GUIDANCE FOR ECOLOGICAL RISK ASSESSMENT AT HAZARDOUS WASTE SITES AND PERMITTED FACILITIES

PART A: OVERVIEW

State of California
California Environmental Protection Agency

Department of Toxic Substances Control
Human and Ecological Risk Division

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PREFACE

The Department of Toxic Substances Control (DTSC), within the California Environmental Protection Agency has the responsibility of managing the State's hazardous waste program to protect public health and the environment. The Human and Ecological Risk Division (HERD) provides scientific assistance in the areas of toxicology, risk and environmental assessment, training, and guidance to the regional offices within DTSC. Part of this assistance and guidance is the preparation of scientific guidelines, and recommended procedures for use by regional staff, local governmental agencies, or responsible parties and their contractors in hazardous waste site mitigation. This document is one of a series of DTSC guidelines for the investigation, monitoring, and remediation of hazardous waste sites and facilities. It presents a general framework for conducting ecological risk assessments. More detailed guidance relating to specific aspects of ecological risk assessment will be developed as information becomes available.

The procedures and suggested approaches set forth here are intended solely as guidance to DTSC and other government employees and contractors. This guidance does not constitute rule making by DTSC and should not be interpreted as an enforceable standard.

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CHAPTER 1

INTRODUCTION

The California Department of Toxic Substances Control (DTSC), a part of the California Environmental Protection Agency (CalEPA), has responsibility under California statutes (California Health and Safety Code, Section 25201, 25351, 25355 and 25358) for investigation of California and Federal Superfund sites, for permitting sites which treat, store and/or dispose of hazardous wastes (California Health and Safety Code, Section 25120 and 25159.5), for corrective action at facilities that treat, store and/or dispose of hazardous wastes (California Health and Safety Code, Section 25200.10) and closure of facilities that treat, store and/or dispose of hazardous wastes (California Health and Safety Code, Section 25246). DTSC is also the lead Department for all CalEPA involvement in Remedial Investigation and Feasibility Studies under the federal Comprehensive Environmental Response Compensation and Liability Act (CERCLA, 1980) as amended by the Superfund Amendment and Reauthorization Act (SARA, 1986). The Human and Ecological Risk Division (HERD), has developed a tiered approach for ecological risk assessments at hazardous waste sites and permitted facilities to assist responsible parties and their contractors in preparing ecological risk assessments which contain the information necessary for DTSC to discharge its public responsibility for mitigation or remediation of these sites.

The purpose of this guidance is to provide a suggested framework and conceptual model for the approach to, and the organization and documentation of:

- the scientifically based estimation of the nature and extent of adverse impact(s) upon the biota from present and/or future exposures to toxicants;

- the scientifically based estimation of concentrations of chemicals in air, water, soil, sediment and other relevant media that do not adversely impact the biota;

- the consideration and incorporation of the findings and conclusions of this ecological risk assessment into the remedial design/remedial action or permitting, corrective and/or closure action.

The principles and recommendations of this guidance are generally applicable to:

- the assessment of environmental risk at hazardous waste sites (sites) and/or hazardous waste facilities (facilities) before, during, and/or after time-critical removal, non-time critical removal, development of remedial alternatives and/or remedy selection and remedial design/ remedial action, for the purposes of this guidance, generally referred to as hazardous waste site actions;

- the assessment of environmental risk at hazardous waste treatment, storage, or disposal facilities, units and/or areas before, during, and/or after permitting, corrective action or closure, for the purposes of this guidance, generally referred to as hazardous waste facility actions;

- the support of declarations of imminent and substantial endangerment;
- use as evidence in enforcement actions;
- the assessment of risk to biota whenever the Department requires corrective action pursuant to Health and Safety Code 25187 or 25200.10;

This guidance addresses issues related to the scope and mission of the Department of Toxic Substances Control. It is not intended to be a universal approach to all environmental problems.

The goal of the ecological risk assessment is to predict potential adverse effects and when appropriate, to measure existing adverse effects, of chemical contaminants on the biota on or near a site or facility, and to determine levels of those chemicals in the environment that would not be expected to adversely affect the biota. Field observations are suggested as a supplement to the predictive ecological risk evaluation when contamination is present and has been present for a period of time sufficient to have caused an adverse ecological impact. In order to allocate resources in proportion to potential ecological threats, a phased approach is suggested, with progression to the subsequent phases dependent, in part, on the results of the preceding phase. The first phase is the scoping assessment, described in Chapter 3. The outcome of this phase is a conceptual site model, identifying contaminants and receptors of concern, potential exposure pathways, and identifying further work needed. In the Phase I predictive assessment, toxicity criteria are obtained or developed for receptors and contaminants of concern, exposure is assessed, and risk to aquatic and terrestrial biota is estimated. In the Phase II validation study, parameters used to estimate the risk to exposed biota are refined and validated by sampling and analysis, or site-specific laboratory and/or field testing is performed to validate the conclusions of the predictive assessment. If it is decided to move directly to remediation, results of the predictive assessment can be used to develop preliminary remedial goals. In the Phase III impact assessment, field testing and/or more extensive laboratory testing is conducted to assess the severity and extent of population and community effects as input to the evaluation of remedial alternatives and refinement of remediation goals.

As a general approach, an individual or population-level effect will generally be assumed to have ramifications at higher levels of ecological organization (e.g. at the community or ecosystem level) unless there is evidence to the contrary. Although the goal of ecological risk assessment is to assess the magnitude and extent of threats to the structure and function of plant and animal communities and ecosystems (the assessment endpoint), many of the measurement endpoints addressed in the risk assessment will be at lower levels of organization, such as the population, the individual, an organ system, or a biochemical response. This is necessary because few chemicals have been tested for their impacts on plant and animal communities or ecosystems, and for many substances, the only available toxicology data is from single-species testing (USEPA, 1989a; USEPA, 1992 and MacDonald et al., 1992). Microcosm ormesocosm data may be available for some

chemicals. When available, these data may have some utility in the prediction of environmental toxicity, and it is suggested they be considered in the ecological assessment.

The ecological risk assessment (ERA) process, as outlined in this guidance, is focused on determination of the severity and extent of potential ecological impacts as part of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) remedial investigation/feasibility study (RI/FS) process. Some of the information gathered during the ERA may be useful as components of a natural resource damage assessment (NRDA) but the ERA is not a substitute for a NRDA. State and Federal natural resource trustees should be contacted regarding the data collection and analysis needs where site-specific characteristics indicate a NRDA may be necessary.

CHAPTER 2

DEFINITIONS

AMBIENT: Local or regional concentrations of elements and compounds which are elevated above background concentrations due to anthropogenic activities.

ASSESSMENT ENDPOINT: The environmental attribute(s) that considered to be critical to the function of the biological community or population and are the ultimate focus of the ecological risk assessment.

BACKGROUND: Concentrations of inorganic elements unimpacted, and thus not elevated, by anthropogenic activities.

BIOTA: All living organisms except humans.

CONTAMINANT: A potentially harmful element, compound or agent that occurs in the environment at elevated concentrations due to human activities.

ENVIRONMENT: All the physical, biological and chemical conditions and influences surrounding and affecting the development and functioning of an organism or group of organisms.

FACILITY: Hazardous waste facilities.

FOOD WEB: The description of the structure of the biological community in terms of primary producers and multiple levels of consumers which describes the transfer of material and energy within the community.

FUNCTIONAL GROUP: Groupings of plants or animals which are based on function within the ecosystem, potential for exposure to various media, and physiological and taxonomic similarity.

HAZARD INDEX: The sum of chemical-specific hazard quotients, othe sum of chemical-specific hazard quotients for chemicals acting by a similar mechanism and/or having the same target organ.

HAZARD QUOTIENT: The chemical-specific ratio of the dosage by an exposure route to the RfD for that route, or the chemical-specific ratio of a concentration in a medium to the RfC for that medium.

LOWEST-OBSERVABLE-ADVERSE-EFFECT-LEVEL: The lowest tested daily dosage, usually expressed in mg per kg body weight per day, which causes known adverse effects upon chronic exposure in the species in question.

MEASUREMENT ENDPOINT: The measurable observable change that is used to evaluate the effects of the chemical(s) of concern on the selected assessment endpoints.

MESOCOSM: A replicated experimental unit, generally outdoors, larger than a microcosm, and containing a collection of species and habitat intended to simulate some ecological interactions.

MICROCOSM: A laboratory-scale replicated experimental unit containing a collection of species and habitat intended to simulate some ecological interactions.

NO-OBSERVED-ADVERSE-EFFECT CONCENTRATION (NOAEC): The maximum tested concentration (e.g. mg/l) in a medium which does not cause known adverse effects upon chronic exposure in the species in question.

NO-OBSERVED-ADVERSE-EFFECT LEVEL (NOAEL): The maximum tested daily dosage, usually expressed in mg per kg body weight per day, which does not cause known adverse effects upon chronic exposure in the species in question.

REFERENCE CONCENTRATION: A concentration in a specified medium, expressed in $mg_{chemical}$ per kg (mg/kg), $mg_{chemical}$ per liter (mg/l) or $mg_{chemical}$ per cubic meter (mg/m^3) that is not expected to adversely affect biota exposed to that medium by all actual and potential pathways when biota are exposed for an extended period of time.

REFERENCE DOSE: A daily dosage, expressed in $mg_{chemical}$ per $kg_{body\ weight}$ per day (mg/kg-day), that is not expected to adversely affect biota.

REPRESENTATIVE SPECIES: A species used to represent a functional group of organisms at the site for evaluation of assessment endpoints. It is chosen based primarily on its function in the ecosystem, and secondarily on taxonomic relatedness and known or presumed similarities in physiology and life history.

SITE: Hazardous waste site.

SPECIAL SPECIES: Rare, threatened or endangered species (California or federal), or recommended or candidate species for California or federal listing, or California species of special concern.

SURROGATE SPECIES: A species from which toxicology or exposure data are extrapolated to infer characteristics of representative species. It is chosen based on taxonomic relatedness and known or presumed similarities in physiology and life history.

UNCERTAINTY FACTOR (UF): The ratio of the NOAEL to the RfD or the ratio of the NOAEC to the RfC. The purpose of a UF is to compensate for uncertainty in extrapolation between species or from one type of effect to another, and it may have components representing different sources of uncertainty.

WILDLIFE: All non-domesticated plants and animals including aquatic plants and animals.

WILDLIFE HABITAT: The place where an animal or plant normally lives, often characterized by a dominant plant form or physical characteristic.

CHAPTER 3

SCOPING ASSESSMENT

3.1 INTRODUCTION

The scoping assessment is an expansion of the existing guidance for an ecological screening provided in the DTSC Preliminary Endangerment Assessment (PEA) Manual (DTSC, 1994). The suggested steps of thescoping assessment are discussed at the end of Part A (Appendix A) and are depicted as a flow chart (Appendix A, Figure 1). At a minimum, it is recommended that ascoping-level investigation be conducted for each site or facility. Ascoping-level investigation consists of a chemical, physical, and biological characterization of the site, and an evaluation of the potential for complete exposure pathways. The purpose of this investigation is to determine the potential for contact between ecological receptors and chemicals of concern. The results of this qualitative assessment may be used to determine the need for and the extent of further assessment.

Even if no currently-complete exposure pathways for biota are identified, the biological characterization of the site is important in that it may become an important consideration in future human health risk management decisions. For example, removal actions to protect human health may adversely impact biota or critical portions of their habitat. The Department of Toxic Substances Control is a State natural resourceco-trustee together with the Department of Fish and Game. The development of thescoping assessment was coordinated with State and Federal natural resource trustees to provide biological information useful in evaluation of natural resource injury. Close coordination with State and Federal natural resource trustees is recommended when preparing a Scoping Assessment.

3.2 SITE CHARACTERIZATION

Chemical and physical characterization of the site are similar to those for human health risk assessment. However, chemical detection limits, exposure pathways, contaminant speciation and mode of toxic action may differ significantly from those evaluated in the human health risk assessment. An assessment of the ingestion exposure via contaminated media and contaminated prey items in the ecological risk assessment will require characterization of trophic level structure and food web transfer of contaminants beyond that required for human health risk assessment. Many components of the ecological risk assessment subsequent to the scoping assessment will rely on comparison to ‘reference’ or ‘background’ locations or samples and the identification and characterization of these ‘reference’ or ‘background’ locations should begin as soon as it appears the investigation will proceed beyond a Scoping Assessment.

This is also the point at which a potentially responsible party (PRP) may choose to demonstrate that inorganic contaminants are present at ‘background’ concentrations and that the site or facility therefore poses no greater ecological risk than the surrounding unimpacted area. If organic chemicals of ecological concern are present or concentrations of inorganic elements are present above ‘background’ concentrations

the scoping assessment proceeds to identify the potentially affected habitats or communities. If no organic chemicals of ecological concern are present or concentrations of inorganic elements are at or below 'background' concentrations the site or facility exits from the ecological risk assessment process upon preparation and acceptance of a minimal scoping assessment report detailing these findings and conclusions. The work plan for any study of inorganic 'background' concentrations should be submitted for HERD review, through the DTSC Project Manager, prior to initiation of the study.

3.3 BIOLOGICAL CHARACTERIZATION

We suggest that the following elements be considered during biological characterization of the site:

- identification of each distinct habitat found on the site, and each off-site habitat which has the potential to be impacted by site-related or facility-related contaminants or remediation activities. An example of such a framework for habitat assessment can be found in Mayer and Laudenslayer (1988);

- identification of the species and types of communities present or potentially present. It is suggested that species be considered to be potentially present if they are known to have been present historically or if they are present or have historically been present in similar habitats in the ecoregion.

- identification of species considered to be essential to, or indicative of, the normal functioning of the ecosystem or community.

- identification of special species and their habitats at or near the site in addition to identification of the more common site-receptors.

Complete biological characterization of the site generally requires observation over a period of time that is sufficient to observe biota that may use the site at different times of the day and/or during different seasons. However, for the purpose of determining biological assets to be protected, it may be sufficient to identify plant communities and habitat types, conduct a short on-site confirmation 'site walk', and develop assessment endpoints based on probable or potential receptors using the identified habitats. The preliminary list of potential representative species will be confirmed by site-specific observations by a trained biologist or field investigator during the 'site walk'.

3.4 PATHWAY ASSESSMENT

Pathway assessment identifies the potential for contact between environmental receptors and chemicals of concern in any medium and by any exposure route. Suggested media to be considered include soil, sediment, air, water and biota. Pathways may be direct (e.g., dermal contact with contaminated soil) or indirect (e.g., via food sources). Consideration of the physical and chemical properties of contaminants may focus attention on exposure pathways for evaluation (e.g., chlorinated pesticides in food web pathways or

volatile organic compounds for inhalation exposure to burrowing animals). For completeness, we recommend that inhalation, ingestion, and dermal contact exposure routes be evaluated for terrestrial receptors. As a working hypothesis, pathways are considered complete unless the chemical will not enter the medium or the receptor will not contact the medium, either directly or indirectly. It is also important to consider off-site movement of contaminants (e.g., transport via storm drain systems or contaminated groundwater) when evaluating potentially complete exposure pathways.

3.5 SCOPING RESULTS AND DECISION CRITERIA

To be effective, all decisions are best made by the project manager in consultation with qualified experts, based upon site-specific considerations. It may not be necessary to conduct an assessment beyond the Scoping Phase if either of the following conditions are met:

1. The scoping assessment demonstrates that both the site and areas actually or potentially impacted by the site are not significantly utilized by biota and do not contain significant wildlife habitats, or

2 . There are no actually or potentially complete exposure pathways.

However, if potentially toxic chemicals have contaminated, or may be reasonably expected to contaminate, media which may directly or indirectly contact wildlife or their habitats, either on-site or off-site, then we suggest this demonstrates a 'release or threatened release of a hazardous substance into the environment' [CERCLA Section 101 (24)], that ecological receptors may potentially be adversely effected and a Phase I predictive assessment is recommended.

3.6 REPORTS

The objective of the reports described below is to describe the approach, calculation and documentation of the scientifically based estimation of adverse effect(s) upon wildlife and wildlife habitats from present and/or future exposures to chemical or physical stressors, and from activities associated with removal of chemical contamination.

We suggest the scoping assessment report contain the following elements:

- A characterization of the site, including location,ecoregion, physical description, climate, and site history, including chemicals handled or used on the site. To enable independent evaluation, we suggest that the report include, or thoroughly reference, all available pertinent information.

- A description of the potential problem including chemical contamination of environmental media, chemical migration pathways, ecological resources and exposure pathways. Natural resources and values to be protected are often described as assessment endpoints. Evaluation of chemical contamination is often facilitated by a discussion of method detection limits or analytic instrument sensitivity in relation to

media concentrations which are predictive of adverse effects on biota. Several regulatory or monitoring programs have developed media -specific effect concentrations which may prove useful. For example the National Oceanic and Atmospheric Administration (NOAA) values for sediments (Long and Morgan, 1990,MacDonald, 1992) or the Federal Ambient Water Quality Objectives are valuable for screening purposes. The DTSC Project Manager should coordinate review of Scoping Assessments with HERD and other Federal and State agencies to ensure proper use of screening criteria. Comparison of media concentrations with 'reference' or 'background' concentrations where available and applicable is often useful. However, none of these screening criteria should be used as 'clean-up' concentrations or criteria.

For clarity and ease in reading, the report should be complete yet concise. Tables, graphs, and maps, may assume a major role in results reporting, and are of great utility provided they are fully described or self-explanatory. The text would serve to guide the reader through the tables and figures.

An outline of the proposed Phase I predictive assessment work plan is required for those sites or facilities which will proceed with more detailed ecological risk assessment based on the conclusions of the scoping assessment. A fully-developed Phase I predictive assessment work plan will be prepared in consultation with regulatory agencies, based on the proposals contained in this outline. The work plan outline should contain:

g. A preliminary conceptual site model.
a. A preliminary list of potential receptors to be evaluated in detail.
b. A preliminary list of potential pathways for each receptor to be evaluated.
c. Field validation of preliminary facility-specific habitats maps.
d. Assessment endpoints to be evaluated.
e. Measurement endpoints to be measured.
f. Proposed data quality objectives.
h. Proposed hypotheses for any statistical testing.

Further detail is provided in the following section on the Phase I predictive assessment.

CHAPTER 4

PHASE I: PREDICTIVE ECOLOGICAL RISK ASSESSMENT

4.1 INTRODUCTION

The suggested steps of a Phase I predictive assessment are discussed at the end of Part A (Appendix A) and depicted as a flow chart (Appendix A, Figure 2). We suggest that the Phase I predictive assessment be viewed, in general, as conditional on the results of the scoping assessment. The purpose of the Phase I predictive assessment is to further characterize and evaluate the potential for ecological impacts.

Predictive assessment of environmental risk, as described herein, is a process of comparison of measured or predicted concentrations or doses of toxic chemicals, in biotic and/or abiotic environmental compartments, with contaminant-specific toxicity data believed to be protective of biota, to arrive at a hazard index for each species evaluated. This process involves selection of representative species and toxicity data, identification of measurement endpoints, evaluation of potential exposure pathways and contact rates, and calculation of hazard quotients and a hazard index. Modeling is sometimes used to predict concentrations of contaminants in various environmental compartments including biota. While this may be useful, these models usually involve large uncertainties, which we suggest be fully accounted for in the hazard index range. In the absence of adequate data on transfer of chemicals among environmental compartments, laboratory or field studies may be of significant value to answer these questions. Toxicity criteria may be pre-existing, or derived by the assessor. They may be expressed as reference dosages (RfDs) for terrestrial receptors or reference concentrations (RfCs) for completely aquatic receptors.

