DATA REQUIREMENTS AND CONFIDENCE INDICATORS FOR ECOLOGICAL BENCHMARKS SUPPORTING EXEMPTION CRITERIA FOR THE HAZARDOUS WASTE IDENTIFICATION RULE (HWIR99)

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Table of Contents

Figures

Tables

1.0 Introduction

The goal of the HWIR99 risk assessment is to identify wastes currently listed as hazardous that could be eligible for exemption from hazardous waste management requirements. For each constituent of concern, the HWIR99 risk assessment estimates potential risks to human and ecological receptors living in the vicinity of industrial nonhazardous waste sites that could manage HWIR exempted wastes. For ecological risks, the constituent-specific concentrations in wastes that are determined to pose de minimis risk (i.e., the exemption criteria) were based on two types of risk metrics: (1) the ecological hazard quotient, that is, the ratio between exposure concentrations or dose and appropriate ecological benchmarks,[1] and (2) the probability of protection for ecological receptors. However, the ecological benchmarks include a variety of receptors (e.g., soil fauna, mammals, plants), and, because the quality and quantity of relevant data varies widely across receptors, the ecological exemption criteria represent different levels of knowledge regarding the exposure and toxicity of chemical stressors. The variability in supporting data suggests that the level of confidence in the exemption criteria is dependent on the quantity and quality of available data. In short, the ecological exemption criteria do not reflect a standard data set; rather, they reflect a continuum of data on toxicity and exposure (e.g., bioaccumulation factors) of varying levels of quality. To provide an effective tool to characterize where on the continuum a given exemption criterion falls, this paper proposes a framework to assign confidence indicators based on the sufficiency of the data set supporting an exemption criterion. Sufficiency, in this framework, is determined according to how well an exemption criterion (1) captures risks to all relevant receptor groups in a habitat, (2) is supported by ecotoxicity data of high quality, and (3) represents all significant routes of exposure to ecological receptors. Consequently, the confidence indicators reflect all three of these "attributes" of an ecological exemption criterion. The remainder of Section 1.0 discusses the background and conceptual framework for assigning confidence indicators. Section 2.0 presents the methodology and the confidence indicators for the 46 constituents currently simulated under the HWIR99 multimedia, multipathway modeling system.

1.1 Background

In 1995, we proposed the Hazardous Waste Identification Rule (HWIR95) to establish constituent-specific concentrations in wastes that posed de minimis risks to human health and

[1] The term "ecological benchmarks" is used here in a broad sense to refer to two descriptors that were used to identify protective levels: ecotoxicological benchmarks and chemical stressor concentration limits. Briefly, this distinction was made to clearly represent the differences in the level of biological organization. Ecotoxicological benchmarks are threshold doses intended to protect wildlife populations from significant adverse effects from the ingestion of contaminated media and prey and are expressed in units of mg/kg-d. In contrast, chemical stressor concentration limits are medium-specific concentrations (e.g., sediment) intended to protect assemblages of species in contact with a contaminated medium.

wildlife. These concentrations, referred to as exemption criteria, were derived for both human and ecological receptors based on a predictive model that simulated the release, fate and transport, exposure, and risks associated with the management of potentially hazardous wastes. For ecological receptors, the HWIR95 used a screening-level approach to evaluate risks to a suite of representative receptors characteristic of generalized aquatic and terrestrial systems. These receptors were selected to represent a variety of exposure pathways across multiple trophic levels. In the terrestrial ecosystem, the representative groups of taxa included terrestrial plants, soil biota, mammals, and birds that forage primarily in terrestrial ecosystems. In the aquatic ecosystem, representative groups of taxa were algae, fish, aquatic invertebrates, benthos, and mammals and birds that forage primarily in freshwater ecosystems. The ecological risk assessment methodology developed to support HWIR95 can be summarized in four basic steps: (1) select a suite of assessment endpoints that reflected the management goals for HWIR95, (2) develop ecotoxicological benchmarks (EBs) and chemical stressor concentration limits (CSCLs) for the receptors (i.e., measures of effect), (3) calculate protective media concentrations for ecological receptors of concern, and (4) backcalculate protective waste concentrations using a concatenation of fate and transport algorithms. The product of the HWIR95 methodology was the proposal of constituent-specific waste concentrations (i.e., exemption criteria) designed to protect human and ecological receptors from adverse effects associated with constituent releases.

As discussed in the Technical Support Document for HWIR95 (RTI, 1995), the data gaps on individual receptors represented a significant limitation of the analysis. Indeed, in their review of the HWIR95 methodology, the Science Advisory Board (SAB) pointed out that the exemption criteria could be greatly improved by addressing the quality and quantity of data supporting the exemption criteria (U.S. EPA,1996a). For example, protective levels for some constituents could be generated only for aquatic biota and, therefore, the exemption criteria did not represent potential risks to all receptors. The SAB suggested that OSW should establish requirements that define an acceptable data set to evaluate ecological risks. We agree with the SAB and recognize that, despite Agency-wide efforts to improve the database on ecotoxicological effects and bioaccumulation, it is unlikely that sufficient data will be available to evaluate all potential ecological receptors for more than a handful of chemical constituents. Consequently, OSW has developed a framework that (1) establishes the data requirements necessary to evaluate ecological risks and (2) assigns relative confidence indicators to ecological exemption criteria. The framework considers the relationship between chemical/physical properties of constituents as well as the quality and quantity of ecotoxicological data identified for those constituents. These data requirements are intended to make HWIR a more effective decision-making tool to risk managers by allowing OSW to focus on constituents that meet the minimum requirements and identifying significant data gaps for other potential constituents of concern.

1.2 Brief Overview of HWIR99 Ecological Risk Assessment

The ecological risk framework developed for HWIR99 increases the resolution of the analysis developed in HWIR95 in several respects. First, the HWIR99 framework delineates the spatial boundary of the assessment at the habitat level (rather than a generalized “ecosystem”) and includes 11 representative habitats that cover freshwater (3), wetland (3), and terrestrial (5) systems. Defining the boundaries for exposure assessment within a habitat allowed for the

use of site-based data on ecological regions, land uses, waterbodies, and wetland areas. This information was used to expand the original suite of ecological receptors to include additional wildlife taxa (e.g., amphibians). For each site in the sample population of waste management facilities, habitats were delineated and appropriate receptors were assigned to the home ranges placed within the habitat. Second, the HWIR99 framework considers the spatial character of the exposure in that (1) average concentrations in contaminated prey items are derived for the home range of a particular receptor, not across the entire habitat, and (2) all prey items are not presumed to originate from the study area; exposures are prorated to reflect partial use of the study area by certain ecological receptors. As a result, exposure for a given receptor is estimated according to location of the habitat relative to the waste management unit (WMU), the size and location of the home range of that receptor within the habitat, and the concentration in prey items and media to which a receptor has access (e.g., prey that are found within the home range of the receptor). This modification provides a mechanism to capture some of the variability in ecological exposures. Third, the ecological risk characterization that supports the exemption criteria allows the risk assessor to determine the risks for selected attributes of risk, including the trophic level, the receptor group (e.g., birds), habitat type (e.g., grasslands), and other attributes relevant to the decision-making process. Thus, ecological exemption criteria may be based on the risk estimates for a certain type of habitat, one or more receptor groups, or across all receptors for all habitats. This flexibility provides a more transparent metric for evaluating the significance of predicted ecological risks and allows for the development of confidence indicators to inform decision-makers as to the quality and quantity of data generated in support of the ecological exemption criteria. The HWIR99 framework for calculating ecological exposures and risks is described in detail in the module documentation (U.S. EPA, 1999).

Several data collection tasks were conducted in parallel during the development of the ecological risk assessment for HWIR99, one of which was an investigation of the major data gaps on ecotoxicity data and studies/models on the uptake and accumulation of chemical constituents into biological systems (e.g., plants, fish, earthworms). This investigation was used to direct critical resources toward addressing the most important data gaps. In addition, the data collection tasks strongly suggested the need for a framework to indicate the confidence associated with a given exemption criterion. At a minimum, the confidence indicators should address the quality and quantity of the ecotoxicity data used to develop the ecological benchmarks and CSCLs. However, we decided that this framework should also reflect the basic unit for the HWIR99 ecological assessment — the habitat — and provide meaningful information for each constituent based on its chemical and physical properties. In short, the relationship between the specific data requirements for developing an exemption criterion (e.g., ecotoxicity data, bioaccumulation factors) and the confidence that the assessor has in the ability of that criterion to reflect potential ecological risks should be clear. The conceptual framework for the confidence indicators is discussed below.

1.3 Conceptual Framework for Data Requirements/Confidence Indicators

The conceptual framework for HWIR99 includes two core components: (1) establishing data requirements for constituents and (2) assigning confidence indicators that relate the available data to the data requirements. Establishing data requirements is based on two premises. First, the potential for adverse ecological effects is related to the potential for exposure. Second,

the potential for exposure is largely a function of the environmental persistence and the number of exposure pathways likely to be completed (e.g., ingestion of contaminated prey). Therefore, the data requirements for a constituent should reflect the potential for exposure to a full suite of ecological receptors. Assigning confidence indicators characterizes our ability to predict adverse effects which, ultimately, depends upon the quantity and quality of information on ecological toxicity and uptake and accumulation in the food web. In short, the data requirements and confidence indicators should be constituent-specific and reflect elements of exposure *and* toxicity.

As suggested by this discussion, the development of data requirements and confidence indicators must address the completeness of the data set with regard to receptors of concern (in each type of habitat), as well as the confidence in data on toxicity and on uptake and accumulation. Consequently, the confidence indicator consists of three parts: (1) the habitat confidence indicator, (2) the benchmark confidence indicator, and (3) the exposure confidence indicator. The critical theme underlying the conceptual framework is the idea that the chemical and physical properties of a constituent, to a large degree, determine the how much and what type of data are needed to meet the requirements of each confidence indicator.

