Guidelines for Assessing Ecological Risks Posed by Chemicals

Developmental Plan

Cal/EPA
Office of Environmental Health Hazard Assessment
Reproductive and Cancer Hazard Assessment Section
Ecotoxicology Unit
301 Capitol Mall, Second Floor
Sacramento, CA 95814-4327

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PREFACE

The primary purpose of this document is to describe the conceptual approach for the development of Guidelines for Assessing Ecological Risks Posed by Chemicals-*Developmental Plan*. Additionally, a brief introduction to the specific topics for which guidance will be initially developed is presented. Drafts of the *Developmental Plan* were reviewed by the Ecotoxicology Inter-Agency Work Group (IAWG) and an informal external peer review panel, and have undergone public review. The IAWG is composed of representatives from Cal/EPA Boards and Departments, including the Air Resources Board, Department of Pesticide Regulation, Department of Toxic Substances Control, Office of Environmental Health Hazard Assessment, State Water Resources Control Board and Regional Water Quality Control Boards, and the Department of Fish and Game of the Resources Agency. External peer reviewers were invited to provide informal comments based on their individual expertise in the field of ecological risk assessment and not necessarily as representatives of their agencies, institutions or companies. External reviewers included Clarence Callahan (US EPA, Region IX), William van der Schalie (US EPA), Susan Norton (USEPA), Greg Biddinger (Exxon USA, SETAC Ecological Risk Assessment Advisory Group), Markus Meier (Zeneca Agrochemicals, NorCal SETAC), John Gentile (University of Miami), Steve Bartell (SENES Oak Ridge, Inc.), and Michael White (Ogden Environmental Services).

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INTRODUCTION

In the arena of environmental regulation and decision-making, ecological risk assessment (ERA) is becoming an increasingly utilized process by which adverse effects of chemical pollutants and other ecological stressors are characterized and predicted. With respect to ERA, a primary objective of the California Environmental Protection Agency (Cal/EPA) is to promote consistency, efficiency and scientific rigor in ERAs conducted or reviewed by Cal/EPA Boards and Departments. One strategic activity in support of this goal is the development of broad, agency-wide ERA guidelines by the Office of Environmental Health Hazard Assessment (OEHHA). Due to the complexity of Cal/EPA environmental protection responsibilities and the diverse nature of California ecosystems, consistent, science-based ERA procedures play a central role in improving risk management and regulatory decision-making. The Cal/EPA ERA guidance is intended to encourage high quality, coordinated ERAs within Cal/EPA. A more uniform approach to ERA will avoid duplication of assessment efforts, leading to a decrease in the burden on the regulated community.

Development of Cal/EPA guidelines will also fill an information gap. While each ERA must be designed to suit the individual needs of a project, there are many cross-cutting issues, common to all assessments, for which there is little guidance. Ultimately, the guidelines will assist both the regulated and environmental communities, as well as California's regulatory organizations, by providing a source of consistent scientific guidance. In keeping with the goals of consistency and general applicability, guidelines will be harmonized as much as possible with appropriate federal guidelines, in particular those of the United States Environmental Protection Agency (US EPA). It is anticipated that, when finalized, the *US EPA Proposed Guidelines for Ecological Risk Assessment* (Figure 1; US EPA, 1996) will be adopted in the Cal/EPA guidelines, thereby avoiding duplication of US EPA's efforts. The Cal/EPA guidelines will serve to augment US EPA's final guidelines by providing additional guidance and information relevant to California in the form of technical resource documents. As recommended in the US EPA proposed guidelines, Cal/EPA will also support an iterative, tiered approach to performing ERAs.

SCOPE AND INTENT

The Cal/EPA ERA guidelines are intended to accommodate the wide range of assessments undertaken by the Cal/EPA Boards and Departments, including air and water quality, hazardous waste and pesticide assessments. Much like the US EPA proposed guidelines (US EPA, 1996), the Cal/EPA ERA guidelines will not be prescriptive but will provide broad guidance and constitute an information resource of available ERA approaches and methods.