4.2 SELECTION OF ENDPOINTS AND REPRESENTATIVE SPECIES

Selection of the assessment and measurement endpoints and the representative species is dependent upon the conceptual site model developed for the site or facility. The conceptual site model integrates the exposure pathways judged to be potentially complete with the potentially exposed ecological receptors to focus the ecological assessment on critical ecological components and functions. The results of the exposure pathway evaluation can be presented in a tabular form or as a figure, such as Figure 1, where the significance of the exposure pathway is indicated by the width of the arrow and the exposure pathways considered complete or incomplete are indicated for the major components of the biological community.

Selection of representative species is frequently aided by preparation of a diagrammatic presentation of the conceptual site model similar to Figure 2. The primary, and less significant routes of exposure are indicated in this presentation along with the site or facility-specific representatives of the different guilds associated with decomposers, primary producers, primary consumers and upper level consumers. This diagram of the conceptual site model is presented as an example only. The original differentiated the significant routes of exposure and assessment endpoints from measurement endpoints through the use of color which was too expensive to reproduce in this document.

The ecological, toxicological and societal criteria used in the final selection of the representative species should be presented in a table similar to Example Table 1. This table presents the assessment endpoints with the associated representative species in the first column with the criteria used to select these representative species and significant comments in the other columns.

In order to ensure cost effective and timely completion of assessments, we recommend that the measurement endpoints, exposure pathways and representative species to be evaluated in the Phase I predictive assessment, as well as the toxicity criteria selected, be submitted for review by DTSC, and other regulatory agencies, prior to the commencement of the Phase I predictive assessment.

4.3 QUANTITATIVE RISK ASSESSMENT FOR AQUATIC BIOTA

We believe that medium-specific RfCs are useful in the evaluation of the potential for impacts on aquatic biota. In this approach, a selected RfC is compared with the estimated or measured environmental concentration (e.g., water or sediment concentration) to derive a hazard quotient. For this approach to be valid, the RfC must take into account all relevant exposure pathways and must be based on a database sufficiently broad to ensure that the RfC adequately reflects the toxicity to the range of species present or potentially present. This practice is appropriate to the extent that the medium in question represents the dominant source of exposure and to the extent that the RfC is protective of all organisms in contact with that medium. Uncertainty factors may be appropriate and, if used, would be documented in the report to facilitate independent evaluation.

4.3.1 FUNCTIONAL GROUPINGS AND REPRESENTATIVE SPECIES

We suggest the following criteria be considered in evaluating the potential representative species (depending on site-specific information, fewer or additional criteria may warrant consideration):

- Contaminated Media - The potential threat from contaminants in sediment in addition to contaminants in the water column warrant consideration. Contaminants which tend to accumulate in sediment due to affinity for organic matter warrant special attention. We recommend that effects associated with increased exposure due to bioaccumulation of contaminants in food items be addressed where the contaminants of concern or potentially exposed organisms indicates this is a potentially significant route of exposure.

- Ecological Niche - To adequately evaluate the ecosystem we suggest that representative species be selected which would include exposure to organisms in the water column as well at least one sediment-dwelling organism. In addition, for completeness, we recommend that an aquatic plant species also be included in the list of representative species.

- Toxic Endpoints - In order to evaluate the entire range of possible adverse effects, it is recommended that endpoints in addition to mortality be evaluated. For example, Endpoints such as completion of larval development, growth and reburial are important in the development of a medium-specific No Observed Adverse Effect Concentration (NOAEC) for sediment-dwelling organisms.

4.3.2 SELECTION AND USE OF TOXICITY DATA

We suggest that Reference Concentrations (RfC) based on chronic exposure from the following sources be used when available (Note : the risk manager would be responsible for ensuring that all pertinent enforceable criteria and standards are met):

- California Water Resources Control Board Ocean Plan or any other applicable California Water Resource Control Board guidance as deemed appropriate.

- The appropriate California Regional Water Quality Control Board local Basin Plan or other appropriate local numerical criteria or narrative objectives.

- U.S. Environmental Protection Agency Ambient Water Quality Criteria for Protection of Aquatic Life.

- National Oceanic and Atmospheric Administration Sediment Criteria (ERLs: Long and Morgan, 1990; McDonald, 1992).

- If RfCs are not available from the above sources, we suggest consultation of California Department of Toxic Substances Control Applied Action Levels for protection of aquatic life for applicability to the specific situation.

Uncertainty factors may be warranted, based on scientific considerations, if the conditions for which the criterion was developed do not match those being assessed, or to account for deficiencies in the data used to derive theRfC. Deficiencies may include, but are not limited to:

- The RfC is based on studies which do not consider exposure via the food chain when that pathway would contribute significantly to total exposure.

- The RfC is based on studies which are of insufficient duration to have achieved the maximum tissue concentration and/or toxic effect.

- The RfC is based on data from a range of species which does not include the species, or closely related species, to which it is to be applied.

- The RfC is based on studies which do not evaluate sufficiently sensitive endpoints (e.g., morality as an endpoint rather than a reproductive endpoint).

- The RfC is based on studies which lack adequate control and documentation of exposure.

In the absence of an established RfC for a particular chemical in an environmental medium, we suggest that consideration be given to adapting anRfC from another medium or deriving an RfC from published toxicity data. One method we suggest for adapting an available RfC from one medium to the medium of concern is to use the partition coefficient between the two media. Such extrapolations are only approximations, and therefore probably warrant uncertainty factors; they are not,*a priori*, a scientifically defensible substitute for an adequate environmental sampling plan. If a criterion for another medium is not available, we suggest that the RfC be derived either from published toxicity data or that site-specific aquatic toxicity testing be performed to develop the toxicity criterion. In general, this would involve determination of a concentration at which no adverse effects on test species were observed, which is divided by uncertainty factors, if necessary. Uncertainty factors would be used to adjust for any of the deficiencies in the available toxicity database (see above for description of deficiencies). Separate analyses evaluating exposures by pathway would probably not be warranted for those pathways which are reflected in the RfCs.

An alternative use of site-specific aquatic or terrestrial toxicity testing would be to define the area requiring remediation based on toxic response in dilution-series bioassays rather than to develop a toxicity criterion for use in the Phase I predictive assessment. Definition of the ecologically-based remediation area based solely on site-specific toxicity testing should be employed only after consultation with DTSC and other regulatory agencies.

4.3.3 EXPOSURE ASSESSMENT

Use of the RfC approach to evaluate threat to aquatic receptors means that exposure via different pathways is not normally calculated separately in ecological risk assessments of aquatic receptors, except where food web transfers are judged to be a significant route of exposure. Bioaccumulation in representative species which utilize both aquatic and terrestrial habitats, such as shorebirds or waterfowl, would usually be addressed in the evaluation of terrestrial representative species.

4.3.4 COMPARTMENTAL TRANSFER FACTORS AND TISSUE RESIDUE LEVELS

Intermedia transfer factors based on modeling methods such asfugacity are sometimes used to estimate tissue concentrations in biota. The results of such modeling efforts frequently contain considerable uncertainty, and therefore, we suggest such modeling be used with caution. One important use of this modeling approach is as a preliminary screen to predict potential problem areas. We recommended that predicted tissue residue levels be verified with site-specific measurements to provide scientific validity to the process. Collection of plants and animals and measurement of tissue concentrations an appropriate and acceptable option to modeling.

4.4 QUANTITATIVE RISK ASSESSMENT FOR TERRESTRIAL BIOTA

Quantitative risk assessment for terrestrial biota, like human health risk assessment, would generally use the RfD and associated methodology. This methodology is believed to

be appropriate and scientifically supportable because of themulti-media, multi-pathway exposure of terrestrial species.

Separate pathway analysis need not be completed for those pathways which are included in an exposure assessment based on RfCs. For terrestrial plants and soil decomposers potential threat is generally evaluated based upon soil concentration, anRfC approach, rather than a dose approach. Terrestrial plant and animal bioassays (U.S. EPA, 1989b; U.S. EPA, 1992; U.S.NPS, 1991) may be used to directly evaluate potential toxicity rather than perform the quantitative Phase I predictive assessment. In general, anRfC approach is also used to evaluate exposure of aquatic receptors to contaminated water or sediment. Performance of site-specific terrestrial or aquatic plant or animal bioassays as an alternative to the Phase I predictive assessment is available by proceeding directly to a Phase III impact assessment.

4.4.1 FUNCTIONAL GROUPINGS AND REPRESENTATIVE SPECIES

Because it would be impractical to individually evaluate the effects of the chemicals of concern on every potentially affected species, functional groups, or ecological guilds, are generally used to represent diverse taxa which may be exposed to contamination at a site or facility. The groupings are generally based on function within the ecosystem, potential for exposure to various media, and physiologic and taxonomic similarity. Examples of such groups are: rooted macrophytes, carnivorous birds, and small omnivorous mammals. Representative species are generally chosen to represent the functional groups that are being evaluated. Representative species need not actually occupy the habitat, but may be used to represent a group which potentially or actually does. To be comprehensive, we recommend the representative species selected include a primary producer, a primary consumer, and higher level consumers, and may include decomposers.

The criteria used to select representative species should be presented. Presentation of biologically-sound rationale for selection of representative species will strengthen the scientific credibility of the report. Scientific studies suggest the selection criteria to be considered would include, but not necessarily be limited to: sensitivity of the representative species, availability of data for the representative species, relationship of the representative species to the assessment endpoint(s), consistency of exposure scenarios with the species or functional group being evaluated, and practical issues such as availability of toxicity data and suitable test protocols. Societal values such as economic importance or high recreational value may also influence the choice of representative species. Groups generally considered in the Phase I predictive assessment are those which occupy or could potentially occupy habitats which are affected, or potentially affected, by contamination related to the site or facility. In general, species are considered potential users of a habitat based on their historical presence or their presence in similar habitats. In choosing representative species, consideration should be given to taxonomic groups which may be particularly sensitive to the contaminants of concern. We recommend that functional groups representing any special species which are known or expected to occur on or near the site, be considered as candidates for inclusion as representative species. If a special species are not evaluated by the functional groups chosen as representative species, we recommend that the scientific justification be included in the report which would discuss the

rationale for the decision to exclude the special species and document that the special species is fully accounted for and protected by the representative species evaluated.

4.4.2 SELECTION AND USE OF TOXICITY DATA

We believe it is scientifically justified to use toxicity data for the representative species and members of the same taxonomic family in estimating toxicity to representative species. If data from the representative species and members of the same taxonomic family are unavailable, or of questionable quality, or are known to be inappropriate because of physiological differences, then it is suggested that a wider range of taxa also be considered. Species chosen from which to develop toxicity or exposure data are termed surrogate species. Data for structurally related chemicals are of value, if data for the chemical in question are judged to be inadequate. Selection of appropriate data, based on a balance of taxonomic and physiological similarity, quality of the data, and expected mode of toxic action, is recommended. Detailed description and scientific justification of the data set selection and summaries of the data used in the report would facilitate independent verification and review. The surrogate species data should be used to estimate the NOAEL in the representative species. Adverse effects include acute and chronic, lethal and sub-lethal toxicity, including, but not limited to, behavioral, reproductive, and some biochemical effects. Other possible adverse effects include excess stimulation of growth or reproduction which may lead to an ecological imbalance.

Where appropriate, a NOAEL for surrogate species should be divided by one or more uncertainty factors to determine the reference dose for each representative species. UFs are generally based on the number, quality, duration, and sensitivity of the studies used in the assessment, and on the taxonomic diversity of the surrogate species tested. For clarity, we recommend that determination of the UFs be clearly described and, when possible, supported by the range of toxicity within a taxonomic group. In general, UFs greater than 1 would be considered to compensate for each of the following:

- study duration less than one full life cycle of the surrogate organism when the most sensitive stages of the life cycle were not tested;

- studies that do not address sensitive indicators of toxicity such as reproduction, behavior, or pathology;

- interspecies extrapolation when the extrapolation is between taxonomically distant species (e.g., the surrogate species and representative species are from different taxonomic families) or the range of species tested is narrow;

- the best studies available have deficiencies that result in uncertainty about the results;

- study duration is insufficient to obtain maximum tissue concentration or toxic effect.

In the absence of toxicity testing which indicates different UFs should be used to adjust RfDs, default UFs for endpoint and exposure period extrapolation for ecological RfDs are:

	UF	Example
1. To adjust from less sensitive endpoints, such as mortality, to a chronic NOAEL.	500	LD_{50} to $NOAEL_{Chronic}$
2. To adjust from an acute LOAEL to a chronic NOAEL. to chronic exposure.	10	$LOAEL_{Acute}$ to $NOAEL_{Chronic}$
3. To adjust from observable effect (LOAEL) to no observable effect levels (NOAEL).	5	$LOAEL_{Chronic}$ to $NOAEL_{Chronic}$

These UFs are for application to RfDs used in assessing the threat to terrestrial receptors. The maximum UF should be 500 using these default UFs when mortality is the only endpoint available. In cases where mortality data is the only toxicity data available, a greater amount of additional field or laboratory testing, beyond that normally required, must be performed as part of the Validation Study or Impact Assessment. When necessary, UFs for RfCs used in assessing threat to aquatic receptors should be developed in coordination with HERD and other regulatory agencies. The UFs for categories 2 and 3 above assume that sensitive life stages and endpoints were tested. Additional UFs may be needed to account for deficiencies in the toxicity data if sensitive life stages or endpoints were not tested.

When Interspecies extrapolation of toxicity data is between taxonomically distant species (e.g. different family or order) and the range of species tested is narrow, making it impossible to base the uncertainty factor on the available toxicity data, use the following default inter-taxa uncertainty factors. No detailed review of toxicity data was performed by HERS to develop these default uncertainty factors for interspecies extrapolation of toxicity data. They are a reasonable compromise between using no uncertainty factors and using an uncertainty factor of 10 at every level of extrapolation. These uncertainty factors are in the range of chronic and subchronic NOAEL comparisons in studies of uncertainty factors currently in preparation (U.S. EPA, In Preparation) and other discussions of uncertainty factors (Dourson and Stara, 1983; Ford, et al., 1992; Opreska, et al., 1994; Sloof, et al., 1986).

Within the Class Mammalia:

	UF	Example
1. Within the same taxonomic family	1	Beagle to fox (canidae to canidae)
2. Within the same taxonomic order	5	Laboratory mouse to ground squirrel (muridae to sciuridae)
3. Between taxonomic orders	10	Laboratory mouse to fox (rodent to carnivore)

4.4.3 EXPOSURE ASSESSMENT

To be comprehensive, we recommend that all complete direct and indirect exposure pathways should be included in the Phase I predictive assessment. Exposure pathways which generally are of concern for each representative species include the following:

- Ingestion of contaminated water;
- Ingestion of contaminated soil or sediment;
- Ingestion of contaminated food, particularly for contaminants with potential to bioaccumulate;
- Dermal contact with contaminated soil, sediment, or water;
- Inhalation of contaminated airborne particles;
- Inhalation of vapors (surface and subsurface locations).

A series of equations may be used to quantify the uptake by the various pathways. To facilitate independent verification, it is recommended that all parameters be supported by literature citations. A useful source of terrestrial exposure factors is the Wildlife Exposure Factors Handbook (U.S. EPA, 1993). Intake equations are generally of the form:

Daily intake = CM * CR * FI * AF * BW^{-1}

where:

CM = Concentrations of potentially toxic chemicals in media of concern. These are typically determined by a combination of measurement and modeling. A source is generally characterized by analysis, whereas movement into other media might be measured or modeled. In either case, spatial and temporal variation are important parameters that warrant consideration.

CR = Contact rates. These may be determined or estimated for each medium and pathway of concern for each representative species, except as noted above. Contact rates are expressed in terms of quantity of the medium (weight or volume) per day. When contact rates for the representative species are not available, they may be estimated using data from surrogate species. In selecting surrogate data, taxonomic, anatomic, physiologic, and behavioral relationships are generally considered, along with the quality of the studies. Inclusion in the report of a discussion and presentation of the scientifically based rationale for the data set selection would facilitate independent verification and review.

FI = fractional intake. The fraction of time spent in contact with contaminated media. This may generally be approximated as the ratio of the home range area to the area of the site-specific appropriate habitat.

AF = absorption fraction. This term may be used if there are data to show that absorption by the route in question is a fraction of that by the route for which the RfD was determined.

BW = body weight of the animal.

For contaminants which act by a threshold mechanism, where the fractional intake (FI) is less than one, that is, the home range is greater than the site area, the intake of inorganics from off-site areas should be factored into the total intake. This may require that intake at 'background' or 'ambient' concentrations be factored into the exposure calculations. The representative species should be selected so that the home range of at least on representative species lies completely within the site boundary, that is the FI is equal to one. It is also necessary to consider the duration and timing of the exposure duration in relationship to the exposure period employed in the toxicity testing. The factors normally described as exposure frequency, exposure duration and averaging time should all be considered when selecting the reference toxicity value. For example, subchronic exposures during the reproductive period may be more indicative of potential threat than chronic lifetime average exposure or yearly exposure.

4.4.4 COMPARTMENTAL TRANSFER FACTORS AND TISSUE RESIDUE LEVELS

Intermedia transfer factors based on modeling methods such asfugacity are sometimes used to estimate tissue concentrations in biota. The results of such modeling efforts frequently contain considerable uncertainty, and therefore, we suggest modeling be used with caution. One important use of this approach is as a preliminary screen to predict potential problem areas. We recommended that predicted tissue residue levels be verified with site-specific measurements to provide scientific validity to the process.

4.5 RISK CHARACTERIZATION

For each representative species under evaluation, a hazard quotient (HQ) may be calculated for each pathway. Hazard quotients for all exposure pathways are added to arrive at a species-specific hazard index (HI). Hazard indices are additive between chemicals when the chemicals have a mechanism of action or target organ in common. Since hazard indices are intended to be conservative estimators of potential hazard, hazard indices less than one for each chemical mode of action or target organ are reasonably good indications that adverse effects on assessment endpoints are unlikely, provided that sensitive indicators of chronic toxicity have been measured in appropriate test species, and that environmental concentrations have not been underestimated. Nonetheless, field and/or laboratory verification of key facets of the predictive assessment is suggested as sound scientific practice. In general, this would be determined in conjunction with the DTSC project manager and be based upon site specific considerations. The duration of the exposure and the toxicity criterion should match as closely as possible (i.e., chronic exposures should be compared with chronic toxicity endpoints). If this is not possible, uncertainty factors are probably warranted to adjust for differences.

4.6 UNCERTAINTY ANALYSIS

For accuracy and thoroughness, we recommend that uncertainties in estimates of chemical fate and transport, exposure, and toxicity should be identified and discussed. In general, a qualitative discussion of the magnitude each component contributes to the overall estimate of risk would be included in a focused uncertainty analysis. A quantitative analysis would be expected to provide more information than a qualitative analysis, and would place upper and lower bounds or a distribution on the hazard quotient(s). A Monte-Carlo uncertainty analysis or other detailed quantitative uncertainty analysis will not be accepted for review without the prior written approval of the DTSC Project Manager and consultation with HERD. Instead, the uncertainty analysis might compare an upper-bound intake estimate to a lower-bound intake estimate or couple these intake estimates with assessment of the hazard using both a LOAEL and a NOAEL for the same representative species. In special cases, where a significant amount of site-specific is collected in a compressed study, a Monte-Carlo uncertainty analysis of the intake equations, and perhaps the toxicity reference value, may be applicable. The parameters included in this stochastic analysis should be approved prior to calculation of any Phase I predictive assessment Monte-Carlo analysis.