Habitat Confidence Indicator - The confidence indicator for habitats is a qualitative statement used to convey the relationship between chemical properties and data availability on receptor groups in terrestrial and aquatic habitats, respectively. For example, to achieve a high level of confidence in assessing a persistent, bioaccumulative constituent, we would require ecotoxicological data on all receptor groups assigned to a habitat. In contrast, we may achieve a high level of confidence in assessing a readily biodegradable constituent that does not bioaccumulate with data on fewer receptor groups because: (1) the spatial impact of the constituent will be extremely limited by rapid breakdown (assuming nontoxic daughter products) and (2) food web exposures are unlikely to be significant. Three habitat confidence indicators were used to establish the data requirements for all combinations of persistence and bioaccumulation potential: "A" indicates high confidence, "B" indicates moderate confidence, and "C" indicates low confidence in the data set. Hence, a habitat confidence indicator of "B" means that, given the persistence and bioaccumulation rating for the constituent, there is moderate confidence in the ability of the data set to assess all appropriate receptors. To afford the maximum flexibility in this indicator, terrestrial and aquatic habitat indicators are reported separately for each constituent.

Benchmark Confidence Indicator - The secondary confidence indicator reflects specific criteria for ecotoxicological data used to develop ecological benchmarks (EBs) and chemical stressor concentration limits (CSCLs). For each EB and CSCL, a data quality confidence indicator was established: a "1" indicates high confidence in the study data, a "2" indicates moderate confidence in the study data, and a "3" indicates low confidence in the study data. For those receptors for which data are available, an average confidence indicator is calculated and assigned to the exemption criterion for the terrestrial and aquatic habitats, as appropriate. This is a critical distinction in interpreting the benchmark confidence indicator. The indicator only refers to the confidence in those data that were actually used to support the development of EBs and CSCLs; it does not address the quantity of receptors for which data are available. For instance, a confidence indicator of "C1" for an aquatic habitat means that, although we have low

confidence in the data set to represent a sufficient number of receptors in freshwater systems, we have high confidence in the benchmarks (or CSCLs) that were developed.

Exposure Confidence Indicator - The tertiary confidence indicator reflects the quality of the data and models that are available to predict exposures through the food chain. In addition, this indicator also acknowledges the importance of these pathways given the bioaccumulation potential and persistence of a constituent. For instance, lack of empirical data on bioaccumulation for a constituent rated as having low potential for bioaccumulation should not necessarily result in a lower indicator of confidence. If exposure via the food web is determined to be insignificant, the data requirements on uptake and accumulation in plants and prey may be lower. Thus, the exposure confidence indicator addresses our ability to evaluate the exposure pathways of concern that are likely to be of concern and acknowledges that, for certain constituents, exposure pathways through the food chain may not be completed. A confidence indicator of "exp-1" indicates that we have high confidence in our ability to evaluate relevant exposure pathways. However, this indicator may be applied to bioaccumulative as well as nonbioaccumulative constituents. For example, an overall confidence indicator of "B2exp-1" could describe two different situations: (1) moderate confidence in sufficiency of the data set across receptors as well as in the toxicity data, and high confidence in the bioaccumulation data for use in terrestrial systems, or (2) moderate confidence in sufficiency of the data set across receptors as well as in the toxicity data, and low potential for exposure via the food web. In either case, our confidence is high that we are able to evaluate relevant exposure pathways of concern. In contrast, an "exp-3" indicator would suggest that the data/models are insufficient to evaluate potential exposure pathways of concern and that our confidence in the exposure profile is low.

Section 2 describes the methodology developed to establish data requirements and confidence indicators and presents the overall confidence indicators for the 44 constituents currently being simulated in the HWIR99 modeling system.

2.0 Methodology

The methodology developed to establish data requirements and confidence indicators is intended to support the risk characterization of ecological exemption criteria under HWIR99. Consequently, it is important to recognize that the confidence indicators are not intended to suggest an absolute scale with which to interpret risk estimates. Rather, the confidence indicators are intended to provide an important context for considering regulatory decisions based on estimates of ecological risk. Indeed, the risk characterization discussion for HWIR99 points out many limitations in the ecological risk assessment given the current state of the science. For example, the ecological benchmarks are derived at the level of the individual organism, and impacts at the population level are inferred from endpoints on reproductive fitness and developmental effects. The chemical stressor concentration limits for community-based receptors are derived from the statistical interpretation of data on individual organisms, including endpoints on growth, survival, and lethality. Moreover, as currently implemented, the HWIR99 modeling system cannot evaluate the potential for adverse effects associated with multiple chemical stressors (or other types of stressors). Hence, the meaning of the confidence indicators is limited to the scope of the HWIR99 analytical framework and should not be extrapolated beyond the boundaries of this analysis. These limitations notwithstanding, the framework for confidence indicators provides a useful and flexible tool for the risk management decisions regarding exemption criteria. The following sections describe the development of confidence indicators and data requirements within the context of chemical/physical properties of constituents relevant to persistence and bioaccumulation in aquatic and terrestrial systems, respectively.

2.1 Confidence Indicators and Data Requirements for Habitats

The basis for habitat confidence indicators is the environmental persistence and bioaccumulation potential of constituents in aquatic and terrestrial systems, respectively. Although we recognize that these two "properties" of chemical constituents are a function of the chemical/physical attributes (e.g., K_{ow}) and the environmental setting,[2] it is convenient to think of persistence and bioaccumulation as intrinsic properties in establishing data requirements at various levels of confidence. Table 2-1 presents the designations for each of the 44 constituents regarding persistence and bioaccumulation potential in aquatic and terrestrial systems.[3]

[2] In this context, the setting refers to a broad range of environmental characteristics, from the physical characteristics of the ecosystem (e.g., dissolved organic carbon; soil pH) to the biology of organisms that inhabit the ecosystem (e.g., soil microbes, fish species).

[3] We recognize that the divisions among high, moderate, and low rankings for persistence and bioaccumulation are the subject of substantial Agency work group efforts and much controversy. It is anticipated that these ratings, particularly for bioaccumulation, may need to be revisited pending Agency work group findings and recommendations.

For both aquatic and terrestrial systems, environmental persistence was measured as a function of the surface water half-lives reported in the *Handbook of Environmental Degradation Rates* (Howard et al., 1991). All metals were ranked as highly persistent, and other constituents were ranked in manner that is consistent with the recommendations presented in Howard et al:

#	high	half-life range $\geq$ 1 year
#	moderate	half-life range $\geq$ 4 weeks
#	low	half-life range < 4 weeks

If the half-life range overlapped two categories, the longer half-life was chosen as a reasonably conservative surrogate for persistence. For bioaccumulation in aquatic systems, rankings were determined using both empirical bioaccumulation factors (BAFs) in fish or using the log K_{ow} values for organic constituents as shown below:

#	high	BAF $\geq$ 10,000, or log $K_{ow} \geq 4.0$
#	moderate	10,000 > BAF $\geq$ 100, or 4.0 > log $K_{ow} \geq 2.0$
#	low	BAF < 100, or log $K_{ow} < 2.0$

For organic constituents that have not been shown to be readily metabolizable, the log K_{ow} value was preferred as the measure of bioaccumulation potential; measured BAFs were preferred for all other constituents. For bioaccumulation in terrestrial systems, the rankings were determined by selecting the highest empirical bioaccumulation factor among earthworms, plants, or vertebrates or using the log K_{ow} values for organic constituents as shown below:

#	high	BAF > 1, or log $K_{ow} \geq 5.0$
#	moderate	1 $\geq$ BAF > 0.1, or 5.0 > log $K_{ow} \geq 2.0$
#	low	BAF $\leq$ 0.1, or log $K_{ow} < 2.0$

Note that, because significant bioaccumulation has been demonstrated for few chemicals in terrestrial systems, a log K_{ow} value of 5.0 (rather than 4.0) was chosen as the appropriate bound for highly bioaccumulative chemicals. As with the rankings for aquatic systems, the log K_{ow} value was preferred as the measure of bioaccumulation potential for organics that have not been shown to be readily metabolizable. Although there is some consensus regarding bioaccumulation rankings for aquatic systems (see, for example, RTI, 1995), little has been published to support criteria for high, moderate, and low categories and, in fact, bioaccumulation has been demonstrated for relatively few constituents in terrestrial food webs. These criteria (i.e., the log K_{ow} and BCF values) were based on the premise that the bioaccumulation potential between aquatic and terrestrial systems should be similar — that is, a constituent with low bioaccumulation potential in aquatic systems would be unlikely to have high bioaccumulation potential in terrestrial systems. Hence, the empirical data cutoffs were based on professional judgement in comparing terrestrial data with similar data from aquatic systems.