Although other useful ERA guidance documents have been developed by various programs within Cal/EPA (see Department of Toxic Substances Control, 1996), these guidance documents are typically focused directly upon program specific issues and are not widely applicable to other programs and ERA needs. The Cal/EPA guidelines are not legally mandated and will not supersede programmatic guidelines, but will provide guidance that may be adopted at the Boards' and Departments' discretion. The guidelines will not address risk management decisions (e.g., what situations warrant an ERA; evaluation of remedial or

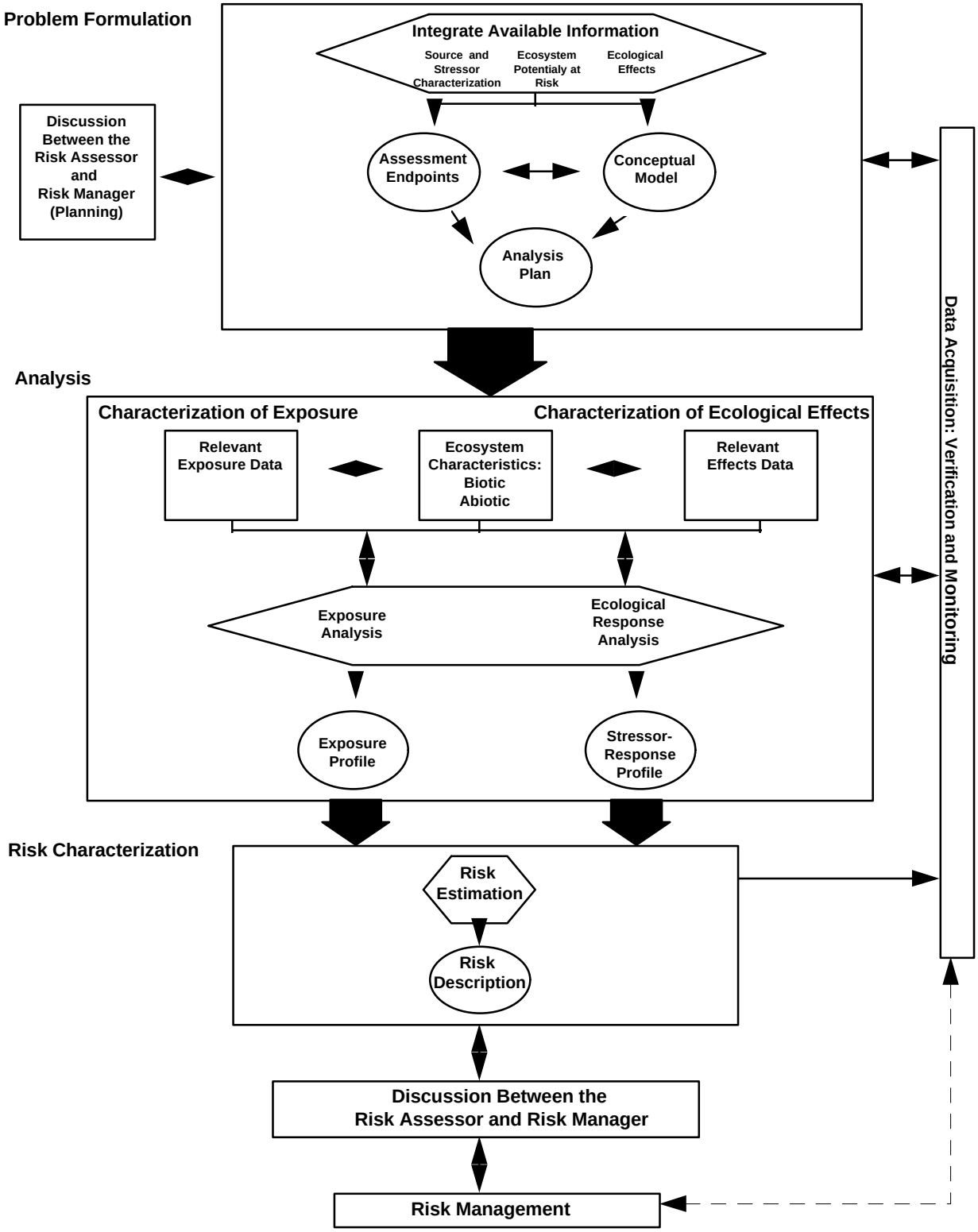

Figure 1. Schematic diagram of the ERA process from the US EPA Proposed Guidelines for Ecological Risk Assessment

restoration options) as these are typically dictated by each Board's and Department's mandate and are outside the scope of Cal/EPA's guidelines.

Furthermore, as the majority of Cal/EPA's mandates are based on environmental protection from chemical exposures, the focus of these guidelines will be primarily the assessment of risks to ecological resources posed by chemicals. However, since physical and biological stressors may also pose risks to ecological resources and may influence toxicity of chemical stressors, non-chemical stressors will be considered where they affect the toxicity of chemical stressors to ecological receptors.

GUIDELINES DEVELOPMENT

The subject areas covered by the Cal/EPA guidelines will fall under the major ERA phases described in the US EPA proposed guidelines. Selection of the topics covered under the different guideline subject areas is largely based on the identification of ERA topics not covered in detail by US EPA, and also on input obtained during a series of public workshops sponsored by OEHHA in 1995 and from suggestions made by the Ecotoxicology Inter-Agency Work Group (IAWG[1]). This section of the *Developmental Plan* includes a description of the guidelines structure and format, content, and review process.

Structure and Format of Guidelines