4.7 APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS (ARARS)

Compliance with ARARs does not *a priori* imply the absence of significant ecological risk unless ecological effects were considered in the development of the ARARs. Regulatory criteria which are not strictly ecologically-based do not necessarily fully account for the range of ecological risks at each and every site or facility. For example, DTSC hazardous waste criteria, such as Total Threshold Limit Concentrations (TTLCs) and Soluble Threshold Limit Concentrations (STLCs), provide no useful estimate of potential ecological threat. DFG, as the State natural resource co-trustee with DTSC, in addition to other State and Federal natural resource trustees, should be consulted for ARARs for each DTSC-lead site or facility.

4.8 PHASE I PREDICTIVE ASSESSMENT RESULTS AND DECISION CRITERIA

Maximum hazard indices greater than one for any chemical mode of action or target organ suggest the possibility, but by no means the certainty, of adverse effects on the species under assessment, and other similarly exposed species. Under these circumstances, one or more of the following courses of action may be undertaken or considered:

- Laboratory or *in situ* testing, as described in Chapter 5 of this guidance, to test key assumptions or points of uncertainty in the Phase I predictive assessment; or

- Phase III impact assessment testing as described in this guidance; or

- Remediation or mitigation as described in this guidance.

4.9 REPORTS

The objective of the reports described below is to describe the approach, calculation and documentation of the scientifically based estimation of adverse effect(s) upon wildlife and wildlife habitats from present and/or future exposures to chemicals, and from activities associated with removal of chemical contamination.

We recommend that a Phase I predictive assessment contain, but not necessarily be limited to, the following:

- Identification of, and rationale for, assessment and measurement endpoints

- Representative species selected for assessment. The representative species for each site or facility will be based on development of the conceptual site model for each site or facility and in consultation with HERD through the DTSC Project Manager, other State and Federal natural resource trustees and other State and Federal regulatory agencies.

- If any chemicals found at the site are not assessed, the rationale for such a decision would be beneficial to an independent reviewer. The scientifically preferred approach would be to include all organic chemicals found at the site and all inorganic chemicals found at concentrations exceeding background. Exclusion of chemicals from the

assessment should be based on sound scientific principles and application of criteria similar to those employed in human health risk assessment. In the absence of such a rationale, we recommend that chemicals not be excluded from the assessment.

- Toxicity criteria for the chemicals to be assessed.

- Sources of criteria and discussion/justification of the scientific basis for choices among available data.

- A toxicity criterion for a representative species. This may be considered as equivalent to a measurement endpoint.

- Quantitative exposure assessment. This would include, but not necessarily be limited to, sources of exposure data and discussion/justification of the scientific basis for choices among available data.

- A detailed description of how the exposure was estimated. For organisms higher on the food chain, this may be a multi-step process, with several intermediate calculations and/or measurements, and multiple exposure pathways. This is a critical step, and we recommend that it be presented in sufficient detail to enable a reviewer to re-create the entire exposure scenario. We recommend documentation, in detail, of all models used to allow for independent verification by a reader.

- Risk characterization would include comparison of the estimated exposure via all pathways with the selected toxicity criteria. In general, this would include an estimate of the range of uncertainty and the probability of adverse effects at the calculated exposure level. Ideally, this would be done by using a distributional approach to exposure and toxicity parameters. If unpublished or site-specific studies are used in this analysis, we recommend they be described in sufficient detail that the reviewer can re-create the study and independently evaluate the conclusions.

For clarity and ease in reading, the report should be complete yet concise. Tables, graphs, and maps, may assume a major role in results reporting, and are of great utility provided they are fully described or self-explanatory. The text would serve to guide the reader through the tables and figures.

CHAPTER 5

PHASE II: VALIDATION STUDY

5.1 SITE-SPECIFIC OR IN SITU TOXICITY TESTING

Suggested steps of the Phase II validation study are discussed at the end of Part A (Appendix A) and depicted as a flow chart (Appendix A, Figure 2). Site-specific or in-situ toxicity testing is suggested to supplement existing data when the database for a chemical is inadequate or when site-specific conditions make the use of established or derived criteria questionable. We recommend that the DTSC Human and Ecological Risk Division be consulted in the design and interpretation of these tests.Biotransfer factors, used in terrestrial food-chain models, often warrant verification by sampling and analysis of environmental media and biota. Toxicity values and contact rates are often estimated or extrapolated from other species. Such extrapolations may involve such large uncertainties as to render them of limited value. Data regarding toxicity to primary producers and decomposers is frequently lacking and therefore tests of soil toxicity to a plant species and a decomposer species will generally be beneficial.

5.2 UNCERTAINTY ANALYSIS

For accuracy and thoroughness, we recommend that uncertainties in estimates of chemical fate and transport, exposure, and toxicity identified and discussed in the Phase I predictive assessment be the basis for development of a list of potential ecological transfer factors or receptors to be tested in the Phase II validation study

5.3 PHASE II TESTING PROTOCOLS

Phase II validation study testing is, by nature, site- and case-specific. Therefore, we recommend Phase II validation study testing protocols be established in conjunction with the DTSC project manager and qualified experts and other regulatory agencies as appropriate, taking into consideration the results of the analysis described in Chapter 4.

5.4 PHASE II RESULTS AND DECISION CRITERIA

The results of a Phase II validation study may lead to the conclusion that no further action is needed, that more study is needed, or that remediation or mitigation is needed. We recommend the decision on Phase III impact assessment testing versus remediation or mitigation or no further action must be made in collaboration with the DTSC project manager. Following Phase II validation studies, the maximum hazard index in the Phase I predictive assessment would generally be re-evaluated. If it is substantially less than one, further testing may be unwarranted. If, however, the potential for adverse effects cannot be ruled out or uncertainties remain, field studies and/or continued monitoring may be appropriate to verify the lack of an effect. If the HI is one or more and there is reason to believe that the Phase I predictive assessment and Phase II validation study has overestimated the hazard index, Phase III impact assessment testing may be warranted. If the HI is one or more and the results of the Phase I predictive assessment and Phase II

validation study appear to be reliable, it may be appropriate to bypass further studies and proceed to remediation feasibility studies. If the decision is to move directly into the remediation phase, we recommend that toxicity data be used to develop remediation goals. In developing remediation goals, it is prudent to consider the risk to habitat and biota from remediation, especially for special species.

5.5 REPORTS

The objective of the reports described below is to describe the approach, calculation and documentation of the scientifically based estimation of adverse effect(s) upon wildlife and wildlife habitats from present and/or future exposures to chemicals, and from activities associated with removal of chemical contamination.

We recommend a Phase II validation study report contain, but not necessarily be limited to, the following:

- Representative species selected for assessment. The representative species for each site or facility will be based on development of the conceptual site model for each site or facility and in consultation with HERD through the DTSC Project Manager, other State and Federal natural resource trustees and other State and Federal regulatory agencies.

- Justification for selection of one representative species over another, in cases where the number of species included in the Phase II validation study is fewer than those included in the Phase I predictive assessment.

- If any chemicals found at the site are not assessed in studies of ecological transfer factors, it would be beneficial to an independent reviewer if the rationale for such a decision were provided. Selection of chemicals for the assessment in the Phase II validation study should be based on sound scientific principles.

- Toxicity criteria and physical characteristics for the chemicals to be assessed in a validation study of ecological transfer factors.

- Sources of criteria and discussion/justification of the scientific basis for choices among available data.

- A toxicity criterion for a specific indicator species may be considered as equivalent to a measurement endpoint.

- If unpublished or site-specific studies are used in this analysis, we recommend they be described in sufficient detail to enable the reader to re-create the study and independently evaluate the conclusions.

- Description of how the results of the Phase II validation study support or contradict the hazard indices and conclusions of the Phase I predictive assessment.

For clarity and ease in reading, the report should be complete yet concise. Tables, graphs, and maps, may assume a major role in results reporting, and are of great utility provided they are fully described or self-explanatory. The text would serve to guide the reader through the tables and figures.

CHAPTER 6

PHASE III: IMPACT ASSESSMENT

6.1 INTRODUCTION

The steps of the Phase III impact assessment are discussed at the end of Part A (Appendix A) and depicted as a flow chart (Appendix A, Figure 3). If the results of Phase II validation study indicate the possibility of adverse effects on the biota, then either a Phase III impact assessment or remediation or mitigation warrant consideration. In contrast to the Phase I predictive assessment, and Phase II validation study, which attempts to verify or refine the predictions made in the Phase I predictive assessment, the Phase III impact assessment considers the severity and extent of impacts and evaluates remediation impacts where appropriate.

The purpose of the Phase III impact assessment is to clearly define the area which would be subject to remediation based on ecological preliminary remediation goals, refined in Phase III impact assessment ecological field studies or laboratory studies. These ecological risk assessment studies are distinct from a natural resource damage assessment (NRDA), which is the responsibility of State and Federal natural resource trustee agencies, to address injuries to natural resources that result from insufficient remedial actions to protect and restore natural resources from hazardous waste releases.

The DFG is the delegated State natural resourceco-trustee, based on designation of the Resource Agency by the Governor in August, 1993. The DTSC is the other delegated State natural resource co-trustee, based on designation of the California Environmental Protection Agency by the Governor in August, 1993. The contact for coordination of ecological risk assessments and DFG natural resource trustee issues is :

Michael Martin, Ph.D.
CERCLA Unit
California Department of Fish and Game
20 Lower Ragsdale Drive, Suite #100
Monterey, CA 93940

(408) 649-7178 Voice
(408) 649-2894 Facsimile

In some cases, a Phase III impact assessment may be undertaken in lieu of, or prior to, the development of remedial strategies. We suggest this alternative be undertaken only with the explicit decision of the DTSC Project Manager, advised by HERD, and appropriate State and Federal natural resources trustees. Factors to be considered in this decision would include, but not necessarily be restricted to:

- The extent and magnitude of chemical contamination. For an environmental impact assessment to yield scientifically sound and interpretable results, the extent and magnitude of chemical contamination would need to be at or near its maximum and

have been at or near maximum levels for a sufficient period of time for potential impacts to be realized.

- It can be very difficult and expensive to demonstrate site-related or facility-related adverse effects without some knowledge of the important ecological receptors and concentrations known to produce specific toxic endpoints in these species. The probability of equivocal results in laboratory testing or field investigation may be high unless contamination is present at concentrations which produce a clearly-demonstrable effect.

- There can be increased adverse ecological effects associated with delaying remediation, as well as performing the remediation itself.

6.2 TESTING PROTOCOLS AND STUDY DESIGN

To ensure that time and resources are not wasted generating data that do not contribute materially to the decision-making process, it is suggested that the protocols for the Phase III impact assessment testing be submitted in advance for Departmental review. We suggest the protocol take into account the following factors:

- A negative finding is not valid unless the extent and magnitude of chemical contamination are at or near their maximum, and have been near maximum levels for a sufficient period of time for potential impacts to be realized.

- The adequacy of the design of the proposed studies. We recommend the study be designed to detect an effect of the minimum magnitude that would be of ecological concern.

- The variety of ecological endpoints examined. In general, we suggest that a variety of ecological endpoints be selected to ensure that no important ecological effect remains undetected.

- The value of the studies in relation to the potential impacts of any delay in remediation associated with the additional studies.

- The availability of baseline data or suitable reference site(s) as a basis for comparison.

- Level of confidence in the results of the Phase I predictive assessment and Phase II validation study.

6.3 SPECIFIC GUIDANCE FOR PHASE III IMPACT ASSESSMENTS

Sources of guidance for Phase III impact assessments can be found in the references listed in Chapter 8.

6.4 MONITORING REQUIREMENTS

Continued monitoring may be beneficial if the results of the Phase III impact assessment indicate that the biota have not been impacted.

6.5 REPORTING REQUIREMENTS

The objective of the reports described below is to describe the approach, calculation and documentation of the scientifically based estimation of adverse effect(s) upon wildlife and wildlife habitats from present and/or future exposures to chemicals, and from activities associated with removal of chemical contamination.

We recommend a Phase III impact assessment report contain, but not necessarily be limited to, the following:

- Representative species selected for assessment. The representative species for each site or facility will be based on development of the conceptual site model for each site or facility and in consultation with HERD through the DTSC Project Manager, other State and Federal natural resource trustees and other State and Federal regulatory agencies.

- Measurement endpoints: This may include census information, health and condition indicators such as weight/length ratios,biomarkers, chemical residues in tissues, or population parameters such as age and sex distribution.

- Measurement techniques: In general, published techniques would be briefly described along with a reference given for more detail. We recommend that unpublished techniques be described in sufficient detail to enable independent verification by the reader.

- Description of reference site(s), including the same information as the site characterization and biological characterization (see section 3.6).

- It is beneficial if results are presented in sufficient detail such that they can be independently evaluated by the reviewer. Fully-captioned tables, graphs, maps and figures warrant consideration for maximum clarity and efficiency of presentation.

- Evaluation and interpretation of the results in terms of scientific basis for the conclusions drawn. This would generally include a discussion of uncertainties and the probability of effects at higher or lower exposures, when this can be predicted using gradient effects or dose-response information.

For clarity and ease in reading, the report should be complete yet concise. Tables, graphs, and maps, may assume a major role in results reporting, and are of great utility provided they are fully described or self-explanatory. The text would serve to guide the reader through the tables and figures.

CHAPTER 7

ROLE OF RISK ASSESSMENT INPUT IN RISK MANAGEMENT

The role of risk assessment is to determine the existence and magnitude of risk to the individuals and/or population(s) of concern. If adverse effects are predicted in a Phase I predictive assessment and supported by a Phase II validation study or demonstrated in Phase III impact assessment, a risk manager may determine that it would be beneficial to determine levels of contaminants that are not expected to adversely impact the environment, and whether the remediation process will be more detrimental to wildlife habitats than the chemicals themselves. One method which may be considered is to establish remediation goals by calculating the environmental concentrations that will result in a HI of one, based on the Phase I predictive assessment and Phase II validation study. The results of Phase III impact assessments may not indicate acceptable environmental levels of contaminants (unless there are concentration and effect gradients), but may provide additional information that could be used to modify the remediation goals. When exposure pathways involve multiple media, we suggest they be assumed to be in equilibrium for the purpose of developing remediation goals.

The development of remedial strategies are optimized by coordination with the human-health-based remediation feasibility study, with interactions between the two carefully considered. This is of benefit to the overall risk management decision making process because the human-health-based remediation goals may also protect the biota, or, conversely, the remedial actions may adversely affect the biota. It is generally accepted that it is sound practice to weigh the benefits of remedial actions, whether based on predicted human or ecological impacts, against environmental costs. All other things being equal, from a strict scientific perspective, the remedy which minimizes the short- and long-term human health effects and ecological impacts may be considered the most beneficial remedy by the risk manager.

CHAPTER 8

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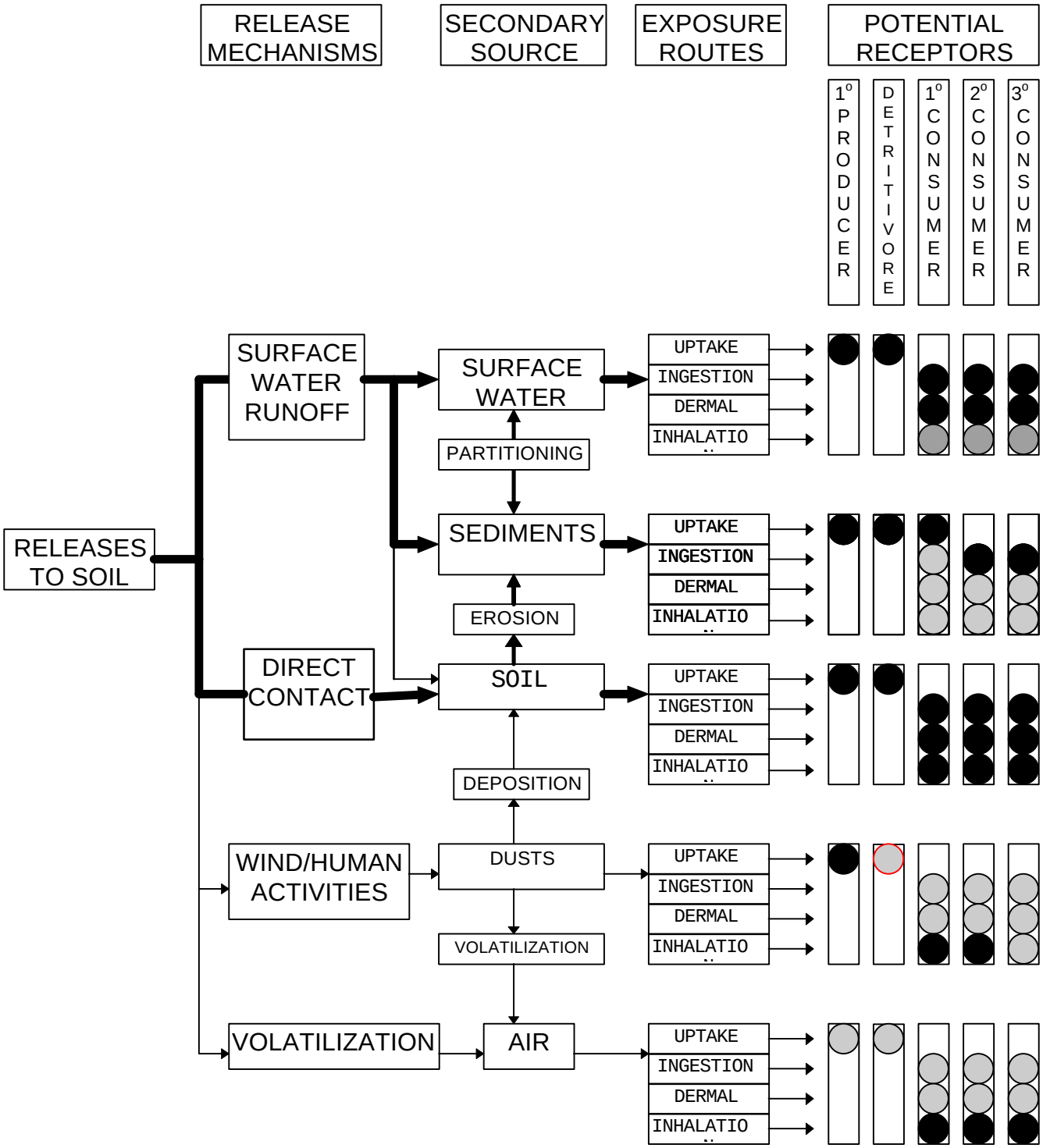

FIGURE 1. EXPOSURE PATHWAY ANALYSIS
● = POTENTIALLY COMPLETE EXPOSURE PATHWAY
○ = POSSIBLY COMPLETE EXPOSURE PATHWAY (INSUFFICIENT DATA)
CLEAR = INCOMPETE EXPOSURE PATHWAYS