Once the persistence and bioaccumulation rankings were determined, data requirements were established for each of the three confidence levels (i.e., A, B, C). For aquatic habitats, six receptor groups represent wildlife across multiple trophic levels: (1) birds, (2) mammals,

Table 2-1. Category Rankings for Persistence and Bioaccumulation Potential for Aquatic and Terrestrial Systems

		Aquatic Systems		Terrestrial Systems	
Constituent	**Chemical Type [1]**	**Persistence**	**Bioaccumulation potential**	**Persistence**	**Bioaccumulation Potential**
Acetonitrile	O	Moderate	Low	Moderate	Low
Acrylonitrile	O	Low	Low	Low	Low
Aniline	O	Low	Low	Low	Low
Antimony	M	High	Low	High	Moderate
Arsenic	M	High	Low	High	Moderate
Barium	M	High	Low	High	Moderate
Benzene	O	Low	Moderate	Low	Moderate
Benzo(a)pyrene	S	Low	Moderate	High	Moderate
Beryllium	M	High	Low	High	Moderate
Bis(2-ethylhexyl) phthalate	S	Low	Moderate	Low	Moderate
Cadmium	M	High	Moderate	High	High
Carbon disulfide	O	High	Moderate	Low	Moderate
Chlorobenzene	O	Moderate	Moderate	Moderate	Moderate
Chloroform	O	Moderate	Low	Moderate	Low
Chromium VI	M	High	Low	High	Moderate
Dibenz(a,h)anthracene	S	Moderate	Moderate	High	Moderate
Dichlorophenoxyacetic acid, 2,4-	O	Low	Moderate	Moderate	Moderate
Ethylene dibromide	O	Moderate	Moderate	Moderate	Moderate
Hexachloro-1,3-butadiene	O	Moderate	High	Moderate	Moderate
Lead	M	High	Low	High	Moderate
Mercury (divalent)	Hg	High	High	High	High
Mercury (elemental)	Hg	High	Low	High	Moderate
Methoxychlor	O	Low	High	High	High
Methyl ethyl ketone	O	Low	Low	Low	Low
Methyl mercury	Hg	High	High	High	Moderate
Methyl methacrylate	O	Moderate	Low	Moderate	Low
Methylene chloride	O	Moderate	Low	Moderate	Low
Nickel	M	High	Low	High	Moderate
Nitrobenzene	O	Moderate	Low	Moderate	Low
Pentachlorophenol	O	Low	High	Moderate	High
Phenol	O	Low	Low	Low	Low
Pyridine	O	Low	Low	Low	Low
Selenium	M	High	Moderate	High	Moderate
Silver	M	High	Low	High	Moderate
TCDD, 2,3,7,8-	D	High	High	High	High
Tetrachloroethylene	O	High	Moderate	High	Moderate
Thallium	M	High	Low	High	Moderate
Thiram	O	Low	High	High	High
Toluene	O	Low	Moderate	Low	Moderate
Trichloroethane, 1,1,1-	O	Moderate	Moderate	Moderate	Moderate
Trichloroethylene	O	High	Moderate	High	Moderate
Vanadium	M	High	Low	High	Low
Vinyl chloride	O	Moderate	Low	Moderate	Low
Zinc	M	High	Low	High	Moderate

[1] O = organic; S = special; D = dioxin-like; M = metal; Hg = mercury

(3) herpetofauna, (4) aquatic plants (and algae), (5) aquatic biota, and (6) sediment biota. For terrestrial habitats, five receptor groups were considered: (1) birds, (2) mammals, (3) herpetofauna, (4) terrestrial plants, and (5) soil fauna. At the highest confidence indicator (A), the data requirements for highly persistent, highly bioaccumulative constituents include all receptor groups. In contrast, the data requirements for a nonpersistent, nonbioaccumulative constituent include a small subset of these receptor groups (e.g., data only required on two groups). Between these two extremes is a continuum of data requirements for each of the confidence indicators. Consider, for example, the data requirements for a moderately persistent and moderately bioaccumulative constituent in an aquatic habitat. To achieve an A-level confidence indicator, data are required on mammals and birds (as top predators) and two of the remaining four receptor groups. Figures 2-1 and 2-2 depict the relationship between confidence indicators and data requirements for aquatic and terrestrial habitats, respectively. For each persistence/bioaccumulation combination, the figures illustrate the progression of decreasing data requirements associated with constituents that are less persistent and less likely to bioaccumulate. The confidence indicators reflect both the number of receptor groups represented as well as the inclusion of specific receptor groups associated with persistence/bioaccumulation combinations. The underlying assumptions used to develop this matrix may be summarized as follows:

- Developing data requirements based on the persistence and bioaccumulation potential of constituents in aquatic and terrestrial habitats, respectively, provides a meaningful framework to consider the implications of data gaps.

- For a given persistence/bioaccumulation combination, assigning confidence indicators such that lower confidence is associated with meeting lower data requirements provides a useful metric for decision-makers to consider the quality of the ecological exemption criteria.

- The data requirements for more persistent constituents should be higher than the requirements for less persistent constituents. Higher environmental persistence increases the temporal window for exposure and may lead to multistressor exposures (e.g., exposure to several persistent constituents).

- The data requirements for constituents with low persistence scores should generally be lower than that for constituents with higher persistence scores. Constituents that degrade quickly in the environment are unlikely to cause long-term adverse ecological effects under the waste management conditions simulated in HWIR99 (i.e., low-level releases rather than episodic events).

- Uptake and accumulation of constituents with low persistence is limited in that steady-state conditions will probably not be reached. As a result, bioaccumulation in plants and prey items may be less than predicted by the steady-state models used to predict exposure concentrations.

- The data requirements for more bioaccumulative constituents should include (at least) mammals or birds since these receptors are likely to be exposed through the food web. Low bioaccumulation potential suggests that exposures through the food web are of lower significance.

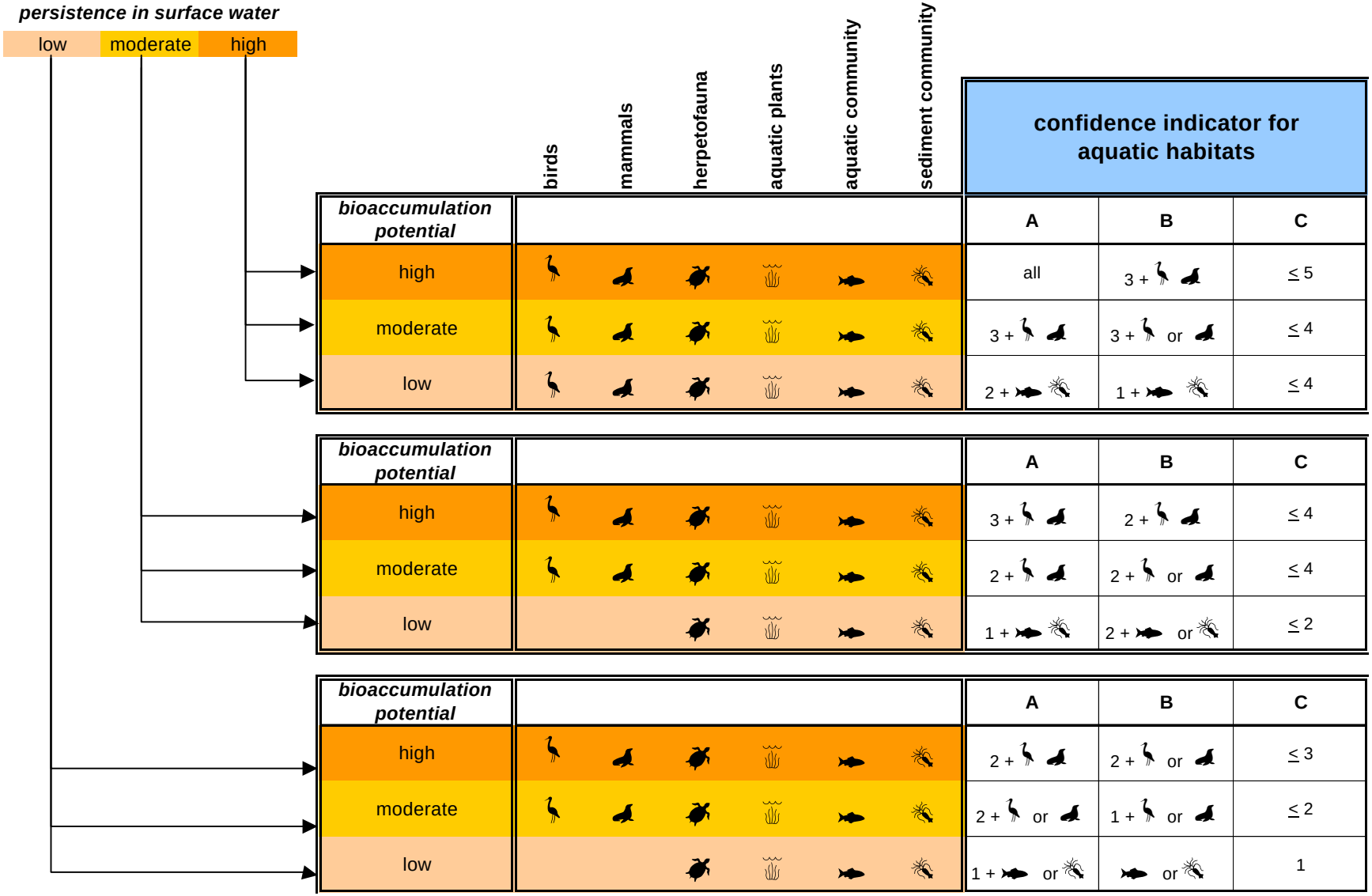

Figure 2-1. Framework to assign habitat confidence indicators for aquatic systems.

