAH-specific properties be used when modeling the fate and transport of mixtures of dioxin/furans, PCBs and PAHs. Ecology's rationale for selecting this option includes the following:

- Technical Basis. The fate and transport of dioxins, furans, PCBs and PAHs are not necessarily not related to their TEFs. A wide range of other physical and chemical characteristics influence the persistence, mobility and transport of contaminants in the environment.

- Scientific Review. NAS (2003) has reviewed the application of the TEF methodology to dioxin/furan mixtures and concluded "…[a]lthough the TEF system is useful for determining toxicity in mixtures of DLC congeners, it cannot be used to simplify environmental fate and transport analyses of DLCs because individual congeners differ in their physical and chemical properties, an important consideration in fate modeling…" (p. 20). NRC (2001) reached similar conclusions in its review of PCB contamination.

- Approaches Used By Other Agencies. EPA Region V has developed a Total Equivalency Approach that is designed to allow variations in bioaccumulation potential to be considered when establishing water quality criteria for dioxin/furan mixtures. This approach involves multiplying each TEF value for each congener by a corresponding bioconcentration equivalency factor (BEFs) to calculate a Total Equivalency for the mixture. This approach is being used by the water quality programs in New York and several other Great Lakes states. The Oregon DEQ is considering adopting a similar approach.

- Practical Considerations. Congener-specific information is available for the physical and chemical characteristics that influence the environmental fate and transport of dioxin, furans, PCBs and PAHs. Site-specific evaluations of fate and transport can be streamlined through the use of spreadsheet models. For example, Ecology has developed a spreadsheet model to estimate the fate and transport of petroleum contaminants (including PAHs) that have been released into soils.

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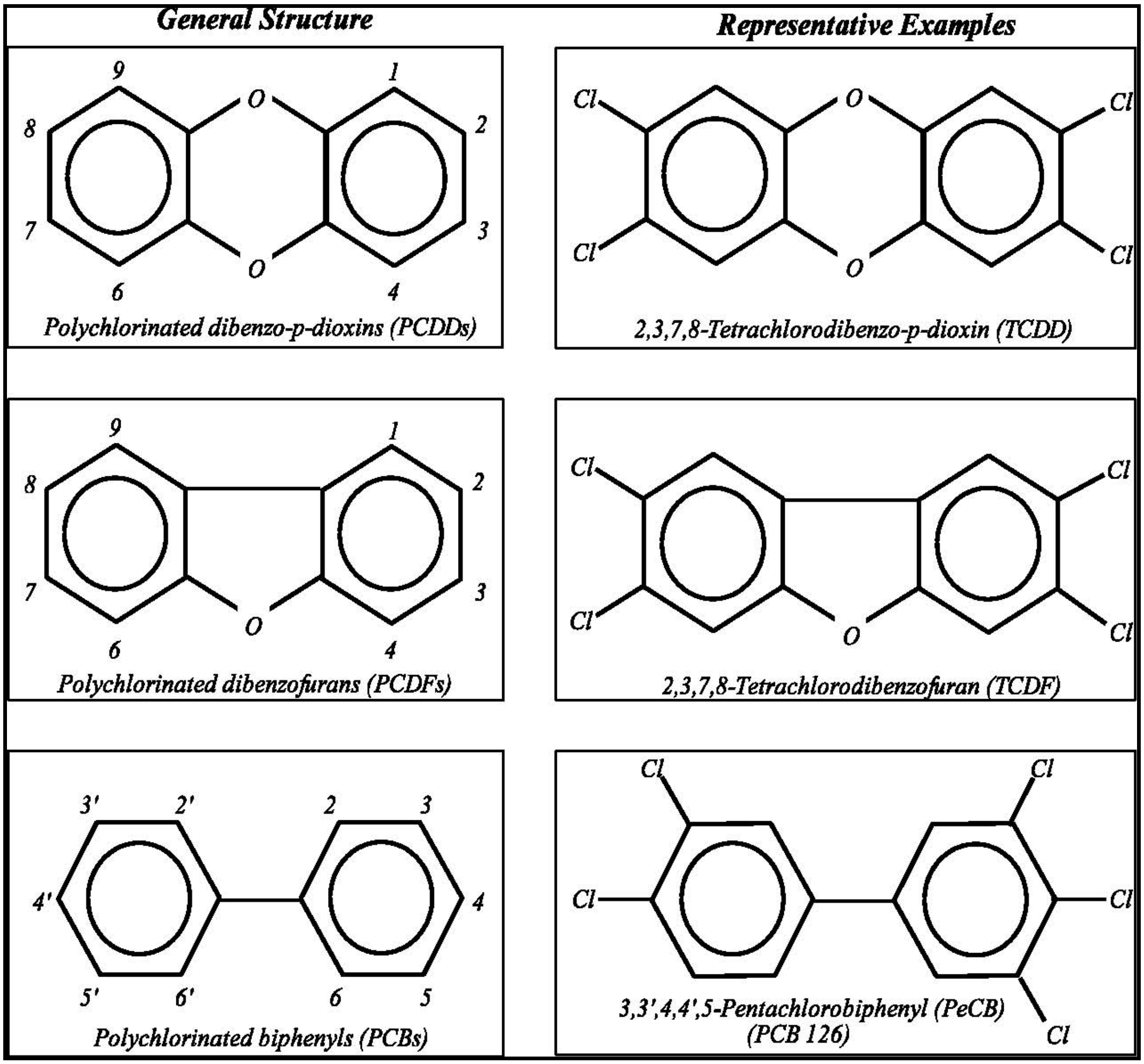
Representative Structural Formulas