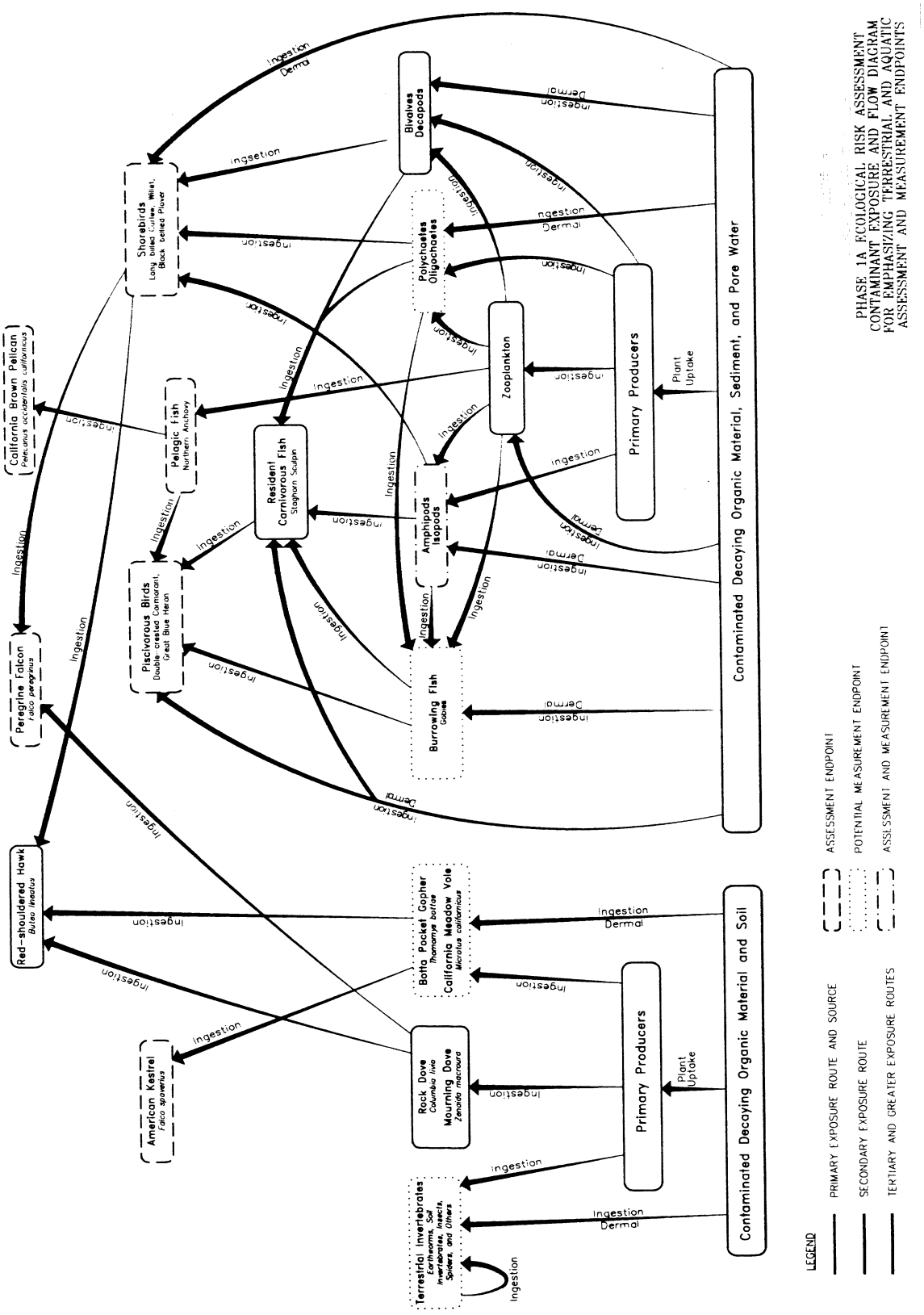

Figure 2. Conceptual site model diagram.

Example Table 1. Ecological, Toxicological and Societal Criteria for Selection of Representative Species.

		Ecological Factors						Toxicological Factors			Societal Factors		
	Observed at Site	High Trophic Level Predator	Important Prey Species	Important to Structure or Function of Ecosystem (i.e. key species)	High Potential for Exposure based on Feeding or Life History	High Potential for Exposure Based on Amount and Type of Site Use	Susceptible to Bioaccumulation or Biomagnification of COCs	Toxicological Literature Available	Likely to Exhibit Toxic Effects	Directly Measure Toxic Endpoint	Species of Special Conservation Concern	Economically Important	High Social or Recreational Value
Assessment Endpoints (numbered)													
1.) Protection of Threatened and Endangered Species													
Northern harrier (Circus cyaneus) reproductive success	x	x			x		x	x	x	x	x		x
2.) Protection of benthic invertebrate community													
Amphipod (Hyallela azteca) population survival	x		x		x	x		x	x	x			
Mayfly (Hexagenia sp.) population survival	x		x		x	x		x	x	x			
3.) Protection of carnivourous fish populations													
Rainbow trout (Onchorynchus mykiss) reproductive success	x	x		x	x	x	x	x	x	x		x	x
4.) Protection of terrestrial mammal populations													
Deer mouse (Peromyscus maniculatus) population success	x		x			x		x	x	x			
Red fox (Vulpes vulpes) reproductive success	x	x			x		x	x	x	x			
5.) Protection of plant community	x			x		x							

Figure 1: Scoping Assessment

Chemicals of ecological concern?

The initial decision criterion evaluates whether chemicals known or suspected to occur at the site or facility present a threat to ecological receptors. This determination is separate from the evaluation of the potential threat to human health as environmental contaminants may present a threat to ecological receptors at concentrations lower than that which would be of concern for human health (Part A, Section 3.2). This is also the point at which a potentially responsible party (PRP) may choose to demonstrate that inorganic contaminants are present at 'background' concentrations and that the site or facility therefore poses no greater risk than the surrounding unimpacted area (Part A, Section 3.2). If chemicals of ecological concern are present or concentrations of inorganic elements are present above 'background' concentrations the scoping assessment proceeds to identify the potentially affected habitats or communities.

Should potential inorganic contaminants be demonstrated to be present at, or less than, 'background' concentrations, a minimal scoping assessment Report is prepared clearly presenting the results of the assessment of inorganic site and 'background' concentrations, and the evaluation of potential ecological impacts associated with remediation for potential human health threats. Once the conclusions of this scoping assessment Report are accepted by DTSC, and other CalEPA regulatory agencies, the site or facility would exit the ecological risk evaluation process.

Identification of Communities and Habitats

A habitat and community survey method is stressed in the scoping assessment to limit the resources required to perform this level of ecological evaluation (Part A, Section 3.3). Habitat and biological community methods of identifying potentially-exposed ecological receptors should be employed at this stage to develop a preliminary list of potential receptors. The preliminary list of potential representative species should be confirmed by site-specific observations by a trained biologist or field investigator (Part A, Section 3.3).

Actual or potential ecological receptors?

Based on the results of the community and habitat investigation, this decision criterion evaluates whether there are ecological receptors which may potentially be exposed to releases from the permitted facility or hazardous waste site. For example, a site or facility which is in a completely industrialized area, with surrounding paved surfaces and no potential habitat which might be utilized by ecological receptors in surrounding habitats (Part A, Section 3.3), would prepare a minimal scoping assessment Report presenting these results and the evaluation of potential ecological impacts associated with remediation for potential human health threats. Upon review

and acceptance by DTSC, and other CalEPA regulatory agencies, the site or facility would exit the ecological risk assessment process at this point.

Potential exposure to wildlife or habitats?

This criterion is an initial assessment of the potentially complete exposure pathways once it has been determined that contaminants of ecological concern are present and there are actual or potential ecological receptors. The beginnings of a conceptual site model (Part A, Section 3.4) are required to make this determination. It is possible that contamination may exist at the site or facility without complete ecological exposure pathways. For example, groundwater may be the only site-contaminated media with no discharge to surface waters or terrestrial habitats and therefore no complete ecological exposure pathways regardless of the level of groundwater contamination. Facilities or sites with no complete ecological exposure pathways would prepare a minimal scoping assessment Report presenting these results, and the evaluation of potential ecological impacts associated with remediation for potential human health threats. Upon review and acceptance by DTSC, and other CalEPA regulatory agencies, the site or facility would exit the ecological risk assessment process at this point.

Scoping Report

When the evaluation of chemicals of ecological concern, the identification of actual or potential ecological receptors and the evaluation of potential ecological exposure pathways indicate that ecological receptors may potentially be exposed to site-related contaminants from a site or facility a complete scoping assessment Report should be prepared detailing these findings. A Phase I predictive assessment work plan outline, which briefly outlines the site-specific components of the Phase I predictive assessment (Part A, Section 3.6), may be included as part of this scoping assessment report. Otherwise the Phase I predictive assessment work plan may be submitted as a separate document.

Will human-based remediation affect ecological receptors?

Those facilities or sites which proceed to this criterion should assess whether any remediation proposed as part of the human health risk assessment and feasibility study will impact ecological receptors. For example, human health-based remediation of the sediments in a contaminated coastal wetland or beach may damage the ecological functions of the biological communities associated with the wetland or beach.

Risk management input.

This is the point where the regulatory agency risk mangers are required to evaluate any potential ecological affects associated with human health-based

remediation based on the nine balancing criteria outlined in the National Contingency Plan (NCP). For example, certain remedial human health-based remedial alternatives may be unacceptable to the public based on the short or long-term loss of harm to ecological receptors or habitats. It is important to remember that all the facilities or sites which reach this decision point pose no threat to ecological receptors based on the evaluation of potential contaminants, receptors and potentially complete exposure pathways. Human health-based remediation is, therefore, the only potential ecological threat and any decision to remediate must be fully documented. The DTSC is a California delegated natural resource co-trustee, together with the California Department of Fish and Game, under the Comprehensive Environmental Resource Compensation and Liability Act (CERCLA, 1980) and the Superfund Amendment and Reauthorization Act (SARA, 1986). The California Department of Fish and Game and Federal natural resource trustees, should be consulted in all human health-based decisions which may affect ecological receptors.

Scoping Report

Facilities or sites with no complete ecological exposure pathways, no potential ecological receptors, and/or no complete ecological exposure pathways and no impact to ecological receptors due to human health-based remediation would prepare a complete scoping assessment Report presenting these results. Upon review and acceptance by DTSC, and other CalEPA regulatory agencies, the site or facility would exit the ecological risk assessment process.

Facilities or sites with no complete ecological exposure pathways, no potential ecological receptors, and/or no complete ecological exposure pathways where ecological receptors will be affected due to human health-based remediation would prepare a complete scoping assessment Report presenting these results. This scoping assessment Report must indicate the concurrence of the other State and Federal natural resource trustees, or the human health-based remedial alternative chosen to obtain concurrence of the other State and Federal natural resource trustees. Upon review and acceptance by DTSC, and other CalEPA regulatory agencies, including State and Federal natural resource trustees, the site or facility would exit the ecological risk assessment process.

Figure 2: Phase I Predictive assessment / Phase II Validation Study

Determine concentration in media of concern

At this point the concentration of contaminants of concern (COCs) should be determined at concentration levels which are equivalent or lower than ecological effect concentrations for the potential ecological receptors identified in the Scoping Assessment. This is the point where any investigation of inorganic 'background' concentrations may be used to identify the inorganic ecological COCs which will be evaluated for potential ecological impacts. All organic COCs should be carried through the analysis. Regional, ubiquitous or 'ambient' concentrations of organic COCs should be discussed in the Uncertainty Section of the Phase I predictive assessment (Part A, Section 4.5).

Established ARARs or criteria?

The available Applicable or Relevant and Appropriate Regulation (ARARs) are reviewed at this point to determine whether there are applicable or relevant numerical criteria for the ecological COCs (Part A, Section 4.6). In the rare case, where ARARs are available for all ecological COCs, determination of the total hazard index is a numerically simple exercise.

Available toxicity data?

If ARARs are not available for some or all of the ecological COCs for the representative species chosen to evaluate the site or facility, the open scientific literature should be surveyed to determine whether toxicity data is available for the representative species (Part A, Section 4.3.2 and Section 4.4.2). The results of the survey of the open scientific literature should be shared with DTSC, and the other CalEPA regulatory agencies, prior to proceeding with the Phase I predictive assessment.

Perform bioassays?

In relatively simple terrestrial investigations, which involve a small number of ecological COCs, or in investigations of the threat to aquatic receptors, it may be advisable to perform bioassays in cases where ARARs or toxicity data are not available in the open scientific literature. Certainly, this is more often the case for investigation of the potential threat to aquatic receptors, but there are cases where a single ecological COC poses a threat to terrestrial receptors which have been investigated via bioassays or toxicological experiments.

Toxicity data on related chemicals?

In the event COC-specific ARARs are not available, no toxicity data exists in the open scientific literature and bioassays are not practical, ARARs or toxicity data from the open literature for compounds related to the ecological COCs may be utilized via structure-activity relationships to develop and estimate of the ecological effect dose or concentration. This method of developing an ecological effect dose or effect concentration must be presented to and approved by DTSC, and the other regulatory agencies, prior to proceeding with the Phase I predictive assessment.

If COC-specific ARARs are not available, no toxicity data exists in the open scientific literature, bioassays are not practical, and ARARs or toxicity data from the open literature for compounds related to the ecological COCs are not available, the investigation of the site or facility should proceed directly to the detailed field or laboratory studies contained in the Phase III impact assessment.

Apply uncertainty factors as needed.

Uncertainty factors must be applied for inter-taxa extrapolation whether toxicity data from the open scientific literature, the results of bioassays or ARARs or toxicity data for compounds related to the ecological COCs are utilized as the basis for the toxicity criterion. Default uncertainty factors are specified for terrestrial receptors (Part A, 4.4.2) where no species-specific or contaminant specific sensitivity ratios are available. Uncertainty factors for aquatic receptors will almost always involve uncertainty factors proposed to convert short-term exposure concentrations (e.g. 2-day) to long-term exposures (e.g. 1 year) or lethal effects (e.g. LC50) to non-lethal effects (e.g. NOAEL).

Develop no-effect dose or concentration.

The result of this toxicity information screening process is to develop an estimate of the no-effect concentration for representative aquatic receptors (NOAEC) or an estimate of the no-effect dose (NOAEL) for terrestrial receptors which will be protective of the species chosen to represent the biological community at the site or facility.

Determine the hazard quotient.

The species-specific, COC-specific hazard quotient is derived by dividing the concentration in the media of concern (usually water or sediment) by the no-effect concentration (NOAEC) for the aquatic receptor. The species-specific, COC-specific hazard quotient for terrestrial receptors is derived by calculating the intake of the terrestrial receptor (in $mg_{chemical}/kg_{body\ weight}$-day) and dividing the intake by the no-effect dose for the terrestrial receptor (NOAEL).

Determine total hazard index.

For the initial analysis the hazard index (HI) for each aquatic receptor and each terrestrial receptor is calculated as the sum of the hazard quotients for each COC. If this initial HI exceeds one for any representative species, the hazard quotients should be grouped by target organ or mode of action if the toxicity data allow such grouping. Grouping HQs by class of chemical, such as polycyclic aromatic hydrocarbon (PAH) is also allowable for ecological risk assessments where carcinogenic endpoints are usually not evaluated.

Phase I report.

The Phase I predictive assessment report should contain information sufficient to allow independent review and verification of the arithmetic calculations (Part A, Section 5.5). The tabular formats presented in this document are available from HERD to aid in the presentation of assumptions and data leading to calculation of ecological hazard for aquatic and terrestrial receptors.

Extremely high hazard index?

If the total hazard index (the sum of the COC-specific hazard quotients) is much greater than one and/or the hazard index for classes of COCs, mode of action or target organ is much greater than one the Phase I predictive assessment indicates that there is cause for concern.

A Phase II validation study is then performed for those facilities or sites which do not proceed immediately to the Phase III impact assessment to address the components of the predictive assessment which contain the greatest uncertainty (Part A, Section 5.1). For example, the validation study might determine the actual transfer from contaminated soil to plants, the transfer from first level consumers (herbivores) to second level consumers (carnivores) or benthic invertebrate uptake from contaminated sediments. The outcome of the Phase II validation study is used to validate the conclusions developed in the predictive assessment. The components to be investigated in the Phase II validation study should be developed in coordination with DTSC and other regulatory agencies.

Phase II report.

A summary of the results of the Phase I predictive assessment, the ecological components selected for further investigation in the Phase II validation study and the results of the Phase II validation study are contained in the Phase II validation study Report (Part A, Section 5.5).

Possible chemical or biological monitoring.

Chemical or biological monitoring may be recommended for facilities or sites with hazard indices less than one in cases where there remains a great degree of uncertainty in the conclusions of the Phase I predictive assessment and the Phase II validation study. For example, an ecological risk assessment of a permitted facility, such as an incinerator, which relied on plume dispersion modeling based on off-site meteorological data might contain sufficient uncertainty to require monitoring as part of the permit conditions.

Phase III work plan.

If the Phase II validation study Report indicates that there is significant potential for facility-related or site-related adverse ecological effects, a Phase III Impact Assessment work plan should be prepared in coordination with DTSC and other regulatory agencies (Part A, Section 6.1). The Phase III Impact Assessment work plan should build on the conceptual site model, assessment and measurement endpoints and representative species selected in the Phase I predictive assessment in defining the more detailed ecological field studies or laboratory studies planned.

Figure 3: Phase III Impact Assessment

Potential Impact from Scoping Assessment or Phase I.

Facilities or sites would begin the Phase III Impact assessment when: 1) the PRP decides, with the approval of regulatory agencies, to move to the Phase III Impact Assessment based on the results of the scoping assessment rather than perform the Phase I predictive assessment and Phase II validation study or 2) the results of the Phase II predictive assessment and Phase II validation study indicate the potential for adverse ecological effects. The type of studies performed in the Phase III impact assessment are field-intensive ecological studies or laboratory studies which may require several months or years for work plan preparation, sample collection, sample analysis, data evaluation and report preparation and should be developed in coordination with the DTSC and other State and Federal regulatory agencies.

Potential impact accepted as probable?

This is a significant branch point in the Phase III impact assessment. If the Phase I predictive assessment and Phase II validation study conclusions regarding potential adverse effects are accepted by regulatory agencies and the PRP, the Phase III Impact Assessment can proceed immediately to determine the media concentrations consistent with no adverse effects and the area defined by these concentrations.

If sufficient uncertainty remains regarding the Phase I predictive assessment and Phase II validation Study conclusions regarding potential adverse effects, the Phase III impact assessment proceeds with ecological field studies or laboratory studies to further evaluate the conclusion of potential adverse ecological effects.

Ecological or laboratory studies.

Ecological field studies or laboratory studies are conducted to determine if the potential adverse ecological effect is apparent in actual toxicity testing or field monitoring of the representative species. Depending on the assessment endpoints and measurement endpoints developed in the Phase I predictive assessment, these studies might include plant growth bioassays using a range of site or facility soils, soil microinvertebrate community studies for terrestrial ecosystems, field studies of avian reproductive success at the site or facility, or age-class investigations of small mammal populations at the site or facility. The nature of these studies should be developed in the Phase III Impact Assessment work plan in coordination with DTSC and other regulatory agencies.

Measurable ecological effect in studies.

If the ecological field studies or laboratory studies demonstrate an effect which can be associated with site or facility contaminants, a Phase III Impact Assessment Report is prepared documenting the results and conclusions of the Impact Assessment. This concludes the ecological risk assessment which would normally be included in the Remedial Investigation (RI) for hazardous waste sites. The remaining activities in this sequence of events most often would be included in the Feasibility Study (FS) for a hazardous waste site, but are outlined for completeness.

If the ecological field studies or laboratory studies do not demonstrate an effect which can be associated with site or facility contaminants, a Phase III Impact Assessment Report is prepared documenting the testing performed and the conclusions of the Impact Assessment. Remediation or monitoring would be necessary only in the event the results of the Phase III Impact Assessment are ambiguous or a high degree of uncertainty remains regarding any potential impact.

Determine concentrations consistent with no impact.