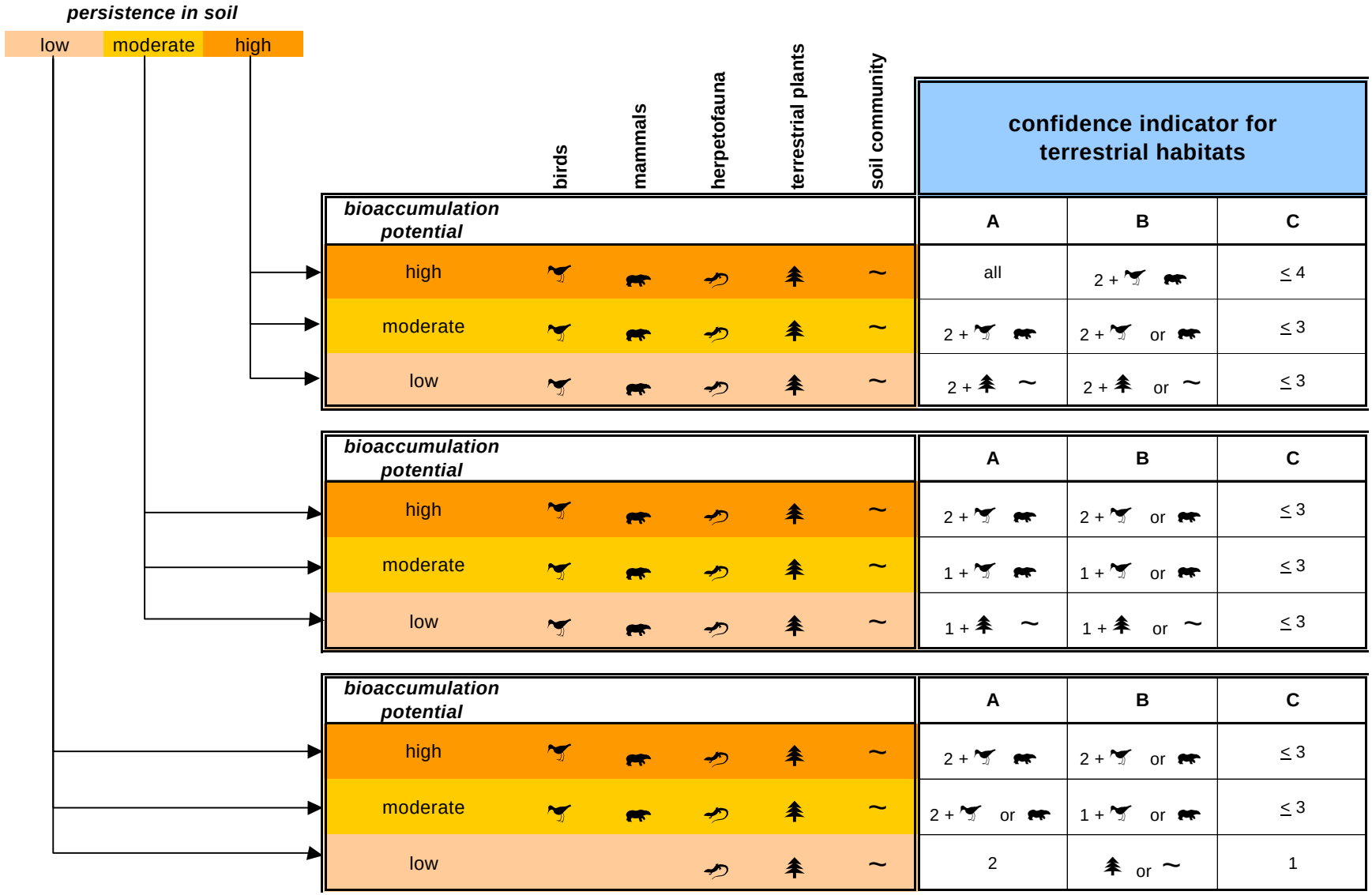

Figure 2-2. Framework to assign habitat confidence indicators for terrestrial systems.

The data requirements developed for each combination were based on these assumptions as illustrated in the following example. Consider a constituent released into an aquatic habitat (freshwater lakes, ponds, streams, and wetlands) that is moderately persistent and moderately bioaccumulative. If benchmarks were available on four receptor groups, including mammals and birds, a rating of "B" would be selected as the habitat confidence indicator. Hence, ecotoxicological data would be available to evaluate exposures through the food chain for mammals and birds and at least two receptor groups could be evaluated for direct exposures (e.g., the aquatic community and amphibians). Table 2-2 presents the persistence/bioaccumulation combinations and the habitat confidence indicators for each of the 44 constituents of concern modeled thus far in the HWIR99 analysis.

2.2 Confidence Indicators and Data Requirements for Benchmarks

The confidence indicators for ecological benchmarks (used broadly here to refer to both EBs and CSCLs) are based on the quality of the ecotoxicological data used to support the benchmark. Criteria (i.e., data quality objectives) were developed for each receptor group to ensure a standard review process and interpretation of the toxicity studies. The study design, toxicity endpoints, measurement techniques, quality control, and data reporting methods were reviewed and compared to this set of criteria. The numerical indicators for confidence correspond to conventions adopted under HWIR95 for data quality; a value of 1 is assigned to benchmarks for which the data set is judged to be of high quality (adequate); a value of 2 is assigned to benchmarks for which the data set fails to meet all of the criteria (provisional); and a value of 3 is assigned to benchmarks that meet minimum standards (interim). The confidence indicators shown in Tables 2-3 and 2-4 reflect the sufficiency of the study data relative to the standard criteria for aquatic and terrestrial habitats, respectively (i.e., lower confidence was assigned to studies that met fewer data quality requirements). The following subsections provide a brief description for each receptor group highlighting the minimum requirements for data used to support benchmark (i.e., EBs and CSCLs) development. To provide the context of each description, the assessment endpoint and measure of the effect for each receptor group is presented at the start of each subsection. Detailed descriptions of the data requirements and evaluation criteria used to support the benchmark confidence indicators — adequate (1), provisional (2), and interim (3) — are included in Appendix A in tabular form. A complete description of the data collection efforts and methodology developed to derive EBs and CSCLs may be found in Section 14.0 of the data collection documentation for HWIR99.

2.2.1 Mammals and Birds

- # <u>*Assessment Endpoint*</u>: *maintain viable mammalian and avian wildlife populations.* The attribute to be protected was the reproductive and developmental success of representative species.

- # <u>*Measure of Effect*</u>: *a de minimis threshold for developmental and reproductive toxicity in mammalian and avian wildlife species.* The threshold was calculated as the geometric mean of the NOAEL and LOAEL, frequently referred to as the the maximum acceptable toxicant concentration (MATC). Implicit in this calculation is the assumption that the toxicological sensitivity is lognormal.

Table 2-2. Habitat Confidence Indicators for Aquatic and Terrestrial Systems

Constituent	Chemical Type [1]	Aquatic Systems		Terrestrial Systems	
		Persistence/ Bioaccumulation	Confidence Indicator	Persistence/ Bioaccumulation	Confidence Indicator
Acetonitrile	O	M/L	NA	M/L	NA
Acrylonitrile	O	L/L	NA	L/L	NA
Aniline	O	L/L	C	L/L	C
Antimony	M	H/L	A	H/M	B
Arsenic	M	H/L	A	H/M	A
Barium	M	H/L	C	H/M	B
Benzene	O	L/M	A	L/M	B
Benzo(a)pyrene	S	L/M	A	H/M	C
Beryllium	M	H/L	C	H/M	B
Bis(2-ethylhexyl) phthalate	S	L/M	A	L/M	B
Cadmium	M	H/M	A	H/H	A
Carbon disulfide	O	H/M	C	L/M	NA
Chlorobenzene	O	M/M	C	M/M	C
Chloroform	O	M/L	A	M/L	C
Chromium VI	M	H/L	C	H/M	B
Dibenz(a,h)anthracene	S	M/M	C	H/M	NA
Dichlorophenoxyacetic acid, 2,4-	O	L/M	NA	M/M	NA
Ethylene dibromide	O	M/M	NA	M/M	NA
Hexachloro-1,3-butadiene	O	M/H	NA	M/M	NA
Lead	M	H/L	A	H/M	A
Mercury (divalent)	Hg	H/H	A	H/H	A
Mercury (elemental)	Hg	H/L	NA	H/M	NA
Methoxychlor	O	L/H	B	H/H	C
Methyl ethyl ketone	O	L/L	C	L/L	C
Methyl mercury	Hg	H/H	C	H/M	B
Methyl methacrylate	O	M/L	NA	M/L	NA
Methylene chloride	O	M/L	C	M/L	NA
Nickel	M	H/L	A	H/M	A
Nitrobenzene	O	M/L	C	M/L	B
Pentachlorophenol	O	L/H	A	M/H	A
Phenol	O	L/L	A	L/L	A
Pyridine	O	L/L	NA	L/L	NA
Selenium	M	H/M	A	H/M	A
Silver	M	H/L	A	H/M	C
TCDD, 2,3,7,8-	D	H/H	C	H/H	C
Tetrachloroethylene	O	H/M	C	H/M	NA
Thallium	M	H/L	C	H/M	B
Thiram	O	L/H	NA	H/H	NA
Toluene	O	L/M	A	L/M	B
Trichloroethane, 1,1,1-	O	M/M	B	M/M	C
Trichloroethylene	O	H/M	B	H/M	C
Vanadium	M	H/L	C	H/L	B
Vinyl chloride	O	M/L	C	M/L	C
Zinc	M	H/L	A	H/M	A

[1] O = organic; S = special; D = dioxin-like; M = metal; Hg = mercury
NA = confidence indicator is not applicable (suitable toxicity data for benchmark derivation were not identified)

Table 2-3. Benchmark Confidence Indicators for Receptor Groups in Aquatic Systems