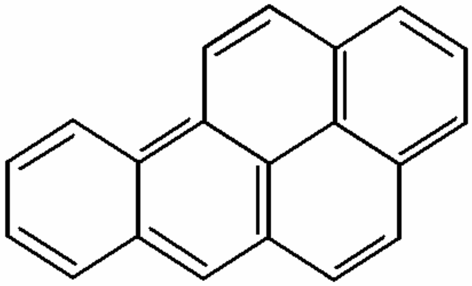
Polychlorinated dibenzo-p-dioxins and dibenzofurans
Polychlorinated biphenyls



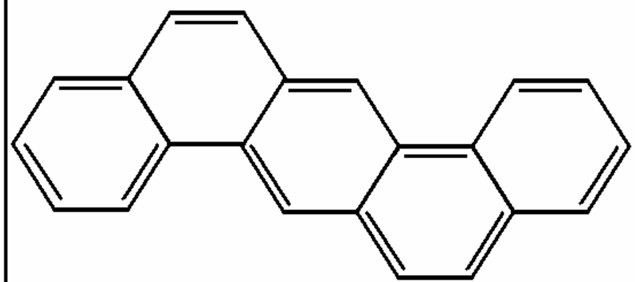
Chemical structures of polychlorinated dibenzo-p-dioxins, polychlorinated dibenzofurans, and polychlorinated biphenyls. Numbers by aromatic ring carbons of general structures represent potential chlorine substitutions.

Polycyclic Aromatic Hydrocarbons

Representative Examples



Benzo[a]pyrene



Dibenzo[a,h]anthracene

Appendix – Information on Bioavailability of Soil-Bound Dioxin

Consolidation of the Dioxin Bioavailability Data			
As Measured by Liver Content (%)		As Measured by AHH Induction (%)	As Measured by P-450 Induction (%)
48		54	117
19		112	91
62		49	90
70		92	76
67		56	105
60		121	65
67		113	71
52		81	84
57		103	
14		60	
22		61	
45		106	
32			
71			
56			
66			
44			
0.25			
24			
30			
# of Studies	20	12	8
Average %	45	84	87
Wittsiepe et. al., 2007 not included, bioavailability determine from various organs & tissues in minipigs			

Summary Tables of Technical Studies –Absorption/Bioavailability Mean Estimates of Relative Oral Bioavailability of TCDD from Soil (Based on liver concentrations, unless otherwise noted)

	Author	Animal	Relative Bioavailability	Notes
Times Beach				
	McConnell	Guinea Pig	<48%	1 µg/kg dose
	McConnell	Guinea Pig	19%	3 µg/kg dose (dead animals only)
	Shu	Rat	63% (reported as 43%)	43% from inappropriate adjustment (real range 52-70%)
	Wendling	Guinea Pig	30%	Liver concentration at high 10 µg/kg dose
	Wendling	Guinea Pig	7%	Liver concentration at low 3 µg/kg dose
Minker Stout				
	McConnell	Guinea Pig	<57%	1 µg/kg dose
	McConnell	Guinea Pig	14%	3 µg/kg dose (dead animals only)
	McConnell	Rat	45%	5 µg/kg dose
	McConnell	Rat	49 – 112%	Based on AHH induction
	Lucier	Rat	22 – 45%	Dose range 0.015 – 5.5 µg/kg
	Lucier	Rat	56 - 121%	Based on AHH induction
	Lucier	Rat	65 - 117%	Cytochrome P450 induction
Seveso				
	Bonaccorsi	Rabbit	32%	
Seveso (recontam)				
	Bonaccorsi	Rabbit	56 – 71%	
	Poiger	Rat	44 – 66%	
Newark (manufact.)				
	Umbreit	Guinea Pig	~0.25%	
	Wendling	Guinea Pig	1.6%	Liver concentration at high 10 µg/kg dose
	Wendling	Guinea Pig	1.6%	Liver concentration at low 5 µg/kg dose
Newark salvage				
	Umbreit	Guinea Pig	24%	
Arable land/ from Hamburg	Wittsiepe	Minipigs	0.6 to 21.9%	I-TEQ bioavailability is 13.8%; liver, adipose, muscle, brain & blood analyzed Rel. bioavail. estimated by comparison of organ/tissue concent. with mixt. Extracted from same soils by solvent