The following evaluation criteria are usually components of the feasibility study (FS), but are included here for completeness. If measurable effects associated with site or facility contaminants are detected in the Phase III Impact Assessment the results of all the components of the ecological risk assessment should be used to determine the media concentrations which will not produce adverse ecological effects. These media concentrations are preliminary ecological remediation goals.

Will human-based remediation solve ecological concerns?

The preliminary ecological remediation goals are compared with the preliminary remediation goals proposed for any remedial action based on the human health risk assessment. If the human-based remediation goals will result in media concentrations at or below the preliminary ecological remediation goals and human-based remediation will not result in significant adverse ecological impact, no ecologically-based remedial action is required. In cases where a risk management decision is made to proceed with a human-based remedial action at the cost of some adverse ecological impact this decision should be clearly stated in the risk management decision document. Consultation with Federal and State natural resource trustees is required prior to implementing a human-based remedial action which results in adverse ecological effects.

Ecologically-based remediation feasible & minimal impacts?

If the human-based remediation goals will not result in media concentrations at or below the preliminary ecological remediation goals, ecologically-based remedial actions capable of remediating media concentrations to the preliminary ecological remediation goals should be evaluated based on the nine 'balancing criteria' presented in the National Contingency Plan (NCP). In addition to the nine 'balancing criteria', the potential adverse ecological effects associated with the remedial alternatives must be compared to the current ecological functioning of the biological community impacted by the site or facility. For example, the no-action alternative may be the most appropriate risk management decision rather than excavating contaminated sediments from a functioning coastal wetland. Consultation with Federal and State natural resource trustees is required when evaluating the significance of potential adverse effects associated with site or facility remedial actions.

Perform ecologically-based remediation.

Ecologically-based remediation is performed if an ecologically-based remediation is deemed appropriate after consideration of the remedial alternatives compared with the potential adverse ecological effects produced by the remedial activities. Seasonal changes in the biological components of the community should be considered to limit the adverse ecological effects. For example, it may be possible to remediate soils during the winter when endangered butterflies are not utilizing plants which bloom in springtime.

Explore off-site mitigation.

In the event ecologically-based remediation is not considered feasible due to adverse ecological impacts produced by the remedial activities, off-site mitigation should be considered. Consultation with Federal and State natural resource trustees is required at this stage to determine whether off-site mitigation is appropriate.

Potential monitoring work plan.

An ecological monitoring program may be necessary to determine that 1) the human-based remedial activities do not produce adverse ecological effects; 2) the ecologically-based remedial activities successfully reduce adverse ecological effects associated with site or facility contaminants; and 3) the ambiguity or high degree of uncertainty associated with the results of the Phase III Impact Assessment studies has failed to demonstrate actual adverse ecological effects. The decision paths leading to this option are presented as dashed lines on the flow chart to indicate that a monitoring plan is not required, but is an option which may be considered.

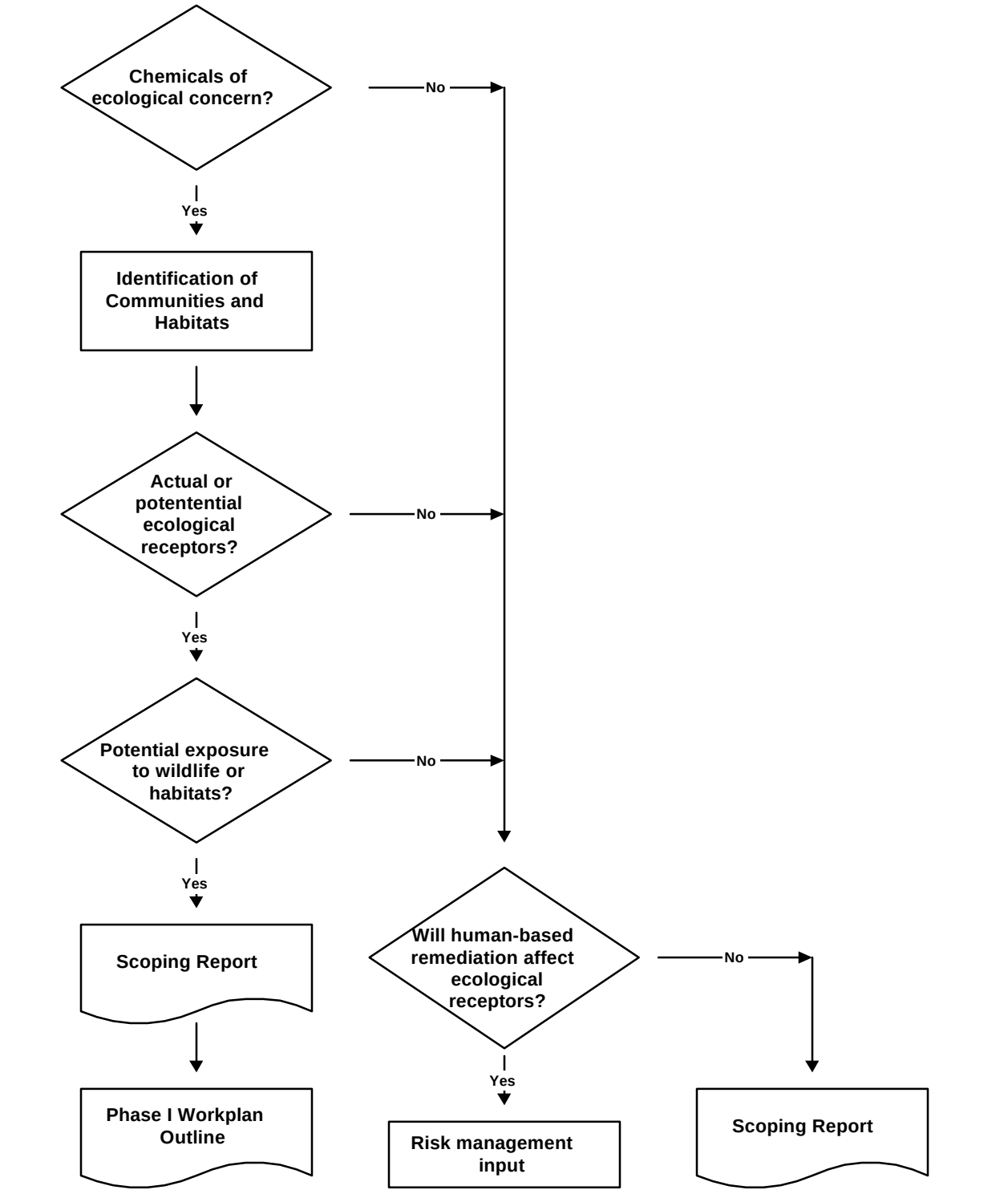

Figure A-1. Scoping Assessment Flow Chart.

Figure A-2 Phase I Predictive Assessment and Phase II Validation Study Flow Chart.

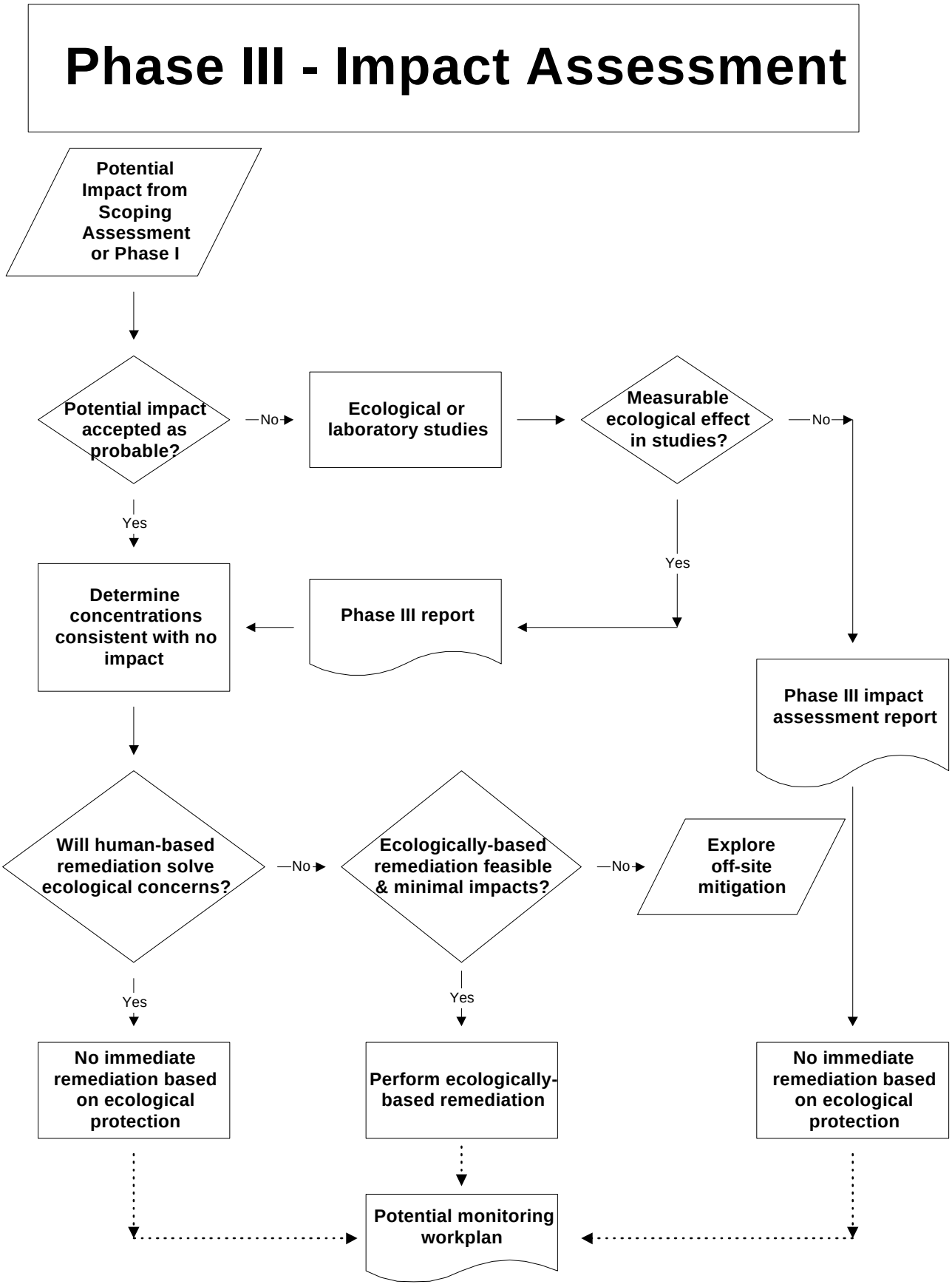

Figure A-3. Impact Assessment Flow Chart.

Appendix B: Response to Comments on Part A and Part B

Shell Development Company, Houston Texas

1. Generally, these documents have failed to consider phylogenetic organization by not including bacteria and plants in the assessments and have focused on mammalian and human health type assessments for use in the ecological assessment.

Response: While the human health analog is employed in the Phase I predictive assessment for terrestrial vertebrate receptors a reference concentration approach is employed for aquatic receptors. Any focus on terrestrial vertebrate receptors in the Phase I predictive assessment is driven mostly by the lack of toxicity data for other terrestrial receptors. The guidance specifically outlines decomposers, plants, herbivores and secondary consumers as groups which should be considered in developing the site conceptual model. An option to conduct terrestrial toxicity testing (e.g. plant toxicity test or soil invertabrate tests), or aquatic toxicity tests, during Phase I has been added.

2. The guidance completely ignored existing guidance from EPA covered in the 'framework' document and associated peer review discussion.

Response: We do not believe we have ignored existing EPA guidance or peer review discussion in developing this guidance. This guidance package specifically calls for consideration of many of the elements such as site conceptual models, assessment and measurement endpoints and selection of representative species which are outlined in EPA guidance and peer review documents. The guidance was developed in concert with EPA Region IX ecological risk assessors to provide the components required by EPA guidance.

3. EPA is developing ecological risk assessment guidance for specific situations and will publish guidance for single chemical/single species in the first quarter of 1995. California should contact EPA to avoid conflicting guidance or possible scientific inaccuracy.

Response: EPA Region IX ecological risk assessors, other federal ecological risk assessors, California regulatory agencies and private parties were consulted during development of this guidance package. The guidance as outlined incorporates changes and additions which evolved in discussion with these groups during the three year development period.

4. The document is mostly focused on single chemical and single species assessments that can be extrapolated to mixtures. The authors have not carefully researched available information concerning ecological risk assessment of chemicals nor have they become familiarized with information on mesocosm testing.

Response: This guidance attempts to incorporate methods employed by ecological risk assessors who favor the 'hazard index' approach as well as those ecological risk assessors who favor field investigations. The guidance calls for each approach to be applied where applicable in assessing ecological risk. It is a rare site which has a single contaminant of concern and the Phase I predictive assessment is meant to be applied to mixtures of chemicals. The included examples have been expanded to make the application to multiple contaminants explicit. The authors recognize the utility of mesocosm studies and would employ the results of mesocosm studies in the Phase I predictive assessment or accept mesocosm studies in the Phase II validation study or Phase III impact assessment.

5. Present guidance by Suter,et al. should be considered before California develops another independent interpretation on the subject.

Response: Guidance by Suter, et al. and other authors was reviewed during preparation of this guidance. We do not view this guidance as an independent interpretation on ecological risk assessment, but rather a logical plan to utilize the existing strategies and techniques to investigate potential ecological threat with a minimum of resource before escalating ecological risk assessments to expensive and intensive field or laboratory investigations.

6. The California guidance misstates the availability of data on single chemicals and mesocosm level experiments for formulating ecological risk assessments.

Response: There are many commonalties in chemicals of concern, exposure pathways and exposed organisms at sites being investigated by the Department of Toxic Substances Control. While the chemicals present represent a small fraction of the total number of chemical compounds the fact that many are relatively common in industrial processes has caused a fair toxicological data base to be developed which can be used to evaluate potential impact on ecological receptors. The guidance allows immediate progression to field or laboratory studies where data is lacking or a responsible party wishes to proceed immediately to this component.

7. SETAC is available to assist in technical guidance in developing the assessment tools.

Response: We are aware of the availability and knowledge of SETAC members and exchange opinions and review with California SETAC members.

8. The impact assessment study design (page 25) requires that negative findings may not be valid unless contamination extent and concentrations are at or near maximum. This is confusing because waste sites will by their nature contain areas of high and low waste concentrations and there may be graded effect/exposure areas.

Response: This statement is meant to define the concentration term used in the Phase I Predictive assessment as the maximum concentration or an upper confidence limit on the mean. We agree that contaminant concentration in an environmental media at any waste site will vary and may exhibit graded effects. Definition of the lateral and vertical extent of

concentration and the associated graded effects would occur in the Phase III Impact Assessment.

9. The study design (page 26) requires an effect be detected at the maximum magnitude of ecological concern. Threshold concentrations may not always be detected in the field because of gradients of differing concentrations that may all be above threshold. Unless the specific toxicants are known and tested in the laboratory (such as soil dilution tests), the threshold level may not always be known. Statistical design and available funds for conducting field assessments may not allow developing a program to detect lowest effect levels.

Response: This section states that “We recommend the study be designed to detect an effect of the minimum magnitude that would be of ecological concern.” The intent was to indicate that the selection of measurement endpoints should concentrate on more sensitive ecological endpoints such as reproduction rather than mortality. We agree that soil dilution tests can provide valuable information and soil dilution tests have been performed at sites with DTSC oversight. Also, this statement refers to a situation where off-site migration is occurring, and there is a time delay to when the maximum concentration will reach a sensitive habitat. For example, a groundwater contaminant plume may be moving off-site toward a surface water body, but the most heavily contaminated part of the groundwater has not yet reached the surface.

10. California should specify what ‘no important effect’ would be as it is not possible to conduct studies that would guarantee all possible effects are studied. Some guidance such as measurement of the effects on survival, growth, reproduction, bioaccumulation, etc are more definitive.

Response: We agree that it is not possible to test for all possible effects. Selection of assessment and measurement endpoints, based on the conceptual site model, is recommended to focus the investigation on ‘important’ ecological effects. Selection of the measurement endpoints is usually made in consultation with State and Federal so that there is agreement that ‘important’ ecological effects are investigated.

11. Bioaccumulation needs to be addressed not only in terms of Kow, but in terms of environmental fate (persistence, solubility and mobility, degradation).

Response: We agree. A more detailed description has been made regarding investigation of bioaccumulation.

12. We suggest the scoping assessment be completed as a series of very few worksheets or checklists, so that this does not become an unmanageable exercise. This may include sections on a qualitative description of observed impacts on flora and fauna on or near the site; a habitat characterization section; a listing of sensitive receptors (threatened or endangered species, economically/sport important species; and a recommendation for further action, if needed.

Response: We envision that a scoping assessment report could be submitted as relatively simple compilation of tables with supporting text. Standardized worksheets or checklists would be difficult to develop for the variety of habitats, chemicals, and exposure pathways which may be present at a site.

US Fish and Wildlife Service, November 30, 1995, FWS/EC94-0099

12. Part A, Page 8: The definition of wildlife should include plants as well as animals.

Response: The definition has been changed to include plants.

13. Part A, Page 9: Biological characterization. 'Special' species may not be the most sensitive indicators of ecological risk. Species with known sensitivity to the contaminants of concern should also receive additional emphasis during biological characterization.

Response: We agree. The 'special species' bullet item has been amended to indicate that both the more common species expected to be sensitive to the contaminants of concern and the rare, threatened or endangered species should be considered during biological characterization.

14. Part A, Page 10: Section 3.4. Exposure of organisms to contaminants of concern via inhalation, ingestion and dermal contact are discussed. Exposure via the gill surfaces of aquatic organisms should also be specifically addressed, either as a separate pathway or included in one of the above.

Response: While we agree that aquatic organisms are exposed via gill surfaces this route of exposure is rarely quantified. We believe that the RfC approach proposed for aquatic receptors in the Phase I Predictive assessment addresses the total dose received via respiratory structures and dermal absorption. The listing of inhalation, ingestion and dermal contact is meant to indicate that these three pathways should be investigated to determine whether they are potentially complete and should not be dismissed in the scoping assessment without sufficient justification.

15. Part A, Page 10: Section 3.5. The last sentence is awkwardly worded. Suggest the following: 'However, if potentially toxic chemicals have contaminated, or may be reasonably expected to contaminate, media which may directly or indirectly contact wildlife or their habitats, either on or off site, then the potential for exposure is considered to exist and a Phase I Predictive assessment is recommended.'

Response: The sentence has been amended.

16. Part A, Page 14: Section 4.2.2. The first full paragraph discusses the application of uncertainty factors. The third bullet in that paragraph describes as a deficiency the use of a reference concentration 'based on data from a range of species, to which it is to be applied.' Deletion of the phrase 'or closely related species' from the sentence is

recommended, since even closely related species can have very different sensitivities to a given toxicant.

Response: While we agree that closely-related species can have very different sensitivities to a given toxicant we believe that in general the response of closely-related species can be used to evaluate potential toxicity if sufficiently protective uncertainty factors are included. The phrase ‘or closely related species’ has been retained.

17. Part A, Page 15: Section 4.3.1. This section equates functional groups to ecological guilds. It should be made clear that the organisms included within an ecological guild can cross taxonomic lines. For example, the guild that includes ground dwelling, insect eating birds would also include ground dwelling, insect eating reptiles.

Response: We agree that ecological guilds can cross taxonomic lines and do not propose that the toxicity data for insect-eating birds could be used for insect-eating reptiles without sufficiently protective uncertainty factors. The examples of carnivorous birds or omnivorous mammals as functional groups are meant to indicate a more restricted range of extrapolation than birds to reptiles.