Constituent	Mammals	Birds	Herpetofauna	Aquatic Plants	Aquatic Community	Benthic Community	Confidence Indicator
Acetonitrile	ID	ID	ID	ID	ID	ID	0
Acrylonitrile	ID	ID	ID	ID	ID	ID	0
Aniline	ID	ID	3	ID	ID	ID	3
Antimony	2	ID	3	3	2	1	2
Arsenic	1	1	3	3	1	1	2
Barium	ID	1	ID	ID	3	ID	2
Benzene	2	ID	3	3	3	3	3
Benzo(a)pyrene	2	ID	ID	ID	3	1	2
Beryllium	ID	ID	3	3	3	ID	3
Bis(2-ethylhexyl) phthalate	1	2	ID	ID	3	1	2
Cadmium	1	1	3	3	1	1	2
Carbon disulfide	ID	ID	ID	ID	3	3	3
Chlorobenzene	ID	ID	ID	3	3	3	3
Chloroform	2	ID	3	ID	3	3	3
Chromium VI	2	ID	ID	3	1	ID	2
2,4-Dichlorophenoxyacetic	ID	ID	ID	ID	ID	ID	0
Dibenz(a,h)anthracene	ID	ID	ID	ID	ID	1	1
Ethylene dibromide	ID	ID	ID	ID	ID	ID	0
Hexachloro-1,3-butadiene	ID	ID	ID	ID	ID	ID	0
Lead	2	2	3	3	1	1	2
Mercury (elemental)	ID	ID	ID	ID	ID	ID	0
Mercury (divalent)	2	2	3	3	1	1	2
Methoxychlor	1	ID	3	ID	3	3	3
Methyl ethyl ketone	2	ID	ID	ID	ID	ID	2
Methyl methacrylate	ID	ID	ID	ID	ID	ID	0
Methyl mercury	1	1	3	ID	3	ID	2
Methylene chloride	ID	ID	ID	ID	3	3	3
Nickel	1	2	3	3	1	1	2
Nitrobenzene	ID	ID	3	ID	ID	ID	3

(continued)

Table 2-3. (continued)

Constituent	Mammals	Birds	Herpetofauna	Aquatic Plants	Aquatic Community	Benthic Community	Confidence Indicator
Pentachlorophenol	1	1	3	ID	1	ID	2
Phenol	ID	ID	3	3	1	2	2
Pyridine	ID	ID	ID	ID	ID	ID	0
Selenium	1	1	3	3	1	ID	2
Silver	ID	ID	3	3	3	1	3
2,3,7,8-TCDD	1	1	ID	ID	ID	ID	1
Tetrachloroethylene	ID	ID	ID	ID	3	ID	3
Thallium	2	ID	3	3	3	ID	3
Thiram	ID	ID	ID	ID	ID	ID	0
Toluene	2	ID	3	3	3	3	3
Trichloroethane, 1,1,1-	2	ID	ID	3	3	3	3
Trichloroethylene	2	ID	3	ID	3	3	3
Vanadium	2	1	ID	ID	3	ID	2
Vinyl chloride	2	ID	ID	ID	ID	ID	2
Zinc	1	2	3	3	1	1	2

ID = Insufficient Data to derive benchmark.
Note: A confidence indicator of “0" means that no benchmarks were developed.

Table 2-4. Benchmark Confidence Indicators for Receptor Groups in Terrestrial Systems

Constituent	Mammals	Birds	Herpetofauna	Terrestrial Plants	Soil Community	Confidence Indicator
Acetonitrile	ID	ID	ID	ID	ID	0
Acrylonitrile	ID	ID	ID	ID	ID	0
Aniline	ID	ID	3	ID	ID	3
Antimony	2	ID	3	3	ID	2
Arsenic	1	1	3	2	3	2
Barium	ID	1	ID	3	ID	2
Benzene	2	ID	3	ID	ID	3
Benzo(a)pyrene	2	ID	ID	ID	ID	2
Beryllium	ID	ID	3	3	ID	3
Bis(2-ethylhexyl) phthalate	1	2	ID	ID	ID	2
Cadmium	1	1	3	2	1	2
Carbon disulfide	ID	ID	ID	ID	ID	0
Chlorobenzene	ID	ID	ID	ID	3	3
Chloroform	2	ID	3	ID	ID	3
Chromium VI	2	ID	ID	3	3	2
2,4-Dichlorophenoxyacetic acid (2,4-D)	ID	ID	ID	ID	ID	0
Dibenz(a,h)anthracene	ID	ID	ID	ID	ID	0
Ethylene dibromide	ID	ID	ID	ID	ID	0
Hexachloro-1,3-butadiene	ID	ID	ID	ID	ID	0
Lead	2	2	3	2	1	2
Mercury (divalent)	2	2	3	3	3	3
Mercury (elemental)	ID	ID	ID	ID	ID	0
Methoxychlor	1	ID	3	ID	ID	2
Methyl mercury	1	1	3	ID	ID	2
Methyl ethyl ketone	2	ID	ID	ID	ID	2
Methyl methacrylate	ID	ID	ID	ID	ID	0
Methylene chloride	ID	ID	ID	ID	ID	0
Nickel	1	2	3	2	2	2
Nitrobenzene	ID	ID	3	ID	3	3

(continued)

Table 2-4. (continued)

Constituent	Mammals	Birds	Herpetofauna	Terrestrial Plants	Soil Community	Confidence Indicator
Pentachlorophenol	1	1	3	3	2	2
Phenol	ID	ID	3	3	3	3
Pyridine	ID	ID	ID	ID	ID	0
Selenium	1	1	3	2	3	2
Silver	ID	ID	3	3	ID	3
2,3,7,8-TCDD	1	1	ID	ID	ID	1
Tetrachloroethylene	ID	ID	ID	ID	ID	0
Thallium	2	ID	3	3	ID	3
Thiram	ID	ID	ID	ID	ID	0
Toluene	2	ID	3	ID	ID	3
1,1,1-Trichloroethane	2	ID	ID	ID	ID	2
Trichloroethylene	2	ID	3	ID	ID	3
Vanadium	2	1	ID	3	ID	2
Vinyl chloride	2	ID	ID	ID	ID	2
Zinc	1	2	3	2	2	2

ID = Insufficient Data to derive benchmark.
Note: A confidence indicator of "0" means that no benchmarks were developed.

For mammals and birds, ecotoxicological data were evaluated to determine the most appropriate study with which to develop ecological benchmarks (in units of dose) to infer risk to the population level. At a minimum, the data set had to contain the following: (1) evidence of reproductive, developmental, and growth/survival effects; (2) toxicity data on at least three species (preferably in more than one order); and (3) dose-response data for at least one study. It is important to recognize that all permutations of toxicity data are not addressed by these criteria. For instance, guidance on study selection does not include decision criteria relevant to selecting the benchmark study when the applied dose for neurological impairment was several orders of magnitude below the dose associated with reproductive effects (assuming adequate dose-response information in both studies). Although it is possible that using the reproductive study may result in a high incidence of neurological effects in a given population, it is not known how this effect will manifest itself at the population level. Indeed, it is not known how most sublethal effects, exclusive of reproductive endpoints, are manifested at the population level (e.g., Hallam et al., 1993; U.S. EPA, 1992).

2.2.2 Herpetofauna

- # *Assessment Endpoint: maintain viable amphibian and reptile populations ("herps").* The attribute to be protected was the survival and developmental success of these receptors.

- # *Measure of Effect*: The measure of effect selected to meet the assessment endpoint was the acute LC_{50}s for lethality and survival and developmental effects resulting from early life stage exposures.

For herpetofauna, the available data on toxicity were limited almost exclusively to acute studies on lethality and, in some cases, growth and developmental effects. Toxicity data were not identified on reptiles, so the following discussion refers exclusively to amphibians. These studies typically involved aqueous exposures to immature organisms and, as a result, the only exposure pathway that could be evaluated for amphibians was direct contact with contaminated surface waters. After a review of several compendia presenting amphibian ecotoxicity data (e.g., U.S. EPA, 1996b; Power et al., 1989) as well as primary literature sources, it was determined that the lack of standard methods on endpoints, species, and test durations made deriving a chronic CSCL for amphibians prohibitive at this time. Consequently, the criteria for selection of amphibian toxicity data were designed to identify studies that met basic standards such as exposure duration and suitable endpoints.

2.2.3 Terrestrial Plants

- # *Assessment Endpoint*: *maintain structure and function of terrestrial plant community*. The attributes to be protected included growth and survival of terrestrial plants.

- # *Measure of Effect*: *soil concentrations related to growth, yield, seedling emergence, and germination endpoints*. The low effects data on phytotoxicity were rank ordered, and the plant CSCL was estimated as the 10^{th} percentile value.

The development of CSCLs for terrestrial plants primarily included endpoints relevant to growth and yield (e.g., seed germination, seedling emergence). Data collection and review activities were focused on these endpoints because they are ecologically significant responses and because the database of phytotoxicity studies provides sufficient coverage of these types of effects (Efroymson et al., 1997). However, very few constituents have toxicity data on a sufficient number of species to represent even a simple plant community including short-lived and long-lived plants, flowering and nonflowering plants, high seed producers, and plants with extensive root systems (Eijsackers, 1994). Consequently, the data quality requirements presented in Efroymson et al. (1997) regarding study preferences (e.g., field studies were preferred over greenhouse studies) were adopted for development of soil CSCLs for plants.

2.2.4 Soil Community

- # *Assessment Endpoint: maintain sustainable community structure and function*. The attributes to be protected were growth, survival, and reproductive success of species that represent key functional roles in the community.

- # *Measure of Effect: concentration in soil based on ecotoxicity studies on endpoints that include lethality, fecundity, growth, and survival*. The CSCLs for the soil community were typically derived at a 95 percent protection level using both no effects and low effects data, as appropriate.

Ecotoxicological data on low effects concentrations[4] were reviewed for soil biota for a number of functional categories in soil systems (e.g., decomposers, predators) to derive the soil community CSCLs. Thus, criteria were required both for individual study reviews as well as to evaluate the entire data set for completeness. Criteria developed for study selection included four categories of exposure: (1) topical application; (2) surface-soil application, in which the soil organisms are placed onto a treated surface; (3) mixed-soil application, in which the soil organisms are placed into a soil that was mixed with a constituent; and (4) food application (i.e., chemical mixed with organic food source). The endpoints for soil species were selected based on relevance to species populations and, in order of preference, included reproduction, growth, mortality, population increase/decrease, sexual development, mobility, and regeneration. The minimum data requirements and associated confidence indicators for the soil community CSCLs include both study-specific criteria (e.g., exposure duration of a particular study) as well as criteria regarding the number of soil receptors that are represented.

