Chapter 5
Uncertainty

What's covered in Chapter 5:

- Uncertainty in the Delisting Risk-Based Process
- Types of Uncertainty
- Uncertainty in Sample

It is U.S. EPA policy that stakeholders in environmental issues be provided with sufficient information to allow them to independently assess environmental risks and the reasonableness of risk reduction actions (U.S. EPA 1995c). Furthermore, all risk characterizations should exhibit transparency, clarity, consistency, and reasonableness (U.S. EPA 1995c). To ensure that all risk assessments exhibit these qualities, the U.S. EPA Administrator has specified two requirements that must be met when characterizing risk: (1) addressing qualitative and quantitative features of the risk assessment and (2) identifying uncertainties as a measure of the confidence in the assessment. U.S. EPA Region 6 intends to meet these requirements in its risk assessments of wastes petitioned for RCRA exclusion (delisting) under 40 CFR 260.20 and 260.22. This chapter identifies and discusses the uncertainties associated with delisting risk assessments, including the uncertainty involved in the delisting risk-based process, types of uncertainty associated with risk characterization, and uncertainties associated with sample analyses used to characterize wastes petitioned for delisting.

Uncertainty is inherent in the delisting process and can be introduced into a risk assessment at each stage of the process outlined in this DTSD. For delisting, uncertainty can generally be classified in terms of sampling and nonsampling errors with regard to the following:

- Determining the total and leachable concentrations of waste constituents
- Estimating the release of pollutants from a waste management unit to the environment
- Predicting and transport of pollutants in a range of variable environments by processes that often are not completely understood or are too complex to quantify accurately

- Estimating the potential for adverse health effects in humans based on animal studies
- Estimating the probability of adverse effects on a human population that is highly variable in terms of genetic predisposition, age, activity level, and overall health.

Uncertainty is inherent in the process even if the most accurate data are used in the most sophisticated models. The methodology outlined in this document relies on a combination of probabilistic and point values—some conservative and some representing central tendencies. These values yield a point estimate of exposure and risk that falls at an unknown percentile of the full distributions of exposure and risk. For example, to develop the waste-volume adjusted DAFs, U.S. EPA Region 6 runs the EPACMTP in Monte Carlo mode, selecting input parameter values from frequency distributions of each mode input parameter to perform thousands of simulations that result in one 90^{th} percentile DAF value. This value is used in combination with point values of the ingestion, dermal absorption, and shower inhalation risk algorithms to derive a final point estimate of risk or a single delisting level. For this reason, while the degree of conservatism in risk estimates is not fully known; the values combine many conservative factors and are likely to overstate actual risk (Hattis and Burmaster 1994). This chapter discusses types of uncertainty, areas where uncertainty can be introduced into a risk assessment, and methods for qualitatively and quantitatively addressing uncertainty in risk assessments.

To describe the uncertainties associated with a delisting evaluation, this chapter discusses the following: (1) uncertainty inherent in the delisting evaluation process, (2) types of uncertainty, and (3) uncertainties specifically associated with sampling and analysis of petitioned waste.

5.1 UNCERTAINTY IN THE DELISTING RISK-BASED PROCESS

To qualify for exclusion from Subtitle C requirements, in addition to showing that a waste does not exceed target risks, a petitioner must demonstrate that a waste generated at a facility does not meet any of the criteria for which the wastes was listed (see 40 CFR 260.22(a) and associated background documents for the listed wastes). In addition, the HSWA of 1984 require that U.S. EPA consider any factors (including additional constituents) other than those for which the waste was listed if there is reason to believe that such additional factors could cause the waste to be hazardous. Accordingly, a petitioner also must (1) demonstrate that the waste does not exhibit any of the hazardous waste characteristics (ignitability, reactivity, corrosivity, and toxicity) and (2) present sufficient information for U.S. EPA to determine whether the waste contains other toxicants at hazardous levels (see 40 CFR 260.22(a), 42 [USC] 6921(f), and the background documents for the listed wastes). Although wastes that are "delisted" or excluded have been evaluated to determine whether

they exhibit any characteristics of hazardous waste, a generator remains obligated under RCRA to determine whether its waste remains nonhazardous.