Since US EPA proposed guidelines on ERA will be utilized to the greatest extent appropriate, completion of various areas of the Cal/EPA guidelines will be largely contingent on availability of the final US EPA guidelines. As a first step, Cal/EPA will initially develop a number of focused technical resource documents to address existing, important issues in California. Guidelines development will proceed in a phased manner, with technical resource documents being released for review as they are completed. Releasing portions of the guidelines in this way will facilitate timely access and provide early feedback from users, in terms of format, level of detail and other aspects of the guidelines. After the US EPA proposed guidelines are finalized, they will be integrated with the technical resource documents developed by Cal/EPA to form the overall Cal/EPA guidelines. For clarity and ease of use of the guidelines, general guidance (i.e., adopted US EPA ERA guidelines) will appear up front in each major section, and will be followed by technical resources to support implementation of the guidance.

Release of the guidelines in stages favors packaging the documents in a ring-binder fashion, which will allow easy addition of new documents over time (Figure 2).
In addition, while these documents will cover discrete areas of the ERA process, they will be designed to be integrated together to form one cohesive guidance document. Finally, a ring-binder format will facilitate incorporation of periodic guideline updates. The purpose of the updates will be, in most instances, to provide additional information. Older portions of the guidelines will not be revised or replaced unless or until new findings or methodological

[1]The IAWG is composed of representatives from Cal/EPA Boards and Departments, including the Air Resources Board, Department of Pesticide Regulation, Department of Toxic Substances Control, Office of Environmental Health Hazard Assessment, State Water Resources Control Board and Regional Water Quality Control Boards, and Department of Fish and Game of the Resources Agency