2.2.5 Aquatic Community

- # *Assessment Endpoint: maintain sustainable community structure and function*. The attributes to be protected were growth, survival, and reproductive success of species that represent key functional roles in the community.

- # *Measure of Effect: concentration in surface water based on ecotoxicity studies on endpoints that include lethality, fecundity, growth, and survival*. The CSCLs for the freshwater community were typically derived at a 95 percent protection level using both no effects and effects data, as appropriate. When available, the Ambient Water Quality Criteria for chronic effects were chosen as the freshwater CSCLs.

The CSCLs for the freshwater community (e.g., fish and invertebrates) reflect endpoints ranging from mortality to growth and reproductive effects. As with the soil community, criteria for individual study evaluation were established as well as criteria applicable to the data set as a whole. The minimum data requirements to derive a CSCL for the aquatic community were based on the Tier II guidelines proposed in the *Water Quality Guidance for the Great Lakes System and Correction; Proposed Rule* (58 FR 20802). The Tier II guidelines present a protocol to calculate

[4] Currently, OSW is updating the soil CSCLs to reflect low effects, rather than no effects, levels.

a surface water CSCL when the data set does not meet all of the requirements in the *Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses* (Stephan et al., 1985). The *Guidelines* (Stephan et al., 1985) require acute toxicity data representing eight taxonomic families (e.g., salmonids) and chronic toxicity data for at least three of the eight families (including an acutely sensitive freshwater species); the Tier II methods require data on only one of the eight genera and include uncertainty factors derived from the statistical analysis complete data sets (Host et al., 1991).

2.2.6 Sediment Community

- # *Assessment Endpoint*: *maintain sustainable community structure and function*. The attributes of the benthic community to be protected included the growth, survival, and reproductive success of benthic biota.

- # *Measure of Effect*: *concentration in sediment based on ecotoxicity studies on endpoints that include lethality, fecundity, growth, and survival*. The CSCLs for the sediment community were typically derived at a 95 percent protection level using both no effects and low effects data, as appropriate, for organic constituents. In addition, field data on the toxicity of metals to sediment communities in salt-water were also used to develop sediment CSCLs and include a number of "true" community-level effects (e.g., abundance of sediment biota).

Development of CSCLs for the sediment community involved two different methodologies; one for nonionic organic constituents and the other for metals. As a result, two sets of criteria were required for study selection and the assignment of confidence indicators. For organic constituents, we used the EPA approach to derive sediment quality criteria (SQC) using surface water CSCLs. Thus, the criteria and data requirements for the sediment CSCL for organics is essentially the same as that described for the aquatic community. For metals, field data on adverse effects to benthic invertebrates in marine sediments were used to develop the sediment CSCLs because: (1) a large dataset was readily available and (2) studies suggest that the sensitivity of marine benthos is similar to freshwater benthos. The confidence indicators are based on the number and suitability of available studies on toxicity to benthic invertebrates. Sediment CSCLs were not developed for metals with fewer than 10 studies.

2.2.7 Aquatic Plants and Algae

- # *Assessment Endpoint*: *maintain primary producers in freshwater systems, including both algal and vascular aquatic plant communities*. The attributes to be protected for this taxa was the growth and biomass.

- # *Measure of Effect*: *surface water concentrations related to gross measures of "health" (e.g., biomass) for the algal community and a variety of endpoints for aquatic plants (e.g., number of fronds, root number, plant number, root length).* For algae, the EC_{20} was selected as an adequate threshold for adverse effects, and, because of the paucity of data, the lowest LOEC for endpoints of interest was chosen for vascular aquatic plants.

The CSCLs developed for primary producers in aquatic systems include data on both vascular aquatic plants and algae. Algae were included in this receptor group because they have a relatively long history of toxicity testing and have often been shown to be more sensitive than vascular aquatic plants (Klaine and Lewis, 1995). Thus, two types of endpoints and associated criteria were needed. For algae, endpoints included EC_{20} and EC_{50} values related to growth inhibition, decreased cell numbers, and reduction in carbon fixation as common responses measured in algal toxicity tests. For aquatic macrophytes such as duckweed (e.g., *Lemna minor*), the endpoints included low effects concentrations for development of fronds, biomass, root number and length, and plant number. The database on algal tests is fairly extensive, especially for metals and pesticides, although the majority of data on algal toxicity is based on a few green algal species such as *Selenastrum capricornutum* and *Chlorella vulgaris*. Toxicity data on vascular aquatic plants are relatively sparse and, as with terrestrial plants, the utility of the data set is limited. Because few data are available on macrophytes and algae, the minimum data set consists of one study on chronic or subchronic effects on algae or vascular aquatic plants.

2.3 Confidence Indicators and Data Requirements for Exposure

Ultimately, the chemical properties of a constituent determine which pathways are likely to result in significant exposures for ecological receptors. For example, constituents that are hydrophobic and persistent tend to accumulate in the food web, and, as a result, apex predators may be highly exposed through ingestion of contaminated prey. As intimated by the habitat confidence indicators, the potential to bioaccumulate in the food web is instructive in determining which receptor groups and exposure pathways are most relevant. However, this assertion is not intended to suggest that ecological receptors are not exposed through direct exposure pathways such as incidental ingestion of contaminated soil or surface water. Nor does it imply that exposure through the food web cannot occur for constituents that are weakly bioaccumulative. Rather, it recognizes the fact that many toxic constituents do not accumulate significantly in the tissues of biota, and, therefore, exposure pathways involving the ingestion of contaminated plants and prey are not completed (particularly for terrestrial systems). Consequently, confidence indicators for exposure should not simply be based on the number of plants and prey items for which empirical data and/or suitable modeling algorithms are available. Rather, the indicators should represent the importance of these data in assessing significant routes of exposure and then determine the level of confidence in the factors and/or models used to consider those exposures.

The database of empirical bioaccumulation factors was examined to assign confidence indicators for exposure. Because the HWIR99 Ecological Exposure module (EcoEx) includes 19 subcategories of plants and prey items, it would have been impractical to aggregate each of these items into a single indicator. Therefore, the 19 subcategories were collapsed into several major categories for aquatic and terrestrial systems, respectively. Collapsing the prey items into a simple scheme provided a useful measure of data availability for analysis of food web exposures. The collapsed categories for aquatic systems included (1) fish (both trophic level 3 and 4), (2) benthic filter feeders, and (3) vascular aquatic plants and algae. The collapsed categories for terrestrial systems included (1) terrestrial vertebrates, (2) earthworms, (3) other soil invertebrates, and (4) terrestrial plants (e.g., forage, grains).

Based on an evaluation of data availability on uptake and accumulation data, exposure confidence indicators were assigned to aquatic and terrestrial systems. Currently, the database of empirical factors includes default values of "1" for plant or prey items for which suitable study data were not identified. For the purposes of assigning exposure confidence indicators, these default values were considered as data gaps. For constituents for which tissue concentrations are predicted using either the Aquatic Food Web module (AqFW) or the Terrestrial Food Web module (TerFW), it was assumed that the algorithms that simulate uptake and accumulation were suitable to estimate ecological exposures and the data element (e.g., fish) was counted as complete. For example, tissue concentrations of hydrophobic organic constituents in fish and other aquatic organisms are predicted using the algorithms developed for the AqFW module. Hence, hydrophobic organic constituents were listed as having no data gaps for aquatic systems. As explained below, constituents were assigned one of three confidence indicators to signify confidence in our ability to evaluate significant exposure pathways of concern: (1) "exp-1" for high confidence, (2) "exp-2" for moderate confidence, and (3) "exp-3" for low confidence.

For aquatic systems

1. For constituents of chemical type "O" (organic) or "D" (dioxin-like), tissue concentrations in all three aquatic categories (i.e., fish, benthic filter feeders, and aquatic plants) are predicted by the AqFW module. Therefore, these constituents are assigned a confidence indicator of "exp-1" designating high confidence.

2. For constituents of chemical type "S" (special), "M" (metal), or "Hg" (mercury), the database was evaluated and the number of data gaps identified. For constituents rated as highly or moderately bioaccumulative, confidence indicators were determined as follows:

#	exp-1	data gaps = 0
#	exp-2	data gaps = 1
#	exp-3	data gaps $\geq$ 2

   For constituents with other persistence/bioaccumulation combinations, confidence indicators were:

#	exp-1	data gaps $\leq$ 1
#	exp-2	data gaps = 2
#	exp-3	data gaps = 3

For terrestrial systems

1. For constituents of chemical type "O" (organic), "S" (special), or "D" (dioxin-like), tissue concentrations in plants are predicted using the TerFW module, and, therefore, the plant data element was always considered complete for these constituents. The empirical database was examined and data gaps were identified on the other three prey categories. For constituents that were rated as highly bioaccumulative, or moderately bioaccumulative and highly persistent, confidence indicators were assigned as follows (based on a possible total of 4 data gaps):

- exp-1 data gaps = 0
- exp-2 data gaps = 1
- exp-3 data gaps $\geq$ 2

For other combinations of persistence and bioaccumulation, confidence indicators were designated by:

- exp-1 data gaps $\leq$ 2
- exp-2 data gaps = 3
- exp-3 data gaps = 4

2. For constituents of chemical type "M" (metal) or "Hg" (mercury), three sets of rules were developed specific to the level of bioaccumulation potential:

high bioaccumulation potential

- exp-1 data gaps = 0
- exp-2 data gaps = 1
- exp-3 data gaps $\leq$ 2

moderate bioaccumulation potential

- exp-1 data gaps $\leq$ 1
- exp-2 data gaps = 2
- exp-3 data gaps = 3

low bioaccumulation potential

- exp-1 data gaps $\leq$ 2
- exp-2 data gaps = 3
- exp-3 data gaps = 4

Table 2-5 presents the exposure confidence indicators for the 44 constituents modeled using the HWIR99 system. As with the assignments of habitat confidence indicators, several assumptions are implicit in this scheme; these assumptions are summarized below.