18. Part A, Page 16: Section 4.3.1. The fourth full sentence of the first paragraph states that ‘In choosing representative species, consideration <u>may</u> (underline added) be give to taxonomic groups which may be particularly sensitive to the contaminants of concern.’ Use of the word ‘should’ instead of may is recommended.

Response: The word may has been changed to should.

19. Part A, Page 16: Section 4.3.2. The fourth sentence in the first paragraph of this section changes between singular and plural when discussing the word ‘data’. Data should be considered plural throughout.

Response: The verbs have been changed so that data is considered plural throughout.

20. Part A, Page 17: Section 4.3.2. Modification of the third bullet discussing the application of uncertainty factors greater than one to read ‘ o interspecies extrapolation;’ is recommended. As previously discussed, closely related species can demonstrate different sensitivities, and an uncertainty factor of at least one should be applied unless the need to do so is demonstrated to be unnecessary.

Response: We agree that, in general, an uncertainty factor greater than one should be applied for extrapolation outside taxonomic families. Demonstrated extreme differences in sensitivity should obviously be addressed by larger uncertainty factors or the ratio of the effective dose or concentration. A more detailed example of uncertainty factors which should address this comment is included in Part C. which is currently in internal review.

21. Part A, Page 17: Section 4.3.3. Exposure via gills should be specifically addressed.

Response: A sentence has been added specifically stating the exposure pathways included in an exposure assessment based on a reference concentration (RfC) approach, which is typically used for aquatic organisms, need not be included in the pathway-by-pathway assessment.

22. Part A, Page 18: Section 4.3.3. In calculating daily intake, consideration should also be given to the rate and pathway of excretion for the contaminant of concern.

Response: The reference dose (RfD) for terrestrial receptors is usually based on the chronic dose administered to produce an effect. The excretion rate is not usually available and not required because it is the administered dose (or rarely the absorbed dose) upon which the RfD is based. Excretion rates and intake rates are used to estimate body burdens.

23. Part A, Page 28: Chapter 7. The last sentence of the first paragraph suggests that when exposure pathways involve multiple media, they be assumed to be in equilibrium for the purpose of developing remediation goals. this suggestion may not be valid depending on environmental factors and the effects of other contaminants. Recent work with cadmium, for example, indicates that the presence of other metals in water increases the residence time of cadmium in water and reduces the adsorption of cadmium onto sediment particles.

Response: The assumption of equilibrium is a general, simplifying assumption to aid development of remedial goals. Site specific information regarding the specific contaminants of concern, dominant exposure pathways and physical changes produced by various remedial alternative, if available, should be used as justification for assuming other conditions than equilibrium when developing remediation goals.

24. Part B, Page 8: Section 4.0. Comments for part A, pages 10 and 18 apply to the second paragraph of this section.

Response: See response to those comments.

25. Part B, Page 11: Subparagraph d. The first sentence seems to be missing some words. It could read ‘This table normally would include all <u>potential ecological receptors</u> (underlined part missing), including those such as piscivorous birds or waterfowl that may have significant exposure via consumption of aquatic food items.’

Response: The first sentence was amended.

26. Part B, Page 13: Figure 1. No potentially complete exposure pathways are indicated for detritivores in surface water runoff.

Response : Figure 1 has been amended. This figure is meant at an example, not as a definitive examination of exposure pathways common to all sites.

California Department of Fish and Game

27. Part A, Page 5. DTSC should consider the list of 'adverse impacts' that have been identified in CERCLA Type B natural resource damage assessment literature for inclusion in the guidance.

Response: A specific list of this nature seems out of place given the general nature of the guidance provided in Part A, but will be evaluated for inclusion in Part B: Scoping Assessment and Part C: Predictive Assessment.

28. Part A, Page 5. The Department of Fish and Game agrees with the statement that the proposed guidance is not intended as a universal approach.

Response: No response necessary.

29. Part A, Page 6. DTSC should revise the document to clearly discriminate between ERAs and NRDAs, since the measurements of existing adverse effects for confirmatory purposes in an ERA can be suitable, if properly done, for application to injury determination in a NRDA.

Response: A paragraph has been added to the introduction of Part A emphasizing that, even though components of an ERA may be useful in a NRDA, a ERA is not a substitute for a NRDA.

30. Part A, Page 7. While the hazard quotient and hazard index approach is fundamentally a useful tool, Fish and Game has some concern regarding the summation process used to develop the overall hazard index.

Response: We envision the process of hazard index development will include a phase process similar to that recommended for human health risk assessments (HHRA) where hazard quotients of each chemical are all summed in the first phase. If this initial hazard index exceeds unity, the chemical-specific hazard quotients are grouped by mode-of-action, target organ or target organ system for further evaluation. We believe this process is protective because the first assessment is based on additivity where additivity may not exist due to differing modes of action or target organ.

31. Part A, Page 7. The sources of toxicity data contained in the draft guidance underestimate concentrations and dosages of chemicals that adversely effect State fish, wildlife species, biota and its habitat.

Response: The toxicity data sources contained in the draft guidance are meant as examples of the type of data that should be used as the denominator in calculating the chemical-specific hazard quotient and should be evaluated for applicability based on site-specific characteristics. The site conceptual model for each site, which details the chemicals of concern, the complete exposure pathways and the potentially exposed functional groups, will serve as the guide for determining the appropriate toxicity data for each ERA. A more detailed list of applicable toxicity data is included in Part B.

32. Part A, Chapter 2. Definitions for the terms biological resources, contaminant or pollutant, endpoint, environment, food web, food chain, natural resources, on-site, and receptors should be included.

Response: The definitions suggested tend to be much more detailed than those given in the draft guidance. The term biological resources occurred only once in Part A and was changed to biota which is defined. A more general definition for contaminant than that suggested was added to the draft guidance. The term environment occurs only once in Part A and a less detailed definition than that suggested has been added. The definition of measurement endpoint was changed slightly. All other endpoint definitions were unchanged. A definition for food web was added to the guidance.

33. Part A, Chapter 2. Definitions for the abbreviations used for reference concentration (RfC) and reference dose should be included.

Response: Definitions have been included for reference concentration and reference dose.

34. Part A, Chapter 3. Contaminants may have moved off-site in the past and may not be present on-site when the scoping assessment is performed leading to a false conclusion that the facility or site poses no ecological threat.

Response: The Office of Scientific Affairs agrees that historical and current off-site transport are important considerations in an ecological risk assessment. Section 3.4 specifically mentions off-site transport mechanisms. Historical and current off-site transport are routinely considered in ecological risk assessments reviewed by HERD and the facility or site property boundary is not considered the 'site' boundary if off-site transport has or is occurring. No change was made to the document based on this comment.

35. Part A, Chapter 3. The biological characterization of a facility or site contained in the scoping assessment may be of use to other natural resource trustees in natural resource damage assessments. Continued coordination between DTSC and Fish and Game is required.

Response: We agree that the scoping assessment will develop information which may be useful in natural resource damage issues. The second paragraph has been amended to clarify this position and include the following language concerning coordination with State and Federal natural resource trustees during preparation of the Scoping Assessment: "The Department of Toxic Substances Control is a State natural resource co-trustee together with the Department of Fish and Game. The development of the scoping assessment was coordinated with State and Federal natural resource trustees to provide biological information useful in evaluation of natural resource injury. Close coordination with State and Federal natural resource trustees is recommended when preparing a Scoping Assessment." We look forward to continued coordination with DFG in facility and site investigations.

36. Part A, Chapter 3, Section 3.2. We recommend expanding the discussion to emphasize the importance of 'reference' or 'baseline' locations which are required for remediation and restoration of natural resources.

Response: While we agree that 'reference' or 'background' locations are critical in guiding remediation and restoration, a large investment in identifying 'reference' or 'background' locations does not seem appropriate for the Scoping Assessment. 'Reference' or 'background' locations assume much greater importance in the subsequent investigations (Phases II and III) outlined in this guidance. Some facilities or sites will exit the ecological risk assessment process with no further action. The Section has been amended to state: "Many components of the ecological risk assessment subsequent to the scoping assessment will rely on comparison to 'reference' or 'background' locations or samples and the identification and characterization of these 'reference' or 'background' locations should begin as soon as it appears the investigation will proceed beyond a Scoping Assessment."

37. Part A, Chapter 3, Section 3.2. Expand the reference to 'food web relationships' to be identify whether the context is exposure relationships, pathway analyses or response analyses.

Response: The text has been modified to include clarification that: However, chemical detection limits, exposure pathways, contaminant speciation and mode of toxic action may differ significantly from those evaluated in the human health risk assessment. An assessment of the ingestion exposure via contaminated media and contaminated prey items in the ecological risk assessment will require characterization of trophic level structure and food web transfer of contaminants beyond that required for human health risk assessment. Many components of the ecological risk assessment subsequent to the scoping assessment will rely on comparison to 'reference' or 'background' locations or samples and the identification and characterization of these 'reference' or 'background' locations should begin as soon as it appears the investigation will proceed beyond a Scoping Assessment.

38. Part A, Chapter 3, Section 3.3. Include identification of species considered essential to, or indicative of, the normal functioning of the ecosystem or community.

Response: The text has been modified to include: "identification of species considered to be essential to, or indicative of, the normal functioning of the ecosystem or community."

39. Part A, Chapter 3, Section 3.4. Include a problem statement and discussion of exposure assessment as part of the pathway assessment.

Response: We agree the individual topics suggested for the problem statement and discussion of exposure assessment are important. The level of detail is greater than planned for Part A of this guidance, which is an overview of the entire ecological risk assessment process. These topics will be included in Part B, which more specifically

discusses the scoping assessment or Part C which describes the Phase I predictive assessment and Phase II validation study.

40. Part A, Chapter 3, Section 3.5. Document the 'release or threatened release of a hazardous substance into the environment' [CERCLA Section 101 (24)], otherwise the recommendation of technical staff to DFG management would be that it is not necessary to conduct an ERA beyond the Scoping phase.

Response: The section has been amended to include the reference to the appropriate section of CERCLA: "However, if potentially toxic chemicals have contaminated, or may be reasonably expected to contaminate, media which may directly or indirectly contact wildlife or their habitats, either on-site or off-site, then we suggest this demonstrates a 'release or threatened release of a hazardous substance into the environment' [CERCLA Section 101 (24)], that ecological receptors may potentially be adversely effected and a Phase I Predictive assessment is recommended."

41. Part A, Chapter 3, Section 3.6. Guidance should be provided to Project Managers so that 'screening' criteria or 'screening' doses are not applied as clean-up or risk assessment endpoints designed to fully protect State natural resources.

Response. The text has been modified to include these directions for use of screening criteria: "Several regulatory or monitoring programs have developed media -specific effect concentrations which may prove useful. For example the National Oceanic and Atmospheric Administration (NOAA) values for sediments (Long and Morgan, 1990, MacDonald, 1992) or the Federal Ambient Water Quality Objectives are valuable for screening purposes. The DTSC Project Manager should coordinate review of Scoping Assessments with HERD and other Federal and State agencies to ensure proper use of screening criteria. Comparison of media concentrations with 'reference' or 'background' concentrations where available and applicable is often useful. None of these screening criteria should be used as 'clean-up' concentrations or criteria."

42. Part A, Section 4.1. The reference to 'criteria for the protection of biota' does not accurately state the lack of consensus in the scientific community regarding media-specific protective criteria.

Response: We did not mean to refer only to regulatory criteria which are protective of biota, but to toxicity doses or concentrations which, based on regulatory criteria or the pertinent scientific literature, are believed to be protective. The word projective was also meant to indicate that the toxicity data preferred would be no-effect doses (NOAELs) or concentrations (NOAECs) rather than partial-effect doses (LOAELs) or concentrations (LOAECs). The text has been modified to state: "with contaminant-specific toxicity data believed to be protective of biota to arrive at a hazard index for each species evaluated."

43. Part A, Section 4.1. The selection of reference chemical and toxicity information, or criteria fro the protection of State fish, wildlife, species, biota, or its habitat for specific sites or facilities, should be accomplished through consultation with DFG.

Response: We agree. We support selection of the most sensitive toxicity information and routinely consult with other regulatory agencies in selection and review of toxicity information. No change made in Part A.

44. Part A, Section 4.1. Which types of models (physical, mechanistic or statistical) for predicting contaminant bioconcentration or bioaccumulation? Several, if not most, of the models are controversial, and require confirmatory measurements in the environment for 'quality assurance' or 'ground truthing'.

Response: We purposefully did not designate specific models so that the most appropriate model could be selected in consultation with the DTSC Project Manager, HERD and other regulatory agencies. We agree with the comment regarding the uncertainty in the modeled predictions. This section already states; "Modeling is sometimes used to predict concentrations of contaminants in various environmental compartments including biota. While this may be useful, these models usually involve large uncertainties, which we suggest be fully accounted for in the hazard index range. In the absence of adequate data on transfer of chemicals among environmental compartments, laboratory or field studies may be of significant value to answer these questions. " No other change was made.

45. Part A, Section 4.1. Measurement endpoints, exposure pathways and representative species for each site should be reviewed by DFG as well, for purposes of scientific review and consultation, as well as, for expediting the resolution of issues related to natural resource injury determination.

Response: We support that continued cooperation. The section states that these components : "be submitted for review by DTSC, and other regulatory agencies, prior to the commencement of the Phase I predictive assessment.". No change was made.

46. Part A, Section 4.2.1. I am concerned that the two categories of 'ecological niche' and 'endpoints' are being considered in the narrow sense of identification of surrogate species and short-term chronic endpoints fro mare easily accomplished toxicity tests. Presumably the detailed guidance document will follow that will provide specific examples and methods for species selection.

Response: There was no intent to focus the selection of representative species or endpoints on less-sensitive surrogate species or short-term endpoints. The three general criteria are meant to initiate the selection of representative aquatic species which should be guided by the conceptual site model. The section states that other criteria may be necessary, or that fewer criteria may be required, depending on site specific conditions : "We suggest the following criteria be considered in evaluating the potential representative species (depending on site-specific information, fewer or additional criteria may warrant consideration)". No change was made.

47. Part A, Section 4.2.2. I am concerned that the data bases used to develop reference concentrations have been generally developed with acute exposure effect and observed adverse toxicity endpoints (LOAELs). These threshold concentrations

should not be used as target clean-up levels directly because they represent the levels of toxic chemicals that are likely to be associated with adverse biological effects, hence resulting in continued injuries to those resources.

Response**:** We agree that some aquatic evaluation criteria have been developed from aquatic toxicity data bases which include acute exposure effect concentrations. This document recommends developing chemical-specific uncertainty factors to apply to aquatic evaluation criteria when the evaluation criteria do not appear to be fully protective. We anticipate continued DFG participation in these site-specific decisions.

48. Part A, Section 4.3.2. The rationale and derivation of Uncertainty Factors (UFs) is not self-evident, although the report indicates that these factors will probably be developed on a site-by-site basis, after an evaluation of the toxicity literature data base, species presence, and site -specific information. I recommend scientific review and consultation with DFG staff for determining acceptable UFs for every site.

Response: Derivation of UFs for aquatic species is a site-specific process as currently planned. Should site-specific experience indicate that certain UFs are appropriate for particular groups of contaminants, extrapolation between taxonomic groups or conversion of different toxic endpoints, those UFs would be presented in later guidance on aquatic receptors. HERD supports continued DFG cooperation in planning and reviewing ecological risk assessments.

49. Part A, Section 4.3.3. There might be exposure pathways included in Phase I predictive assessment which have more complicated source terms than described (for example, sediment re-suspension, bioturbation, pore-water versus overlying-water exposure), which may result in multiple phase exposures (part dermal/part ingestion). Basing the exposure assessment on incremental exposures can result in unpredictable effects from multiple or jointly-acting agents. On page eighteen, the report describes a particular mathematical model to “quantitate the uptake by various pathways.” Assuming that this is one of the proposed models to be utilized in an ERA where appropriate, site investigators should utilize this model after an evaluation of the sensitivities of the model results to errors (estimates) or variations in the input data.

Response: The approach recommended in this guidance for aquatic receptors is a reference concentration (RfC) approach which compares the concentration in a medium to a no-effect concentration (NOAEC). The mathematical model referenced is in the terrestrial ecological risk section (Section 4.4) and outlines a generalized formula for an intake approach more applicable to terrestrial receptors. We know of no commonly-applied aquatic risk characterization methodology other than incremental summing of exposure via different media. HERD would support evaluation of a methodology which could assess exposure of aquatic receptors to multiple media.

50. Part A, Section 4.4. Ecological hazard quotients and hazard indices are of concern because there is a bias in the risk ranking results. For example, it scores effects based upon the most hazardous component of the waste, but waste quantity is scored on the basis of all components. Therefore, sites with a large amount of fairly

innocuous material and a small amount of highly potent material can receive a high health and ecological risk assessments.

Response: We agree with the comment. DTSC exists to deal with amounts of toxic or highly toxic materials which may have an effect on human health or the environment. Perhaps we misunderstand the intent of the comment, but the purpose of this guidance is to direct the investigation and remediation efforts to those sites which pose the greatest threat to ecological receptors. This guidance does not provide a methodology for prioritizing facilities or sites for clean-up, but rather to evaluate the potential ecological threat posed by a facility or site. Coordination with State and Federal regulatory agencies is incorporated into the process. No change was made in the document based on this comment.

51. Part A, Section 4.4. The second concern is of integrating human health and ecological risk assessments. Risk managers have little difficulty in risk management when human health risk concerns “drive’ the cleanup. We believe the corollary is equally important, however there is no widely-acceptable scaling factor which can address this issue. I recommend that any scoring system adopted by DTSC at the sites be carefully evaluated for sensitivities to assumption and ability to correctly rank sites based upon risk to ecological components and effects.

Response: HERD is sensitive to the concern that human health concerns will “drive’ the clean-up concentrations and the remediation of facilities or sites. This guidance has been structured to allow consideration of the clean-up goals based on human health considerations, while also considering the potential ecological impacts of the human health based remediation. This guidance directs consideration of the ecological impacts associated with human-based remediation, consultation with other natural resource trustees and investigation of potential off-site mitigation in cases where the ecological impact of remediation cannot be avoided. Please see Appendix A for a description of the decision path and criteria for evaluating remedial actions at facilities or sites. No change was made in the document based on this comment.

52. Part A, Section 4.5. A quantitative uncertainty analysis is recommended where “some uncertainty factors (e.g. interspecies extrapolation) could range from 0.1 to 10, while others (e.g. LOAEL to NOAEL or acute to chronic) would logically only range from 1 to 10. An explanation of that logic (i.e. the relative values of the UFs) might allow a more complete understanding of how those conclusions or values were derived.

Response: The reasoning for this methodology was that the assumption that a representative species was ten times more sensitive than a tested species was equally likely, in the absence of toxicity testing data, to be 10 times less sensitive than the tested species. Therefore, HERD recommended that a dual calculation be performed which used a lower bound estimate of toxicity as well as an upper bound estimate of toxicity. As the comment points out, it would not be logical for uncertainty factors accounting for LOAEL to NOAEL or acute to chronic extrapolations, to be less than 1.

53. Part A, Section 4.6. Total Threshold Limit Concentrations (TTLCs) and Soluble Threshold Limit Concentrations (STLCs) are principally related to protection of human health and have had little or no consideration in development to the protection of ecological receptors. The discussion of ARARs should indicate the need to consult with DFG, and other agencies, to provide laws and regulations regarding the protection of fish, wildlife species, biota, and it's habitat. I recommend that the document include a reference to the Department of Fish and Game and its delegated State trust resources, as well as encouraging the site manager to coordinate with DFG on their ARAR interests.