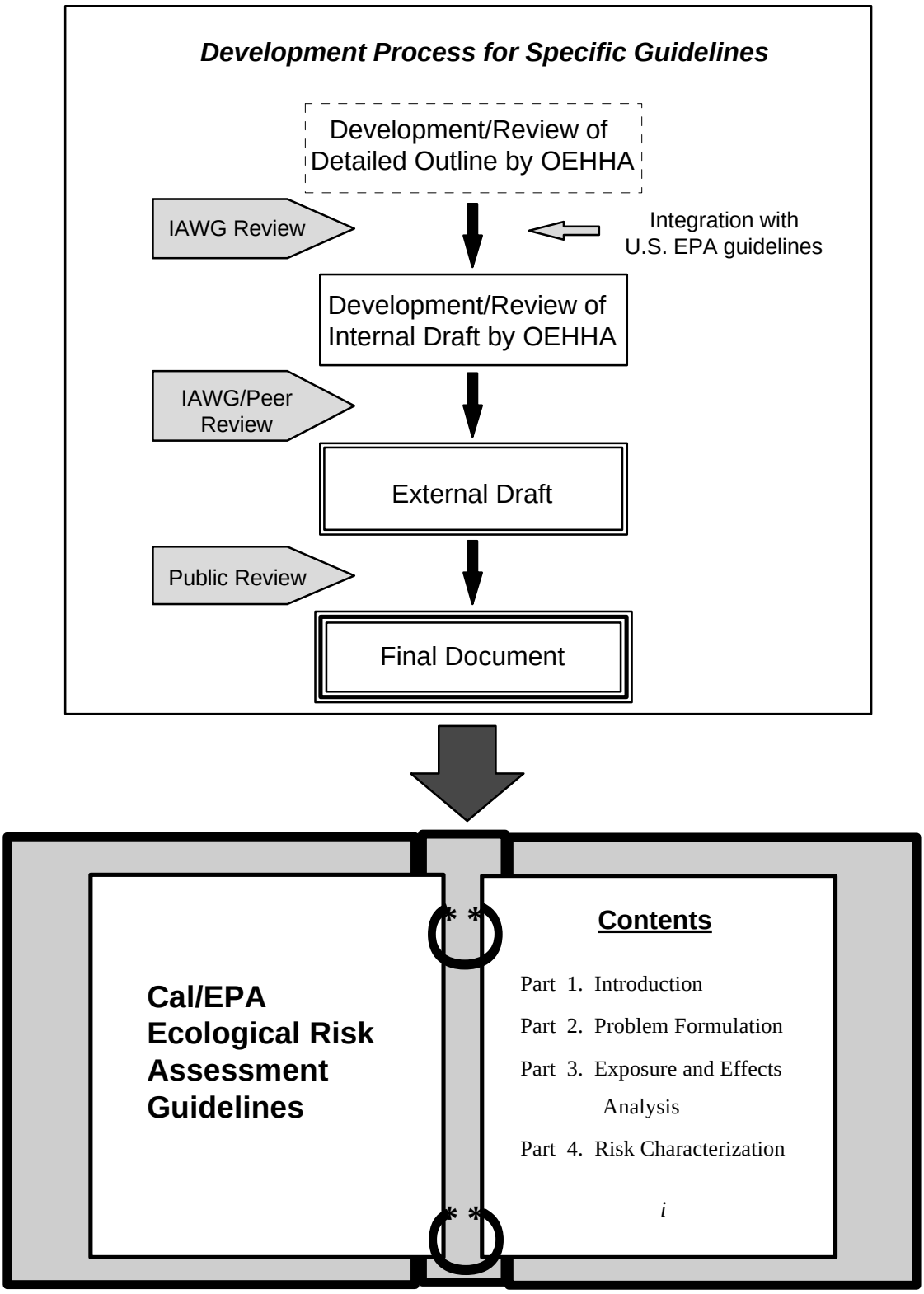

Figure 2. Cal/EPA Ecological Risk Assessment Guidelines Development

advances make this necessary. The ERA technical resource documents developed will also be available in electronic form on the OEHHA homepage (www.calepa.cahwnet.gov/oehha).

Guidelines Content

Cal/EPA Boards and Departments are responsible for protecting a diverse array of ecosystems for which compiled information on ecology, susceptibility to stressors and potential assessment endpoints may be lacking. To address these varied needs, Cal/EPA's guidelines are intended to provide a flexible approach and will focus on ERA technical issues particular to assessments done in California. Initial selection of the proposed areas to be covered in the guidelines have been based on these requirements, on identified areas in US EPA proposed guidelines that contain insufficient detail for California assessments, and on input obtained in three public workshops on ERA held in 1995 by OEHHA. During these workshops, recommendations for Cal/EPA guidelines development were prioritized and summarized in workshop proceedings (OEHHA, 1995; Appendix 1). Identification of areas for development by OEHHA has also been based on input from the IAWG, and on overall feasibility and appropriateness. Subsequent input from interested parties will be sought during guidelines development to identify emerging priorities.