- Significant bioaccumulation in terrestrial systems has been demonstrated for relatively few constituents. Therefore, relative to data requirements for aquatic systems, the confidence indicators for terrestrial systems are somewhat less demanding.

- The lack of knowledge with regard to long-term effects in food webs from moderately bioaccumulative constituents merits a more conservative approach to confidence indicators. As a result, moderate bioaccumulators that tend to be persistent were subject to relatively high data requirements.

The algorithms and underlying theory used in the AqFW module to predict tissue concentrations in aquatic organisms are sufficiently advanced to support high confidence in our ability to evaluate food web exposures in a national analysis.

Table 2-5. Exposure Confidence Indicators for the Assessment of Significant Pathways

Constituent	Chemical Type [1]	Aquatic Systems			Terrestrial Systems		
		Data gaps	P / B	Confidence Indicator	Data gaps	P / B	Confidence Indicator
Acetonitrile	O	0	M/L	exp-1	3	M/L	exp-2
Acrylonitrile	O	0	L/L	exp-1	3	L/L	exp-2
Aniline	O	0	L/L	exp-1	3	L/L	exp-2
Antimony	M	2	H/L	exp-2	3	H/M	exp-2
Arsenic	M	2	H/L	exp-2	0	H/M	exp-1
Barium	M	3	H/L	exp-3	1	H/M	exp-1
Benzene	O	0	L/M	exp-1	3	L/M	exp-2
Benzo(a)pyrene	S	3	L/M	exp-3	3	H/M	exp-2
Beryllium	M	3	H/L	exp-3	2	H/M	exp-2
Bis(2-ethylhexyl) phthalate	S	1	L/M	exp-2	3	L/M	exp-2
Cadmium	M	1	H/M	exp-2	0	H/H	exp-1
Carbon disulfide	O	0	H/M	exp-1	3	L/M	exp-2
Chlorobenzene	O	0	M/M	exp-1	3	M/M	exp-2
Chloroform	O	0	M/L	exp-1	3	M/L	exp-2
Chromium VI	M	3	H/L	exp-3	4	H/M	exp-3
Dibenz(a,h)anthracene	S	3	M/M	exp-3	3	H/M	exp-2
Dichlorophenoxyacetic acid, 2,4-	O	0	L/M	exp-1	3	M/M	exp-2
Ethylene dibromide	O	0	M/M	exp-1	3	M/M	exp-2
Hexachloro-1,3-butadiene	O	0	M/H	exp-1	3	M/M	exp-2
Lead	M	1	H/L	exp-1	0	H/M	exp-1
Mercury	Hg	2	H/H	exp-3	0	H/H	exp-1
Mercury (elemental)	Hg	3	H/L	exp-3	4	H/M	exp-3
Methoxychlor	O	0	L/H	exp-1	3	H/H	exp-3
Methyl ethyl ketone	O	0	L/L	exp-1	3	L/L	exp-2
Methyl mercury	Hg	2	H/H	exp-3	3	H/M	exp-2
Methyl methacrylate	O	0	M/L	exp-1	3	M/L	exp-2
Methylene chloride	O	0	M/L	exp-1	3	M/L	exp-2
Nickel	M	2	H/L	exp-2	0	H/M	exp-1
Nitrobenzene	O	0	M/L	exp-1	3	M/L	exp-2
Pentachlorophenol	O	0	L/H	exp-1	1	M/H	exp-2
Phenol	O	0	L/L	exp-1	3	L/L	exp-2
Pyridine	O	0	L/L	exp-1	3	L/L	exp-2
Selenium	M	2	H/M	exp-3	0	H/M	exp-1
Silver	M	2	H/L	exp-2	1	H/M	exp-1
TCDD, 2,3,7,8-	D	0	H/H	exp-1	1	H/H	exp-2
Tetrachloroethylene	O	0	H/M	exp-1	3	H/M	exp-3
Thallium	M	3	H/L	exp-3	2	H/M	exp-2
Thiram	O	0	L/H	exp-1	3	H/H	exp-3
Toluene	O	0	L/M	exp-1	3	L/M	exp-2
Trichloroethane, 1,1,1-	O	0	M/M	exp-1	3	M/M	exp-2
Trichloroethylene	O	0	H/M	exp-1	3	H/M	exp-3
Vanadium	M	3	H/L	exp-3	1	H/L	exp-1
Vinyl chloride	O	0	M/L	exp-1	3	M/L	exp-2
Zinc	M	1	H/L	exp-1	0	H/M	exp-1

[1] O = organic; S = special; D = dioxin-like; M = metal; Hg = mercury

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Appendix A

Summary of Data Requirements for Ecological Benchmarks

Table A-1. Criteria and Data Requirements Used to Establish Confidence Indicators for Mammals and Birds

Study Selection Criteria	Confidence Rank Requirements
• *Endpoints:* Measurement endpoints reporting a no observed adverse effects level (NOAEL) and a low observed adverse effects levels (LOAEL) in units of daily dose (i.e., mg/kg-d) were preferred. From these data, the geometric mean between the NOAEL and the LOAEL (i.e., MATC) was calculated. The MATC is the preferred benchmark for representative mammalian and avian species. Studies reporting effects to reproductive and developmental endpoints were preferred to other measurement endpoints (e.g., growth, mortality). • *Methods:* No specific test methodologies are indicated. However, standardized methods (e.g., control dose groups) should be applied when available. Field data may not be appropriate to develop a daily dose exposures. • *Receptor requirements*: Data reflecting exposures to wildlife species were preferred. However, data are more likely to represent exposures to surrogate species (e.g. rats, mice). • *Durations:* Study exposures to surrogate species should continue for chronic or subchronic durations extending over a large percentage of the test species lifetime, over multiple generations, or over a particularly sensitive lifestage. • *Exposure routes:* Studies indicating oral exposure (e.g., dietary, gavage) were preferred to studies using other exposure routes (e.g., subcutaneous, intraperitoneal). • *Dose-response:* Dose-response curves characterized by at least three data points were preferred.	• **Adequate**—This rank was applied to benchmarks reflecting an MATC calculated from a study reporting NOAELs and LOAELs to reproductive, developmental, growth, or survival endpoints. In addition, the study was conducted over chronic or subchronic durations, or during a sensitive life stage. • **Provisional**—This rank was applied to benchmarks that were an MATC derived using a measured LOAEL and a predicted NOAEL. The predicted NOAEL was derived by applying a LOAEL-to-NOAEL extrapolation factor of 10. Data also reflected measurement endpoints associated with reproductive, developmental, or growth/survival endpoints. In addition, the study was conducted over chronic or subchronic durations, or during sensitive life stages. • **Interim**—This rank was applied to benchmarks that were based on a NOAEL to reproductive, developmental, or growth/survival endpoints. In addition, the study was conducted over chronic or subchronic durations, or during sensitive life stages.

Table A-2. Criteria and Data Requirements Used to Establish Confidence Indicators for Herpetofauna [1]

Study Selection Criteria	Confidence Rank Requirements
• *Endpoints:* Data reflecting LOECs to reproductive and developmental endpoints in surface water were preferred; however, given the lack of chronic data for amphibians, acute data were used. Data reporting LC_{50}s for amphibians were used. • *Methods:* No specific test methodologies were indicated. However, standardized methods for acute toxicity testing (e.g., control dose groups) should be applied when available. The geometric mean of LC_{50}s identified in the literature were calculated for each constituent. • *Receptor requirements*: Toxicity data reflecting exposures to early life stage amphibians (e.g., tadpoles) were preferred. • *Durations:* Study exposures to amphibians reflected acute exposure durations that did not typically exceed 96 hours. • *Exposure routes:* Studies were selected that indicated exposure to contaminated surface waters. • *Dose-response:* Dose-response data used to derive an LC_{50} typically required partial kill data; however, the sources did not report the raw data used to derive the LC_{50}.	• **Adequate**—The preferred toxicity data reflecting chronic exposures to amphibians were not available; therefore, no amphibian CSCLs were applied to this confidence rank. • **Provisional**—This rank was applied to those amphibian CSCLs that were derived using more than ten LC_{50} values and represented at least three different species of amphibians. Ten studies should not be considered an absolute threshold rather they should be viewed as only a guide to the relative confidence in the CSCL based on data quantity. • **Interim**—This rank was applied to those amphibian CSCLs that were derived using less than ten LC_{50} values and represented fewer than three amphibian species. Ten studies should not be considered an absolute threshold rather this cutoff should be considered a guide to the relative confidence in the CSCL based on data quantity.

[1] Herpetofauna includes species of reptiles and amphibians. However, given the lack of ecotoxicological data for reptiles, the development of confidence ranks was based on amphibian ecotoxicological data.