If U.S. EPA grants an exclusion for a petitioned waste, the delisted waste is no longer controlled under federal hazardous waste regulations. The petitioner must then manage and dispose of the waste in accordance with local and state requirements or specifications. In some cases, U.S. EPA grants an exclusion on the condition that a facility or waste meet certain requirements. For example, for a waste that is highly variable in composition, U.S. EPA often imposes postexclusion testing requirements that the petitioner must meet prior to waste disposal. Only those batches of waste that have met the verification testing conditions provided in the final exclusion can be managed as nonhazardous waste; batches that fail to meet the verification testing conditions must be managed as hazardous waste.

To demonstrate that wastes do not meet any of the criteria for which the wastes were listed, U.S. EPA Region 6 uses risk assessment algorithms for the disposal, release, and exposure scenarios (see Chapters 2, 3, and 4). The uncertainties inherent in the use of the algorithms and the uncertainties in characterizing the disposal, release and exposure scenarios are described in the following sections.

5.1.1 Use of Risk Assessment Algorithms for Delisting Evaluations

During a delisting determination for a petitioned waste, U.S. EPA uses fate and transport models and risk assessment algorithms to (1) predict the concentrations of hazardous constituents that may be released from the petitioned waste after disposal, (2) determine the means by which receptors would be exposed to the released constituents and (3) estimate the risks and hazards that such exposures would impose on the receptors. Appropriate fate and transport models are used to estimate the potential for leachable hazardous constituents to be released to the underlying aquifer and also to estimate the potential for release of waste constituents to air and surface water. Chapter 2 outlines the methodology used to generate waste constituent concentration values that receptors would be exposed to at a defined POE.

Specifically, U.S. EPA uses acceptable health-based levels for hazardous constituents of concern at a specified POE. These levels, also known as toxicity factors, include RfDs, RfCs, Unit Risk Factors (URFs), and CSFs. These health-based levels are applied in addition to U.S. EPA's acceptable risk range of 1×10^{-6} to 1×10^{-4} for known or suspected carcinogens and an HQ of less than 1.0 for noncarcinogens (U.S. EPA 1990g). To determine the allowable concentrations (or the delisting levels) for specific waste constituents in standard multiyear delistings, the target risk level for Region 6 is based on a 1×10^{-5} risk level for

carcinogens an HQ of 0.1 for noncarcinogens. Other regions or delisting authorities may assign slightly different target risk levels. A waste constituent's delisting level is the maximum allowable total and leachate concentrations that a petitioned waste can contain at the petition-specified annual waste volume. In multiyear RCRA delistings, an order of magnitude safety factor is applied to carcinogens and noncarcinogens in order to account for possible multiple exposure pathways and multiple waste constituent exposures over time.

The delisting level for a multiyear delisting can be back-calculated by applying the acceptable health-based level at the target risk level. If the total or leachate concentration of a constituent in a petitioned waste is greater than the back-calculated delisting level then the petitioned waste is deemed to have failed the risk evaluation and is considered to have the potential to adversely affect human health and the environment. Conversely, if the waste constituent total and leachate concentrations are less than the corresponding maximum allowable levels then the waste remains a candidate for a standard multiyear delisting.

To estimate the total aggregate risk and hazard for a petitioned waste, U.S. EPA Region 6 uses the maximum waste volume, the maximum total waste constituent concentrations and the maximum leachate concentrations. The aggregate risk and hazard for a petitioned waste can be useful for a one-time delisting where establishing more conservative delisting levels is not necessary. Toxicological determination for the delisting can be performed at the lower end of the risk range for several reasons. First, because the future variability of additional batches of the wastes does not have to be accounted for, delisting levels need not be established. Second, the risk assessment is aggregate and assumes that the receptor is exposed to all waste constituents at the maximum concentrations via each exposure pathway; however, this is a very conservative assumption and is not likely to occur. Therefore, for a one-time delisting, if the computed aggregate risk and hazard for a petitioned waste do not exceed the cutoff risk level of 1×10^{-4} and HI of 1.0, the waste may qualify in Region 6 as a candidate for a RCRA delisting. Other Regions and delisting authorities may chose to set a different cutoff risk level for one-time delistings.