Soil From	Reference	Relative Bioavailability	Endpoint Measured	Animal	Gavage Dose (µg TCDD/kg body weight)	Soil Concentration (µg TCDD/kg soil)	Particle Size	Notes
Times Beach, MO								
	McConnell	<48%	Liver content	Guinea Pig	1.3	770 µg/kg	< 250 µm	Dead animals
		19%	Liver content	Guinea Pig	3.8			
	Shu	62%	Liver content	Rat	0.0032			
		70%	Liver content	Rat	0.007			
		67%	Liver content	Rat	0.04			
		60%	Liver content	Rat	0.037			
		67%	Liver content	Rat	0.175			
		52%	Liver content	Rat	1.45			
	Wendling	30%	Liver content	Guinea Pig	10	510		
		7%	Liver content	Guinea Pig	3	510		
Minker Stout, MO								
	McConnell	<57%	Liver content	Guinea Pig	1.1	880 µg/kg	< 250 µm	
		14%	Liver content	Guinea Pig	3.3			Dead animals
		54%	AHH induction	Rat	0.22			
		112%	AHH induction	Rat	0.44			
		49%	AHH induction	Rat	1.1			
		92%	AHH induction	Rat	5.5			
	Lucier	22%	Liver content	Rat	1.1	880 µg/kg	< 250 µm	
		45%	Liver content	Rat	5.5			
		56%	AHH induction	Rat	0.015			
		121%	AHH induction	Rat	0.044			
		113%	AHH induction	Rat	0.1			
		81%	AHH induction	Rat	0.22			
		103%	AHH induction	Rat	0.5			
		60%	AHH induction	Rat	1.1			
		61%	AHH induction	Rat	2.0			
		106%	AHH induction	Rat	5.5			
		117%	P450 induction	Rat	0.015			
		91%	P450 induction	Rat	0.044			

		90%	P450 induction	Rat	0.1			
		76%	P450 induction	Rat	0.22			
		105%	P450 induction	Rat	0.5			
		65%	P450 induction	Rat	1.1			
		71%	P450 induction	Rat	2.0			
		84%	P450 induction	Rat	5.5			
Seveso, Italy								
	Bonaccorsi	32%	Liver content	Rabbit	0.56	81 µg/kg	30-74 µm	7 x 80 ng/kg doses
Seveso								
(recontaminated)	Bonaccorsi	71%	Liver content	Rabbit	0.28	30 day soil contact		7 x 40 ng/kg doses
		56%	Liver content	Rabbit	0.56	30 day soil contact		7 x 80 ng/kg doses
	Poiger	66%	Liver content	Rat	0.11	15 hour soil contact		
		44%	Liver content	Rat	0.11	8 hour soil contact		
Arable land/								
from Hamburg Germany	Wittsiepe	10%	Various tissues	Minipigs	2.63 ng I-TEQ/kg bw-day	0.5 g/kg bw/d of PCDD/F mixture	30.6% sand 36.5% silt 32/9% clay 6.83% organic carbon Particle size < 1mm	
Newark mfg site								
	Wendling	1.6%	Liver content	Guinea Pig	10	1400		
		1.6%	Liver content	Guinea Pig	5	1400		
	Umbreit	~0.25%	Liver content	Guinea Pig	12	Mghing site:1500 to 2500 ppb; Salvage yard: ~180 ppb	For both sites: medium dense, black, coarse to fine-grained sand fill with some medium to fine gravel, traces of silt, organic matter & cinders	
Newark salvage site								
	Umbreit	24%	Liver content	Guinea Pig	0.32			