Table A-3. Criteria and Data Requirements Used to Establish Confidence Indicators for Terrestrial Plants

Study Selection Criteria	Confidence Rank Requirements
• *Endpoints*: Studies reporting LOEC endpoints were preferred. Toxicity endpoints related to growth, germination success, root/shoot height and weight, yield, and seed production were appropriate. • *Methods*: Studies used should be of comparable methods. Those reporting soil conditions and composition were preferred. The 10th percentile of the LOEC values was estimated as the CSCL if the data set contained a minimum of 10 values (i.e., the ER-L method). If there were fewer than 10 studies, the lowest LOEC was selected as the plant CSCL. • *Receptor requirements*: Multiple species representing both agricultural and native species were included in the data set. • *Exposure routes*: Only soil-based studies that reported concentration-response data were considered suitable for CSCL derivation. • *Dose-response:* Dose-response curves characterized by multiple data points were preferred.	• **Adequate**—At present, the phytotoxicity database is very limited and the Agency has not proposed standard protocols to develop toxicological CSCLs for plants. At a minimum, further research is needed on: (1) quantifying the impact of soil characteristics on phytotoxicity, (2) identifying endpoints with high biological significance to plant physiology and toxic response, and (3) selecting species and testing methods (e.g., duration of exposure) before CSCLs can be applied to this category. • **Provisional**—This rank was applied to CSCLs derived using the ER-L method (i.e., the 10th percentile of LOEC data that included a minimum of 10 values). • **Interim**—This rank was applied to CSCLs that represented the lowest LOEC presented in Efroymson et al. (1997) or identified in the open literature.

Table A-4. Criteria and Data Requirements Used to Establish Confidence Indicators for the Soil Community

Study Selection Criteria	Confidence Rank Requirements
• *Endpoints*: LOECs reporting effects to reproductive or developmental endpoints were the preferred measurement endpoints. For each of the eight taxa representing the soil community, the lowest value that was a: (1) a single LOEC, (2) a geometric mean of LOEC data for a species, or (3) species-specific geometric mean for similar endpoints (e.g., $EC_{10,20}$) was used to represent species in that taxa. • *Methods:* Studies reporting soil conditions and composition are preferred since these parameters are closely linked with exacerbating or inhibiting toxicity. • *Receptor requirements*: Multiple species should be represented in the toxicity data set. Ideally, studies would represent the eight distinct taxa categories indicated in the methodology. • *Durations:* Exposures should be conducted over chronic or subchronic durations, or during sensitive life stages (e.g., developmental). • *Exposure routes:* Direct contact exposures to contaminated soil media are the preferred exposure route, but exposures will also occur through incidental ingestion pathways. Field studies are preferred to laboratory studies because field studies tend to reflect a more likely exposure pathway than those conducted using artificial soils in the laboratory. • *Dose-response:* Dose-response curves reflecting multiple data points were preferred.	• **Adequate**—The CSCLs assigned to this confidence rank fulfilled all eight of the data requirements for the representative soil taxa groups. For each species requirement, a LOEC was identified with sufficient information on soil characteristics to calculate normalized effects levels. Appropriate studies were limited to exposure routes that matched the spatial location of the soil organisms preferred habitat. • **Provisional**—The CSCL assigned to this confidence rank were of equal quality as the adequate category. However, the minimum data set was reduced to five of the eight representative soil taxa groups. • **Interim**—For CSCLs assigned to this confidence rank, LOEC data met four of the representative soil taxa groups (Slooff, 1992; Okkerman et al., 1993). When insufficient data were available to meet the species taxa data requirements, selection of the lowest LOEC reported for earthworms or microbial receptors was selected and assigned to this confidence rank.

Table A-5. Criteria and Data Requirements Used to Establish Confidence Indicators for the Freshwater Community

Study Selection Criteria	Confidence Rank Requirements
• *Endpoint:* Both acute and chronic measurement and toxicity endpoints were required to calculate the surface water CSCLs. The preferred endpoint of the final surface water CSCL was the FCV developed using NAWQC or GLWQI methods and data. These CSCLs were designed to be protective of 95% of the species in the freshwater community. • *Methods:* Given that standard methods are available for aquatic toxicity testing, these methods should be applied in selected studies. Studies reporting water quality parameters are preferred since water quality can influence toxicity. • *Receptor requirements:* Acute and chronic data should adhere to taxa requirements prescribed in the NAWQC and Tier II Guidelines which include 8 categories of aquatic receptor taxa. The minimum data set prefers at least one data point for daphnids given their characteristic sensitivity to many constituents. • *Durations:* Exposures should be conducted over chronic, subchronic, and acute durations, or during sensitive life stages (e.g., developmental). • *Exposure routes:* Direct contact exposures to contaminated surface water media are the preferred exposure route. • *Dose-response:* Dose-response curves characterized by multiple data points were preferred.	• **Adequate**—This confidence rank was applied to CSCLs that were final chronic values (FCV), in order of preference, from the following sources: (1) an FCV derived for the Great Lakes Initiative, or (2) an FCV from an Ambient Water Quality Criteria document. • **Provisional**—This confidence rank was applied to CSCLs that were draft FCVs, in order of preference, from the following sources: (1) an FCV that was calculated by the U.S. EPA Environmental Research Laboratory in Duluth or Narragansett or (2) an FCV that was estimated from data extracted from AQUIRE (or literature) meeting the general 1985 guidelines for study selection. • **Interim**—This confidence rank was applied to CSCLs that were secondary chronic values (SCV) estimated using Tier II methods on data extracted from AQUIRE (or literature) meeting the general 1985 guidelines for study selection.

Table A-6. Criteria and Data Requirements Used to Establish Confidence Indicators for the Benthic Community

Study Selection Criteria	Confidence Rank Requirements for Predicted Benthic CSCLs	Confidence Rank Requirements for Measured Benthic CSCLs
• *Endpoints:* Since FCVs and SCVs are used to derive sediment CSCLs for organics, measurement endpoints applied for surface water are analogous for sediment. For other constituents, measurement endpoints in the NOAA data set range from no observed effects concentrations to lethal concentrations. • *Methods:* Depending on the constituent, various methods were applied to benthic CSCLs. Predicted benthic CSCLs were calculated from water quality criteria. Measured benthic CSCLS were calculated from field data corresponding to effects levels in the benthic community. • *Receptor requirements*: The only specific data requirement was that toxicity data reflect effects to benthic and epibenthic species. • *Durations:* No specific duration requirements were indicated. • *Exposure routes:* Direct contact exposures to contaminated sediment were the preferred exposure route. • *Dose-response*: For organics, dose response data should meet the NAWQC data requirements. For other constituents which were derived from field studies, no definitive dose-response data were identified.	• **Adequate**—The benthic CSCL was based on a final chronic value (FCV), in order of preference, from the following sources: (1) an FCV determined for the sediment quality criteria, (2) an FCV derived for the Great Lakes Initiative, or (3) an FCV from an Ambient Water Quality Criteria document. • **Provisional**—The benthic CSCL was based on a draft FCV, in order of preference, from the following sources: (1) an FCV calculated by EPA's Environmental Research Laboratory in Duluth or Narragansett or (2) an FCV estimated from data extracted from AQUIRE (or literature) meeting the general 1985 guidelines for study selection. • **Interim**—The benthic CSCL was based on a secondary chronic value (SCV) estimated using Tier II methods on data extracted from AQUIRE (or literature) meeting the general 1985 guidelines for study selection. The data set contained at least one usable data point on a daphnid species.	• **Adequate**— This rank was applied to CSCLs that were developed from data sets containing at least 100 toxicity values for sediments biota. This level of data was presumed to adequately reflect an array of toxic responses on a variety of benthic species. • **Provisional**—This rank was applied to CSCLs that were developed from data sets containing at least 20 data points. Twenty studies should not be considered an absolute threshold rather the quality of the data and the toxicity endpoints (e.g., abundance, growth, lethality) of these studies should also be considered. • **Interim**— This rank was applied to CSCLs that were based on data sets containing less than 20 data points. Twenty studies should not be considered an absolute threshold rather the quality of the data and the toxicity endpoints (e.g., abundance, growth, lethality) of these studies should also be considered.

Table A-7. Criteria and Data Requirements Used to Establish Confidence Indicators for Algae and Aquatic Plants

Study Selection Criteria	Confidence Rank Requirements
• *Endpoints:* For vascular aquatic plants and algae, the lowest observed effect concentrations (LOECs) were preferred to no observed effects concentrations (NOECs) or other effective concentrations (e.g., EC_{20}). Toxicity endpoints on biologically meaningful responses in algae (e.g., growth inhibition, cell number) and vascular plants (e.g., biomass, development of fronds) were preferred. • *Methods:* Studies utilizing standard methods for toxicity testing were preferred when available. The CSCL was derived by applying the ER-L approach to the LOEC data set with more than 10 values. In cases where less than 10 values were available, the lowest LOEC was selected. • *Receptor requirements:* Data on both algae and aquatic plants were preferred in development of the CSCL; however, data were typically insufficient to evaluate aquatic plants. • *Durations:* Exposure durations vary according to test species. Exposure durations should be correlated with life span such that organisms are exposure over a large portion of their expected life span, or organisms are exposed during critical lifestages. • *Exposure routes:* Exposures will occur primarily through direct contact of the algae and aquatic plants with contaminated surface water. • *Dose-response:* Dose-response curves characterized by multiple data points were preferred.	• **Adequate**—Test endpoints, methods, and interpretation of results to evaluate toxicity to algae are not well standardized and their relevance to the field are less clear than for animals (Lewis, 1990; Klaine and Lewis, 1995). Further research is needed in these areas before the adequate confidence rank can be assigned to any CSCL. • **Provisional**—This confidence rank was applied if a CSCL met the following conditions: (1) the benchmark study provided a LOEC for a vascular aquatic plant estimated from at least two data points *or* the lowest EC_{20} value from representative algal species, (2) phytotoxicity studies were available on at least one species of floating macrophytes, one species of submersed aquatic vegetation, and one species of emergent aquatic vegetation, and (3) EC_{20} values were available for at least three of the six algal classes proposed by Swanson et al. (1991), including green and blue-green algae, diatoms, and dinoflagellates. • **Interim**—This confidence rank was applied in the CSCL selected is the lowest LOEC identified for vascular aquatic plants or the lowest effective concentration (EC_{xx}) identified for a species of freshwater algae. As stated above, laboratory studies on algae were from which effects could be inferred at the population level (e.g., growth) were appropriate.