5.1.2 Disposal, Release, and Exposure Scenarios

Fate and transport models are used to determine the maximum allowable waste constituent concentrations and to compute aggregate risk and hazard. U.S. EPA's approach in using such models has been to represent a reasonable worst-case waste disposal scenario for the petitioned waste rather than to rely on site-specific factors. U.S. EPA believes that a reasonable worst-case scenario is appropriate when determining whether a waste should no longer be managed under RCRA Subtitle C. The use of a reasonable worst-case scenario results in conservative values for the point compliance concentrations and ensures that the waste, regulated

as hazardous, will not pose a threat to human health or the environment if the petitioner chooses to dispose of the waste in accordance with Subtitle D requirements. Site-specific factors (for example, site hydrogeology) are not considered in the risk assessment because a delisted waste is no longer subject to hazardous waste control and may be disposed of in any Subtitle D landfill or surface impoundment. Therefore, conservative default parameters are used to predict reasonable worst-case scenarios for waste disposal in any Subtitle D landfill or surface impoundment.

5.2 TYPES OF UNCERTAINTY

Uncertainty can be classified as one of four types: (1) parameter uncertainty, (2) model uncertainty (that is, does the model accurately represent and simulate conditions that may exist at a waste disposal site?), (3) decision rule uncertainty and (4) variability (Finkel 1990).

Parameter Uncertainty

Parameter uncertainty arises when parameters used in equations cannot be measured precisely or accurately because of either (1) equipment limitations or (2) spatial or temporal variances between the quantities being measured. Random or sample errors are common sources of parameter uncertainty, especially for small sample sizes. However, it is more difficult to recognize nonrandom or systemic errors that result from sampling, the experimental design, or the choice of assumptions. Examples of parameter uncertainty include uncertainty in waste characterization data and uncertainty regarding the data and input parameters used in the release and exposure algorithms. Uncertainty associated with waste characterization data may arise from the uncertainty inherent in measurement of a waste volume petitioned for delisting, whether it is estimated or measured. Uncertainty also arises with regard to waste constituent data, especially if (1) chemicals are present in the waste that are not listed as chemicals of concern, (2) chemicals are present at less than analytical detection levels, or (3) the measured concentrations are not representative of the entire waste being petitioned for delisting. In addition, the leachable concentration of a chemical is estimated with the TCLP test, which is only a laboratory approximation of what will actually happen in a landfill scenario.

Model Uncertainty

Uncertainty is associated with models used in all phases of a risk assessment, including (1) animal models used as surrogates to test human health effects, (2) dose-response models used in extrapolations, and (3) computer models used to predict the fate and transport of chemicals in the environment. Use of rodents

as surrogates for humans introduces uncertainty due to the considerable interspecies variability in sensitivity. In addition, computer models are simplifications of reality and may exclude some variables that influence predictions but cannot be included in models because of (1) increased model complexity or (2) lack of data. The risk assessor and modeler should consider the importance of excluded variables on a case-by-case basis because a specific variable may significantly affect uncertainty in some instances and not in others. A similar problem can occur when a model that is appropriate for use under average conditions is used to model conditions that significantly differ from the average. For many situations, choosing the correct model can be difficult because conflicting theories may appear to explain a specific phenomenon equally well.