Response: Total Threshold Limit Concentrations (TTLCs) and Soluble Threshold Limit Concentrations (STLCs) are regulatory criteria which govern the storage, transport and disposal of hazardous wastes. However, contrary to the comment, several of the STLCs are based on effects to ecological receptors as opposed to humans. HERD supports coordination with natural resource trustees on ARAR identification and the section has been amended to include: "DFG, as the State natural resource co-trustee with DTSC, in addition to other State and Federal natural resource trustees, should be consulted for ARARs for each DTSC-lead facility or site.".

54. Part A, Section 4.8. The document indicates that there is a "default suite of species suggested by DTSC." I suggest that DTSC and DFG consult and develop those representative species for assessment, including the "default suite of species....for the ecoregion under study."

Response: HERD has abandoned the initial proposal of a default group of representative species based on the ecoregion of the facility or site in favor of site-specific receptors selected in coordination with State and Federal agencies. The conceptual site model forms the basis for selection of the representative species. The section has been amended to state : "The representative species for each facility or site will be based on development of the conceptual site model for each facility or site and in consultation with HERD through the DTSC Project Manager, other State and Federal natural resource trustees and other State and Federal regulatory agencies."

55. Part A, Chapter 6. This chapter is of great concern because of its potential to overlap with natural resource injury determination and State natural resource trustee responsibilities under Federal and State laws. If the purpose of this Phase III assessment activity is solely to monitor, or "ground truth" predictions and observations from the previous three phases, then we have limited concerns. There are, however, several indications that the intent of the Phase III goes beyond this monitoring function or purpose. Although ERAs and NRDAs (as defined under CERCLA and accompanying Department of Interior regulations) may share some commonly used scientific and legal terms, the overall intent, purposes, and conduct of the two activities are distinct in the end result, as well as the conduct. ERAs are performed to evaluate the ecological effects cause by human activities, such as release(s) of hazardous chemicals. The uses of those data are to provide the risk manager with information that is relevant to selection of a remedial alternative that will protect the environment. In contrast, NRDAs are solely the responsibility of State and Federal natural resource

trustee agencies, to address injuries to natural resources that result from insufficient remedial actions to protect and restore natural resources from hazardous waste releases. The references to terms such as impact, adverse effects on biota, impact assessment, impact mitigation, severity and extent of impacts, impact assessment testing, environmental impact assessment, and environmental costs should be review and modified where appropriate to emphasize the use as an ERA activity, clearly separate from NRDA activities. I recommend that these terms be revised to relate directly to receptor responses, endpoints and pathways of an ERA.

Response: HERD and many State and Federal regulatory agencies discussed the terms to be applied to each the critical components of the DTSC ecological risk assessment guidance prior to distribution of the draft documents. The purpose of the Phase III Impact Assessment is to clearly define the area which would be subject to remediation based on ecological preliminary remediation goals refined in ecological field studies or laboratory studies which appear warranted based on the Phase I predictive assessment and Phase II validation study. There is no intent by HERD to imply that investigations performed under this guidance constitute the injury determination or damage assessment phases of a NRDA. In fact, HERD has gone to great lengths, as a State natural resource co-trustee, to provide notification and coordination with other natural resource trustees. The introduction to the Phase III impact assessment section has been modified to include an introduction stating the difference between ERA studies outlined in this guidance and NRDA.

56. Part A, Section 6.1. It is not intuitively obvious to site managers the appropriate contact point for State natural resource trustee issues for fish, wildlife, biota and its habitat. The correct contact person should be indicated. The last paragraph uses the term “environmental cost associated with delaying remediation.” Could you provide me with the detail of what is meant by this statement?

Response: A statement regarding the DFG contact has been inserted. The term environmental ‘costs’ has been amended in light of the particular CERCLA definition of costs.

57. Part A, Section 6.2. There needs to be careful consideration of the NRDA process, regulations, and methods for determining pathways and injuries to fish, wildlife, biota and its habitat, in addition to other potential natural resource trustees. Rather than provide lengthy and detailed recommendation of factors to be considered, as well as difference between the two activities, I recommend that our agencies meet, confer, and agree upon a cooperative approach in this area.

Response: The DTSC has no intent, at this time, of performing natural resource damage assessments, nor of performing any State natural resource co-trustee actions, but to notify DFG, which is also a State natural resource co-trustee, of apparent releases of hazardous materials and coordinating on ecological risk assessments at hazardous waste facilities or sites. We look forward to continued cooperative efforts in facility and site remediation with DFG. HERD representatives will be happy to meet to discuss common goals.

58. Part A, Figures 1 and 2. The figures are not discussed nor referenced in the text.

Response: The figures were previously referenced, however an expanded text description of the tasks HERD considers contained in each component on the flow charts is now appended as Appendix A, with Figure 1, Figure 2 and Figure 3.

State Water Resource Control Board, Sacramento, California.

59. The Scoping phase of the assessment only examines the potential sources and pathways of chemicals of concern. Retrospective ecological risk assessments generally assume that the source, exposure and effects are occurring or have occurred in parallel. The scoping phase should be expanded to include effects to biota seen even if no source or exposure pathway has been identified.

Response: We agree that retrospective investigations assume that source, exposure and effects are occurring or have occurred in the past. The DTSC regulatory responsibilities include regulation of facilities or sites which generate, store, transport or treat hazardous wastes. In order to determine whether an ecological risk assessment is required for this group of facilities or sites it is necessary to document that a release of hazardous materials has occurred and ecological receptors are exposed. Investigation of observed ecological effects in the absence of a hazardous materials release would seem more properly the role of natural resource trustees. No change was made in the text.

60. The Scoping phase only includes an examination of exposure pathways from chemicals of concern. This will not fully address all impacts to biota. The Scoping phase should include an examination of all pollutants at the site which have the potential to impact biota.

Response: This guidance is meant for ecological assessments of hazardous waste facilities or sites and the emphasis is therefore on contaminants which demonstrate adverse impacts on biota. The guidance calls for coordination with other regulatory agencies during the investigation and State Water Resources Control Board and Regional Water Quality Board input regarding the ecological contaminants of potential concern will be solicited. No change was made in the text in response to this comment.

61. Part A, Section 4.2.1. The discussion of endpoints should note that selection of ecological endpoints needs to be performed prior to the selection of indicator endpoints.

Response: We agree that assessment endpoints and measurement endpoints are selected prior to toxic endpoints for a particular representative species. The text has been modified to make clear the reference is to ‘toxic endpoints’ rather than assessment endpoints.

62. Part A, Section 4.3. The section recommends the use of quantitative methods similar to those employed in human health risk assessments. It should also be recommended

that should these methods be used, an uncertainty analysis (e.g. Monte Carlo Analysis) of results would also be appropriate.

Response: Uncertainty analysis in risk assessment need not be restricted to quantitative analysis such as Monte Carlo Analysis. In Phase I assessments, there is much model uncertainty (such as uncertainty related to toxicological effect levels or trophic transfer models), to which Monte Carlo techniques are not useful. Therefore, the guidance discourages use of quanitative anlaysis techniques in a Phase I assessment. However, in Phase II and Phase III, after field validation or toxicity testing has been conducted to validate Phase I results, we believe quanitative analytical techniques may have utility if the objective is to evaluate variability (as opposed to model uncertainty). The guidance has been modified to clarify these points.

63. Part A, Section 4.8. The section recommends a discussion on the selection of measurement endpoints. This discussion should be expanded to include a discussion on the selection of ecological endpoints used. The section also recommends a discussion of chemicals not selected for assessment which were found to exist on site. This should be expanded to include a discussion of any pollutants found on site that were not included in the assessment.

Response: We are unsure of the meaning of the first part of this comment. The measurement endpoints referred to can include ecological endpoints as well as toxicological endpoints. They are the measurement endpoints selected as indicative of the ecological assessment endpoints deemed important for protection. Some chemicals detected are not always carried forward in the ecological risk assessment. For example, cations which are typical of ocean waters such as magnesium, potassium and sodium, are frequently not carried forward in an ecological assessment of marine or estuarine sites. No change was made in the document based on this comment.

64. Part A, Chapter 5. The discussion of the Phase II validation study components should consider an evaluation of the ecological and indicator endpoints. This would help to refine the ecological risk assessment should additional information be required prior to a decision being made concerning the direction the ecological risk assessment will take following completion of Phase II.

Response: We agree that the purpose of the Phase II validation study is to refine the analysis performed in the Phase I predictive assessment. This may include many different types of ecological or toxicological investigation. We assume 'indicator' endpoints refer to ecological measurement endpoints which will, or course, help direct the Phase II validation study. No change was made in the document based on this comment.

San Francisco Regional Water Quality Control Board, Oakland, California.

65. Part A, Section 4.2.2. California Water Resources Control Board Objectives for Enclosed Bays and Estuaries and Inland Surface Waters Plans were invalidated as a result of a October, 1993 (later finalized on March 23, 1994) court decision. The Ocean Plan remains in effect.

Response: We understood that the documents were being challenged, but assumed finalization of the documents would make them available. The text has been amended to read: “California Water Resources Control Board Ocean Plan or any other applicable California Water Resource Control Board guidance as deemed appropriate.”

66. Part A, Section 4.2.2. This paragraph should include language which urges the risk assessor to also consult with the appropriate Regional Water Resources Control Board to determine if there are region-specific criteria which could be utilized as primary benchmarks.

Response: The text has been amended to recommend contact with the appropriate Regional Water Board.

67. Part A, Section 4.2.3. Consideration should be given to exposure pathways from aquatic systems to terrestrial receptors, which may be implicit in the text, but is not clear.

Response: This section was meant to discuss wholly aquatic representative species with consideration of ‘terrestrial’ species which utilize aquatic food sources contained in the evaluation of terrestrial species. The text has been amended to state specifically that : Bioaccumulation in representative species which utilize both aquatic and terrestrial habitats, such as shorebirds or waterfowl, would usually be addressed in the evaluation or terrestrial representative species.”

68. Part A, Section 4.2.3. The paragraph should explain how determining exposure in aquatic systems differs from terrestrial systems (i.e., ingestion or dermal contact vs. exposure via gill structures to either sediments or water, or adverse effects such as abnormal larval development). Region 2 staff consider toxicity or other adverse effects as well as bioaccumulation in aquatic organisms a threat or potential threat to the beneficial uses.

Response: The differences in evaluation of exposure in terrestrial compared to aquatic representative species is discussed more fully in the expanded description of the scoping assessment contained in Part B. The section has been amended to state that: “Use of the RfC approach to evaluate threat to aquatic receptors means that exposure via different pathways is not normally calculated separately in ecological risk assessments of aquatic receptors, except where food web transfers are judged to be a significant route of exposure.”

69. Part B, Section 2.2. Please modify the text to reflect the need for a biological survey or ‘site walk’ at various times of the day to determine all potential receptors.

Response: We agree. The section has been amended to state that: “This ‘site walk’ should be conducted at various times of the day to maximize the identification of potential receptors.

70. Part B, Section 5.0. Please include storm drains and outfalls as important characteristics of facilities or sites.

Response: Storm drains and storm water outfalls have been added to the text.

71. Part B, Section 5.1. Please include storm drains and outfalls as important characteristics of facilities or sites to be noted on site maps.

Response: Storm drains and storm water outfalls have been added to the facility-wide map characteristics.

California Central Valley Regional Water Quality Control Board

72. There needs to be some discussion in the assessment on how Regional Board and State Board water quality objectives will be integrated into the process. The objective adoption process includes many of the steps included in the risk assessment and some additional considerations.

Response: We agree that State or Regional Water Board water quality objectives are valuable evaluation criteria. Coordination and consultation with regulatory agencies is recommended in many locations in this document. For example, Section 4.2.2 recommends appropriate State or Regional Water Board criteria.

73. The document says that these guidelines don't constitute rule making or and enforceable standard. It is unclear how this works. It was assumed that guidance documents like this had to comply with CEQA and be reviewed by OAL.

Response: This document is intended to inform DTSC Remedial Project Managers of the information HERD considers necessary to evaluate the ecological threat posed by a facility or site. No requirement is made to perform the ecological risk assessment in the manner described, in fact the document states that this methodology is meant as a conceptual framework, but is not the only method for performing ecological risk assessments.

74. Part A, Page 6. A statement is made that demonstrated individual or population effects will generally be assumed to have ramifications at higher levels of organization (e.g., community or ecosystem level). This is always the area that is most controversial. It would help if this document sited studies that supported this assumption.

Response: We agree that this can be an area of controversy depending on the magnitude and extent of any adverse biological effect at the individual or population level. Certainly there would be little argument that an adverse non-reversible effect on a large proportion, or a population important to the ecological functioning, would be a significant ecological effect. Selection of the representative species, based on the conceptual site model and development of the assessment and measurement endpoints, is critical to concluding that a demonstrated adverse effect presents a significant ecological threat.

Adverse biological effects on individuals are more important in evaluating the potential threat to rare, threatened or endangered species, where protection of individual organisms is critical to survival of the species. The extrapolation from demonstrated individual or population effects to community level or ecosystem level is a site-specific conclusion arrived at by a weight-of-evidence approach, and therefore no specific criteria can be presented which would cover all types of facilities or sites. No change was made in the text.

75. Part A, Page 15. There is a discussion of representative species and the use of a default list of species. It would be helpful to us if the default list included the species that we commonly use in our effluent and receiving water bioassay testing program (Ceriodaphnia dubia, Pimephales promelas and Selenastrum capricornutum).

Response: HERD has abandoned the initial proposal of a default group of representative species based on the ecoregion of the facility or site in favor of site-specific receptors selected in coordination with State and Federal agencies. The conceptual site model forms the basis for selection of the representative species. The species mentioned are, however, frequently used in the assessment of threat to aquatic species at DTSC-lead sites.

76. Part A, Page 16. There is a statement that it is justified to use toxicity data from species in a family to estimate toxic effects to representative species. We often find significant differences within a family.

Response: The reference to use of toxicity data with a family refers to assessment of terrestrial species using the dose methodology. The section on the RfC methodology for aquatic receptors states that : “For this approach to be valid, the RfC must take into account all relevant exposure pathways and must be based on a database sufficiently broad to ensure that it adequately reflects the toxicity to the range of species present or potentially present.”

Lahontan Regional Water Quality Control Board/Victorville Office

77. Water Quality Control Plans (WQCPs) developed by the California State Water Resources Control Board or the Regional Water Quality Control Boards have both narrative and numerical water quality objectives established to protect water quality objectives established to protect water quality from toxic substances. Plans such as the Inland Surface Water Plan and Enclosed Bays and Estuaries Plan have numerical water quality objectives for toxic substances. USEPA also has established numerical water quality objectives for toxic substances in its National Ambient Water Quality Criteria publications. State WQCPs are required by USEPA for implementation of the Federal Clean Water Act. For these reasons application of the Ecological Risk Assessment (ERA) may be limited to releases where numerical objectives are not established for a specific constituent.

Response: We are aware of the criteria and objectives promulgated and developed by Federal and State regulatory agencies for protection of ecological receptors and other beneficial uses of water. We do not agree that performance of ecological risk assessment is limited to releases where numerical objectives are not established for a specific constituent. Performance of a multi-media ecological risk assessment requires consideration of exposures to many media which do not have numerical objectives established, such as sediment. Sediments certainly influence the concentrations of contaminants in overlying waters as well as provide an additional exposure media to aquatic receptors. There are known dose effect levels for some terrestrial receptors for chemicals typically found at facilities or sites. Consideration of terrestrial receptors at facilities or sites requires some type of ecological risk assessment. No change was made in the text.

78. WQCPs require that beneficial uses of water resources be protected from impacts by any discharge to water bodies, including discharges of toxic substances. These beneficial uses often include protection of wildlife dependent on those water bodies. The ERA may be an effective tool for evaluating remedial actions (such as habitat mitigation) for wildlife impacted by toxic substances, particularly for bioaccumulative substances.

Response: The guidance calls for coordination with other regulatory agencies and specifically mentions regional water quality control boards. This ecological risk assessment guidance was developed specifically to characterize the ecological risk and guide selection of remedial alternatives at sites or determine permit conditions for facilities. No change was made in the text.

79. The State Water Resources Control Board adopted Resolution 68 -16, requiring that any discharges that may impact water quality maintain the highest quality of water consistent with the maximum benefit to the people of the State. The State Water Resources Control Board and Regional Water Quality Control Boards generally have established the goal to remediate contaminated waters to background water quality to the extent feasible both technically and economically. Therefore, the State Water Resources Control Board and Regional Board Control Boards view that any degradation of existing water quality to be inappropriate and that a health based risk analysis (described in the ERA guidance) may not be conservative enough to protect water quality. Any risk analysis performed must demonstrate that surface or ground water quality are not threatened by existing soil contamination or other contaminant sources.

Response: We are familiar with the water board's charge to protect the quality of State waters and this guidance recommends consultation with regulatory agencies including the State and Regional Water Quality Control Boards. Evaluation of remedial alternatives requires an assessment of the ecological impact of the no-action remedial alternative as well as some ecological preliminary remediation goal to evaluate other remedial alternatives in cases where the ecological threat 'drives' the selection of remedial alternatives. The guidance recommends that RfCs and RfDs be based upon no-observed-adverse-effect-levels, which should protect the beneficial uses of the water body. No change was made in the text.

80. It is possible that a released constituent that does not have a toxic effect on wildlife will still require remedial action pursuant to the California Water Code, Section 13304, if it causes or threatens to cause nuisance conditions or impacts beneficial uses of water resources as detailed in WQCPs or degrades existing water quality as referenced in Resolution 68 -16. For example, the following conditions may not trigger remedial action under the ERA but could trigger remedial action under the California Water Code, Resolution 68 -16 or WQCPs: presence of taste and odor causing substances, coloration, presence of floating material suspended material and settleable material, sedimentation, presence of oil and grease at concentrations that cause a sheen on water surfaces, presence of biostimulatory substances, turbidity and exceedence of specific chemical constituent water quality objectives. Violation of these water quality objectives may also have indirect impacts to wildlife that are not evaluated by the ERA.

Response: We agree that there are some released constituents which would not be effectively evaluated by the ecological risk assessment process. We agree that resource trustees such as the State and Regional Water Quality Control Boards are the appropriate avenue to address these problems. No change was made in the text.

81. The ERA discusses the incorporation of contaminant transport models for predicting potential future toxic effects to wildlife. This suggests the need for continually monitoring the affected media and updating the reference dosages and concentrations. This is because ongoing contaminant transport continually changes the risk to the environment and because regulatory agencies are generally not willing to accept model simulation data without field verification and monitoring.

Response: We agree. HERD routinely recommends field validation of modeled media concentrations, such as sediment or water, and tissue concentrations. This guidance strongly recommends field validation of modeled parameters.

DTSC, Site Mitigation Branch, Region 3

82. I would recommend combining Part A and B into one document.

Response: Part A is intended an overview of the entire process, while Part B is the first document of the more detailed guidance for each component. The documents are being kept separate to facilitate review and comment and decrease the size of any one document.

83. Regarding work plans - are these intended to be incorporated in RI/FS work plans?

Response: Work plans for ecological risk assessments are frequently included in the remedial investigation (RI) work plan.

84. Does the Eco Risk guidance supersede the PEA discussion?

The scoping assessment contains all the components of the ecological risk assessment section in the Preliminary Endangerment Assessment (PEA) manual and should be used to implement ecological risk screenings which would be equivalent to the ecological risk assessment sections contained in the PEA manual. The scoping assessment guidance provides more detail regarding presentation which should make review by DTSC Remedial Project Managers less onerous.