The models used by U.S. EPA Region 6 that are described in this document were selected on the basis of scientific policy. The EPACMTP groundwater transport model was selected because it provides the information needed to conduct risk assessments and is considered by U.S. EPA to be a state-of-the-science model that has undergone review by independent peer review panels and the U.S. EPA Science Advisory Board. This model was developed in the context of setting national regulatory levels and as such attempts to account for the uncertainty that may be encountered during modeling of contaminant transport in groundwater nationwide. As with all models, the simplifying assumptions used to implement the EPACMTP can introduce uncertainty with regard to the models simulation of conditions at a specific sites.

Other fate and transport models recommended by this guidance may also introduce uncertainty. For example, the model used to estimate chemical concentrations in surface water bodies may be particularly conservative because it does not consider chemical decay or sorption processes. Downstream dilution of chemical concentrations in water and sediment is not considered in a delisting risk assessment; therefore, its results will likely be conservative for chemicals in surface water.

Decision Rule Uncertainly

The uncertainty associated with risk analysis influences many policy and risk management decisions. Decision rule uncertainty (that is, the uncertainty introduced in the determination of appropriate risk levels) is probably of greatest concern to risk managers. This type of uncertainty arises, for example, out of the need to balance different social concerns when determining an acceptable level of risk. Possibly the most important aspect of the risk assessment is the selection of constituents to be included in the analysis.

A second area of decision rule uncertainty involves use of standard U.S. EPA default values in the risk analysis. Standard default values used in most U.S. EPA risk assessments include inhalation and

consumption rates, body weight, and lifespan. Inhalation and consumption rates are highly correlated to body weight for adults. Using a single-point estimate for these variables instead of a joint probability distribution ignores the variability that may influence the risk assessment results by a factor of as much as two or three.

A third area of decision rule uncertainty involves use of U.S. EPA-verified CSFs, RfDs, and RfCs. These health benchmarks are used as single-point estimates throughout the risk analysis, introducing both uncertainty and variability. However, U.S. EPA has developed a process for setting verified health benchmark values to be used in all U.S. EPA risk assessments. Exception for the dioxin toxicity equivalency methodology, all health benchmarks recommended for use in all analyses are verified by U.S. EPA work groups and are available in IRIS. The information in IRIS is now maintained on the U.S. EPA web site at "http://www.epa.gov/ngispgm3/iris/index.html/". This DTSD does not estimate the uncertainty associated with using U.S. EPA-verified health benchmarks or the dioxin toxicity equivalency methodology.

5.2.1 Variability

"Variability" is often used interchangeably with the term "uncertainty," but the two terms have specific differences. Variability may be tied to variations in physical and biological processes, and it cannot be reduced with additional research or information; however, it may be known with greater certainty (for example, the age distribution of a population may be known and represented by the mean age and its standard deviation). Uncertainty is a description of the imperfect knowledge of the true value of a particular variable or its real variability in an individual or group. In general, uncertainty can be reduced through additional information gathering or analysis activities (that is, with better data or better models); additional data will not change real variability, although it may be more accurately known (Hattis and Burmaster 1994).

5.3 UNCERTAINTY IN SAMPLE ANALYSES

Based on lessons learned from previous U.S. EPA OSW delisting decisions, U.S. EPA Region 6 recognizes that a significant amount of uncertainty may result from (1) the sample analysis method used to analyze a petitioned waste and (2) the use of a delisted material. The uncertainties associated with these two aspects of delisting risk characterizations are discussed in this section.

5.3.1 The Toxicity Characteristic Leaching Procedure (TCLP)

The TCLP is a test method designed to simulate the leaching that a waste will undergo when the waste is disposed of in a sanitary landfill. This test is designed to determine the mobility of both organic and inorganic analytes present in liquid, solid, and multiphasic wastes. When performed as prescribed in Appendix II of 40 CFR Part 261, Method 1311, an analysis of any liquid fraction of the TCLP extract will indicate whether a regulated waste constituent is present in the waste. The test method is used to determine if, even after accounting for dilution from the other fractions of the extract, the concentration of the waste constituent exceeds the regulatory level allowed in that media. If the TCLP test determines that the waste constituent concentration exceeds allowable levels, as indicated by a risk assessment, the petitioned waste is hazardous and may not be delisted under 40 CFR 260.20 and 260.22.

Limitations in the use of the TCLP have been identified, specifically in the Reynolds Metals Company (RMC) delisting (U.S. EPA 1991b). Problems associated with the RMC delisting petition resulted from a combination of phenomena not accounted for in the assumptions of the TCLP. As described in the November 15, 1996, "Hazardous Waste Characteristics Scoping Study," the high alkalinity of some wastes may make the TCLP an inappropriate predictor of leachate composition. Very basic or high pH wastes contain enough hydroxyl ion to release certain other analytes to the leachate. In high pH ranges, certain waste constituents are quite soluble (that is, they have a low K_d), which makes consideration of the dilution factor very important.

Another potential problem highlighted by the RMC delisting petition involves the disposal scenario. The TCLP assumes that the waste will be commingled with 95 percent industrial waste in a municipal landfill. The TCLP, however, does not account for waste disposed of in a monofill. The TCLP assumptions are also inadequate with regard to degradation and dilution factors. For example, the TCLP uses a liquid to solid ratio of 20:1; however, the liquid to solid ratio in the RMC monofill is 0.09-0.15:1. This range of liquid to solid ratios cannot be simulated in bench-scale tests. Consequently, TCLP tests that use a liquid to solid ratio of 20:1 would dilute results for the RMC monofill. U.S. EPA Region 6 conducted limited experiments that varied the liquid to solid ratios and pH of the extraction media (U.S. EPA 1997). These limited experiments indicated that the pH and liquid to solid ratios significantly alter the TCLP leachate concentrations.

Based on results of analyses performed for the RMC delisting, it is reasonable to conclude that the TCLP is not always an adequate assessing a petitioned waste in terms of leaching considerations and associated risk. U. S. EPA's regional offices continue to investigate the TCLP and acknowledge that further testing must be

conducted U.S. EPA Region 6 intends to supplement the TCLP with additional tests for waste disposed of in a monofill. Supplemental testing may include the Synthetic Acid Precipitation Leaching Procedure, the Multiple Extraction Procedure, and column tests similar to those developed by RMC in order to predict the leaching potential of a monofill. Selection of an appropriate additional test should consider two primary goals: (1) the test should adequately predict the potential leachate concentrations of the waste, and (2) the test should approximate the volume of rainfall that the waste will be exposed to. Using a total solids concentration for a given waste constituent in place of leachate testing is not recommended.

5.3.2 Use of a Delisted Material

Under the U. S. EPA Region 6 Delisting Program, the EPACMTP has been adapted for use in predicting groundwater impacts for two Subtitle D disposal scenarios: (1) landfill and (2) surface impoundment. One assumption of the EPACMTP is that these disposal scenarios represent reasonable worst-case scenarios for waste that will be delisted. However, use of the waste for road bed material, fill material or other purposes has not been modeled in this delisting risk-based approach. In addition, the model does not evaluate waste disposal in a monofill, use of waste as fill material in a mine reclamation project or other disposal scenarios.

To avoid problems encountered in the RMC delisting or similar problems in future delisting decisions, U.S. EPA Region 6 has removed the discussion of beneficial use and recycling from the boilerplate language of the FR notice. A waste will be delisted only if it meets the criteria for which it was modeled. After an exclusion has been granted, if a facility finds an additional use for the waste or determines that the waste can be recycled and reused, the facility must submit appropriate information to U.S. EPA for evaluation before the waste can be delisted and used for the proposed purpose.

In addition, U.S. EPA Region 6 has adopted language from the Conversion Systems, Inc., delisting exclusion (U.S. EPA 1993a) that limits disposal of a delisted waste to the modeled landfill or surface impoundment. If a facility can provide a model for scenarios that are not addressed by the EPACMTP or the surface pathway modeling default parameters, U. S. EPA will evaluate that model to ensure that the appropriate pathways and assumptions have been considered before allowing the waste to be delisted.