85. Part A, Section 4.3. Shall we establish a more general term for the uncertainty analysis?

Response: This is the term typically applied to this type of analysis in both human health and ecological risk assessments. No change was made in the text.

86. Part A, Section 4.7. "Maximum hazard indices greater than one for any chemical made of action or target organ..." - shall we add any receiver from the ecosystem?

Response: Hazard indices are representative species-specific, so a 'receiver' is already specified. No change was made in the text.

87. Part A, Section 4.7. Shall we consider the cumulative effect of multiple chemicals?

Response: The hazard index is calculated by adding together all the appropriate chemical-specific hazard quotients, and therefore considers multiple chemicals. No change was made in the text.

88. Part B, Section 3.0. Shall we consider background concentrations in the eco risk evaluation? (e.g. several studies have shown that the biodegradation of humic and fulvic acids into phenols and chlorophenols outweighs man-made sources.

Response: The decision on how, or whether, to incorporate intake from off-site is a site-specific decision based on the 'ambient' concentrations and the sensitivity of ecological receptors to these contaminants. No change was made in the text.

Department of Toxic Substances Control, Site Mitigation Branch, Headquarters

89. I strongly recommend combining Part A and B into one document.

Response: See response to Site Mitigation Branch, Region 3 above.

90. The documents imply that a biologist should be engaged to scope and assess eco risk for each site. Is this your intent?

Response: Yes, the identification of actual or potential ecological receptors is critical to the scoping assessment and any other portions of the ecological risk assessment performed for the facility or site. The potential receptors are also important for facilities or sites which do not proceed to subsequent steps of the ecological risk assessment based on the conclusions of the scoping assessment because the list of potential ecological

receptors may influence the choice of remedial alternatives based on human health concerns. In our experience the DTSC does not employ the biologist to perform these activities, but reviews the results when submitted and we would anticipate this mode of interaction will continue.

91. With the push to drive decision to an expeditious selection of remedies, including designation of presumptive remedies, how does Eco risk assessment fit into the process for designating presumptive remedies?

Response: A clear and concise presentation of the potential contaminants of ecological concern, the potential receptors and the potentially complete exposure pathways, as contained in the scoping assessment Report, seems to be the appropriate basis for risk management consideration of remedial actions to sever exposure pathways or risk management consideration of applicable Presumptive Remedies such as capping or excavation.

92. Work Plans and Reports: Are these intended to be stand alone documents or incorporated into the PEA, RI/FS work plans and reports?

Response: The work plans and reports are frequently folded into the RI/FS process or PEA process as either stand alone documents or incorporated into the human health risk assessment volumes.

93. The PEA Manual only has limited discussion about Eco Risk. It doesn't currently require a biologist to do the assessment. The Scoping document which is stated to be based and part of the PEA manual does. It also goes into more detail. Does the Eco risk guidance supersede the PEA discussion of ecological risk?

Response: The text has been amended to explain the relationship between the ecological risk section of the PEA Manual and this document. The scoping assessment contains all the components of the ecological risk assessment section in the Preliminary Endangerment Assessment (PEA) manual and should be used to implement ecological risk screenings which would be equivalent to the ecological risk assessment sections contained in the PEA manual. The scoping assessment guidance provides more detail regarding presentation which should make review by DTSC Remedial Project Managers less onerous.

94. The document focuses on wildlife, and suggests that the document can be used for livestock, should existing and potential family pets (e.g. dogs and cats, birds, etc) be considered too?

Part B states that "The term 'biota' generally refers to non-domesticated terrestrial and aquatic plants and animals, but may include domesticated species, such as livestock." The intent of this definition was that if domesticated animals exhibit an adverse effect when exposed to a chemical there is little reason to suspect that a similar effect would not be elicited in a related non-domesticated animal. For example, a toxic effect exhibited in domestic goats would also be expected to occur in mountain goats.

95. Part A. The flow charts are excellent as is the text in the main document. However, the text does not follow the progression of the flow charts. I suggest including an appendix with BRIEF text description of decision philosophy or criteria used in moving from box to box in the flow charts.

Response: Appendix A of the overview document (Part A) now includes a text description as well as the flow diagrams.

96. Each section on Scoping, Phase I, II and II discusses potential outcomes which are not reflected in the flow chart. For example, Phase II outcomes include the potential for no further studies, yet in the flow chart all pathways lead to the phase III work plan. I suggest checking the flow charts to verify that all outcomes discussed in the text are reflected in the chart as possible ending points.

Response: We have checked the flow charts and believe that combined with the text description of the process, the flow charts agree with the main body of text. In the example cited above, the Phase II outcome which would exit from the process is the 'Possible chemical or biological monitoring' based upon a negative finding of 'Ecological Impact' after the Phase II report.

97. Uncertainty Factor: Explain how the Uncertainty Factor is used in the decision making process. The document references that it should be considered, but when in the process...each step (box)? at the end of each phase?

Response: Uncertainty factors are typically applied in extrapolating toxicity dose or concentration values to account for shorter-than-optimal exposure periods or when using toxicity information developed from an experiment on one species as an approximate toxicity value for another species. The description of uncertainty factors has been increased and been made more specific.

98. Could the ecorisk be used in assessing damages under the Natural Resources Damages Compensation program?

Response: Some of the information collected in the scoping assessment and later phases may be of use to natural resource trustees in conducting and injury determination. The term 'damages' in the natural resource damage assessment process has the specific meaning of an economic cost of the injury, and therefore loss of use, sustained by the natural resource. This ecological risk guidance was prepared with review by State and Federal natural resource trustees to ensure that the maximum amount of information gathered for the ecological risk assessment would be useful to the natural resource trustees.

99. How does Phase II fit into the 'following actions' discussion of outcomes from phase I? Is the validation study needed for all Phase I decisions to narrow the uncertainties in the decisions as suggested in section 5.2? If not, what criteria should be used to assess this need?

Response: We could not locate the phrase 'following actions' in the current revisions of Part A or Part B. That phrase may have been removed during response to comments. The Phase II validation study is recommended for all Phase I predictive assessments unless the degree of uncertainty in the Phase I predictive assessment is minimal and the conclusion of the Phase I predictive assessment is that there is no threat to ecological receptors. This would not normally be the case, and exclusion of the Phase II validation study should be considered only with concurrence of other State and Federal regulatory agencies and natural resource trustees. No change was made in the text.

100. Part B, Section 2. Suggest adding discussion on consideration of sensitive or critical habitat areas for wildlife in general, not just rare, endangered or threatened species. This would include areas such as winter deer range, ponds and water bodies used by water fowl and other wildlife, key migratory routes. Considering these habitats as well as those for rare, endangered or threatened species is vital for environmental protection assessment as a whole.

Response: There was no intent to concentrate only on rare, threatened or endangered species of habitats critical only to these species. The identification of the most significant ecological components to be evaluated is made based on the conceptual site model. Presence of rare, threatened or endangered species would usually lead to selection of appropriate representative species, to be indicative of the threat to the rare, threatened or endangered species, as well as other representative species indicative of the threat to other receptors associated with the facility or site. The text specifically states that :" In addition to the rare, threatened or endangered species, the initial list of potential receptors includes those species which can be expected to occupy the habitats identified for the site based on the available literature." The word 'habitat' has been used in place of 'systems' to indicate the importance of habitat evaluation.

101. Part B, Section 3. Identification of Potential Contaminants of Concern: Suggest adding discussion of background levels of naturally occurring trace elements and how background concentrations should be considered in the eco risk evaluation.

Response: The identification of chemicals of ecological concern has been amended to include an investigation of background inorganic concentrations. The decision on how, or whether, to incorporate intake from off-site is a site-specific decision based on the background concentrations of inorganics, the sensitivity of ecological receptors to these contaminants and the site-specific dose. These are threshold effects, and as the site-specific dose approaches the threshold dose (RfD), the chance that off-site (background) will contribute enough intake to exceed the RfD, increases.

102. Part B, Example tables, include a column for the standard deviation in order to get an idea of the variability of the data. This is especially important if more than 4 or 5 samples are collected to characterize chemical contamination. May want to look at high end of data in significant variability over a large area with few samples (i.e. hot spots which require further characterization and us contaminant concentrations in

these areas to 'represent' contaminant concentration for the eco assessment rather than the mean concentration for all samples collected).

Response: The standard deviation has been added as a column in the referenced table.

103. Part B, Page 9. The first sentence is confusing.

Response: The sentence has been reworded.

104. Chapter 2. It was a great idea to include definitions of terms used in the guidance. In my experience, many of our misunderstandings with Cal/EPA have resulted from differences in our understanding of the various terms we use.

Response: No response is necessary.

105. Chapter 3. I recommend that the text be organized to conform to the flow chart cited (Figure 1) or that the flow chart be altered to more closely conform to the text. In the current form, the two do not seem to be closely related.

Response: Appendix A has been added to more clearly describe the process in the flow charts, and to relate the steps in the flow chart to specific sections in the text.

106. Subchapter 3.1, paragraph 2. Biological characterization of the site may indeed be useful for the purposes of planning remediation activities based on human health risk, but biological characterization to the extent described in Subchapter 3.3 is not necessary at sites at which no contamination is found. Figure 1 illustrates this point by showing that the absence of chemicals of ecological concern and the absence of potential ecological receptors moves the process down a different path from that containing habitat characterization.

Response: No response is necessary

107. Subchapter 3.6, bullet 2. The description of the potential problem should also include potential chemical migration pathways.

Response: The text has been amended to include chemical migration pathways.

108. Chapter 4. At least two places in this chapter (paragraph 2 of Subchapter 4.1 and paragraph 2 of Subchapter 4.3.2) indicate that ranges of HQs and/or HIs are expected rather than single point estimates. If ranges are expected, what part of the range will be used to make decisions on whether (or how) to proceed with the next phase of investigation? If ranges are not expected, please clarify.

Response: The plural form of hazard quotient noted in Subchapters 4.1, 4.3.2, and 4.4 refers to the hazard quotient (HQ) estimated for each chemical and each exposure pathway. When there are multiple chemicals and exposure pathways, there will be several HQs. The sum of the HQs is the hazard index (HI), which is a single number which represent to total hazard for that representative species. There may be several HIs, each representing the total hazard to a representative species.

Section 4.5, on Uncertainty Analysis, provides for a range of HQs and HIs to be developed as a way to provide upper and lower bounds on the estimate of hazard. The purpose is to identify those parameters or factors most contributing to uncertainty; those parameters or factors are the focus of the next phase of the investigation. So, the purpose of the range is to provide information to the manager on the magnitude of the uncertainty, and to focus subsequent investigations.

109. Subchapter 4.1. To avoid confusion, I recommend that the text use the same terminology as the flow chart cited (Figure 2) or that the flow chart use the same terminology as the text.

Response: The same terminology has been used as much as possible. Also see the response to Comment No. 105.

110. Subchapter 4.2.1, bullet 2. I recommend that rather than choosing two sediment dwellers (top dwellers and burrowers) as representative species, that only one be chosen. My recollection is that the NOAA sediment criteria cited on the top of page 14 was developed using both types of organisms.

Response: The section has been amended to suggest at least one sediment-dwelling organism.

111. Subchapter 4.3.1, paragraph 1, sentence 6. When developing a list of default representative species, please also consider recommending exposure parameters for those species or recommending the use of US EPA's (1993) Wildlife Exposure Factors Handbook.

Response: At this time, HERD has abandoned the initial proposal of a default group of representative species based on the ecoregion of the facility or site in favor of site-specific receptors selected in coordination with State and Federal agencies. Section 4.3.1 has been modified. Reference to U.S. EPA’s Wildlife Exposure Factors Handbook has been added to Section 4.3.3.

112. Subchapter 4.3.2, paragraph 2, sentence 1. The use of uncertainty factors for the development of a range of reference doses is not clear. Would the range include the adjusted (by uncertainty factors) to the unadjusted

reference doses or would the range include the adjusted reference doses of an entire taxonomic group (as alluded to in sentence 3)?

Response: Subchapter 4.3.2 has been rewritten to clarify the intent. The intent is to use the information on the range of toxicity (for the same or similar toxicological endpoints) in the range of species tested to develop a UF for the representative species. For example, if the literature on a chemical contained a narrow range of toxicity values based upon reproductive effects for a wide variety of taxonomic groups, then it can be inferred that the interspecies sensitivity is narrow and a smaller UF is supportable. Conversely, if there is a wide range in toxicity valued for a small number of taxonomic groups tested, then there is greater uncertainty in the appropriate UF to apply for the representative species, and a larger UF for interspecies sensitivity is supported.

113. Subchapter 4.3.4. The rationale for verifying predicted tissue levels when the preliminary screen indicates that the potential for ecological risk is minimal is not clear. It is an unwise use of resources to do so when the use of conservative factors yields acceptable ecological risk.

Response: The intent of this subchapter is to highlight the limited availability of Inter-media transfer factors presently available in the open literature, and the uncertainty inherent in applying Inter-media transfer factors developed for a particular habitat type or group of receptors, to other habitats and receptors. Therefore, application of generic Inter-media transfer factors may, or may not, be “conservative”. It is our experience that food-chain pathways often contribute significantly to estimated dose in ecological risk assessment. Therefore, we will continue to recommend that predicted tissue residue levels be verified where this pathway is likely to be a driver, until such time that the open literature provides a more complete picture of this complex subject. No change was made in the document based on this comment.

114. Subchapter 4.4. Verification of the predictive assessment is not a wise use of resources if the predictive assessment indicates that ecological risk is minimal. Why waste time and money trying to verify the results of an extremely conservative process? As stated in bullet 2 on page 25, it is very difficult to prove the lack of an effect. Therefore, our resources would be best spent verifying predictive assessments which indicate that ecological risk is unacceptable. In that case, we may even be able to design our studies such that contaminant concentrations which pose acceptable risk could be developed simultaneously.

Response: In contrast to human health risk assessment, typically average exposure factors are used (e.g. body weight, ingestion rates, etc.) in an ecological risk assessment. Therefore, depending on how the ecological risk assessment was conducted, it may or may not be, an extremely conservative process. The intent of the validation phase is to do a reality check on those factors in the Phase I assessment most contributing to uncertainty. This applies both to guarding

against incorrectly concluding in Phase I that there is not an effect when there has been impacts to the environment, as it does to preventing unnecessary remediation of wildlife habitat when there is no impact. As this subchapter indicates, the decision to proceed would include risk management input. We agree in conserving resources to focus on problems with the most potential for harm to the environment, and the phased approach is designed to do this. The intent of Phase II and III is to design studies to define the contaminant concentrations or areal extent for remediation, which poses an acceptable risk. No change was made in the document based on this comment.

115. Subchapter 4.6. Please expound on the calculation of HIs from ARARs. Figure 2 shows that HIs can be derived from ARARs.

Response: The example we have in mind are water quality objectives, which are standards promulgated by the State, are generally based upon water quality criteria for the protection of aquatic life, and based upon whole-body exposure. Dividing the contaminant concentration in water by the water quality objectives would give a HQ for that chemical, for direct contact exposure to aquatic organisms. We admit this is the only instance of an ecological ARAR currently available, we wanted to provide flexibility in the guidance in the event that other ecologically-based ARARs are developed in the future. No change was made in the document based on this comment.

116. Subchapter 4.7. I think the options for proceeding when HI > 1 are too limited. I suggest adding an option for a risk management decision for no further ecological risk assessment activities. We cannot afford to take one of the steps listed every time an HI $\geq$ 1. Some have suggested that a more realistic scale to consider is 1-10, 11-100 and > 100 (unfortunately I have loaned out my reference for this). My recollection is that HI values of 1-10 indicate possible ecological effects, while 11-100 indicates probable ecological effects and > 100 indicates likely ecological effects. I suggest that we use this or a similar scale to evaluate whether further work is necessary and to prioritize those efforts deemed to be necessary. We do not have the resources to study every HI > 1. Bullet 2. For clarity, the testing described in Chapter 5 should be identified as a Phase II study.

Response: By definition, an HI greater than one implies there is the possibility of an adverse effect. The magnitude of the effect is not directly discernible from a single number, since dose-response information is not reflected in a single toxicity value. The risk characterization and uncertainty sections of the ecological risk assessment can provide some perspective on the types of effects expected to occur at the dose levels estimated in the ecological risk section. We anticipate that site-specific risk management decisions will be made regarding further studies, based on the degree of uncertainty in the predictive assessment, the representative species predicted to be affected and the magnitude of the calculated ecological hazard. For example, if an HI of 10 is estimated, and there is a steep dose-response curve and there is some confidence in the choice of the

RfD for the representative species, then it is reasonable to conclude there is the possibility of an effect on the individual. This would provide a more sound scientific basis for evaluating an HI greater than 1 than would arbitrarily qualifying HI as to the magnitude of an ecological effect. As noted in our response to comment No. 114, there is risk management input into the decision to proceed with further evaluation. No change was made in the document based on this comment.

117. Subchapter 5.4. It makes even less sense to study everything with an HI $\geq$ 1 when we have reason to believe it is overestimated! Again, I suggest using a scale similar to that mentioned above to prioritize our Phase II and Phase III efforts. We do not have the resources to study every overestimated HI > 1.

Response: The Phase II validation study is meant to be a fairly rapid and simple field or laboratory evaluation of the parameter(s) judged to contain the most uncertainty in the Phase I predictive assessment. The results of the Phase II validation study would then be available to bound the uncertainty in the Phase I calculation of ecological hazard and available for use at sites with similar habitats, contaminants and species, such as at many Air Force bases. Please see responses to Comments Nos. 114 and 116.

118. Figure 1 on page 31. It seems more appropriate to place "Identification of Communities and Habitats" before "Are there actual or potential ecological receptors?" since the identification of habitats is the manner in which we identify receptors. "HHRA" is undefined in this document.

Response: The question in Figure 1, " Are there actual or potential ecological receptors?" is meant to be a broad initial assessment prior to doing a more in-depth characterization of habitats. For example, if the site is a parking lot or industrial site, there would be no need to spend effort in identifying habitats further. We believe our intention to eliminate sites which clearly pose no ecological threat from consideration as early in the process as possible, is consistent with this comment's implication. We have changed "HHRA" in Figure 1 to "remediation for human health".

119. Figure 2 on page 32. "Toxicity Data on Related Chemicals?" should come before "Perform Bioassays?" since the general recommendation is to perform a thorough literature search before planning field and/or laboratory activities. What is meant by "Total Hazard Index"? That terminology was not used in the text. Even with an extremely high hazard index, it may be worthwhile to perform validation studies rather than proceeding to the Phase III work plan. Validation studies could be designed so that acceptable contaminant concentrations are determined.

Response: In Figure 2 there is a step "Available Toxicity Data?" prior to "Perform Bioassays?" It is implied in "Available Toxicity Data" that a thorough literature

search would be included as part of evaluating the available data. The step, "Toxicity Data on Related Chemicals" is meant for the special situation where data is not available, or there is an inadequate data set, for the chemical of interest, but there is available data on a related chemical. The box "Total Hazard Index" has been changed, and Appendix A has been added to more fully explain the flow diagrams and how the steps relate to the guidance. We agree that Phase II work could be an extension of a validation study designed to that ecologically-based cleanup levels are determined.

120. Figure 3 on page 33. What is the significance of the dashed lines?

Response: The text description of the flow chart has been amended to indicate that the dashed lines indicate that not all sites proceed to monitoring, but some sites may require monitoring to evaluate the remediation/no remediation risk management decision.