Currently, a number of technical resource documents are either in progress or being proposed as briefly described below. Other areas of guidance may be developed or substituted according to availability of US EPA guidance and identification of higher priority areas for development. An overview of the proposed content for the guidelines is discussed in the following pages and is outlined below:

I. INTRODUCTION

II. PROBLEM FORMULATION
- A. General Guidance for Problem Formulation (US EPA)
- B. Technical Resources
  - California Ecological Endpoint Selection

III. ANALYSIS
- A. General Guidance for Analysis (US EPA)
- B. Technical Resources
  - Wildlife Exposure Factor/Toxicity Database (Cal/Ecotox)
  - Toxicity Extrapolation
  - Population Model for Ecological Risk Assessment
  - Measurement Endpoint Test Methods
  - Non-Chemical Stressors

IV. RISK CHARACTERIZATION
- A. General Guidance for Risk Characterization (US EPA)
- B. Technical Resources
  - Communication of Risk Assessment Findings

Problem Formulation

The problem formulation phase of an ERA establishes the goals and context for the risk assessment. During this phase, assessment endpoints (ecological values to be protected) are identified, key relationships among assessment endpoints and stressors are described in the form of a conceptual model, and an analysis plan is developed. US EPA has provided a valid general approach for this phase of ERA; however, OEHHA recognizes the need for more detailed information regarding endpoint selection with respect to California species and ecosystems. This was also a high priority recommendation from the OEHHA workshops. Suggested areas for development included population, community and ecosystem level endpoints, indicator species selection, and consideration of direct and indirect effects. Accordingly, the problem formulation area of the Cal/EPA guidelines will contain technical resource documents focusing on endpoint selection for California ecosystems. One such document that is under development is briefly described below.

Documents Currently Under Development:

California Ecological Endpoint Selection: Scientific Considerations

Endpoint selection for ERA in California is especially complex because the State has diverse habitats with many unique species and a variety of environmental contaminant issues. To provide a framework for initiating this process, scientific criteria for ecological endpoint selection will be developed. In addition, these criteria will be utilized to develop examples of the endpoint selection process in various California ecosystem classes. Other important criteria for endpoint selection include societal values and management goals, and the guidelines will recommend that these be carefully considered along with scientific criteria when selecting appropriate endpoints. Within Cal/EPA, management goals must be defined by individual Boards and Departments, since such goals are largely determined by program-specific requirements. Endpoint selection criteria will be developed in close conjunction with a reference on endpoint test methods (see Analysis section below).

Analysis

The analysis phase of an ERA involves scientific evaluation of relevant data, in order to assess the conceptual stressor-effect model developed in problem formulation. The two main products of this phase are exposure and stressor-response profiles, both of which serve as primary inputs for risk characterization. Several high priority recommendations for analysis guidance development by Cal/EPA were generated at the workshops. These included: exposure factors for California species, compilation of toxicity data for California species, bioavailability and trophic transfer (including examples for California), toxicity data extrapolation (emphasizing California species), and reference site selection for California ecosystems.

A common thread among workshop discussions was the need to provide guidance on effects and exposure analysis that would be applicable to California species or ecosystems. Consequently, the Cal/EPA guidelines will supplement the US EPA proposed

analysis guidelines by targeting issues specific to California. Cal/EPA guidelines will include recommendations in several areas relevant to exposure or effects analysis, including exposure factors, toxicity data, extrapolation approaches, measurement endpoint methods, and non-chemical factors relevant to ecological toxicity evaluation (described below).

Documents Currently Under Development:

California Wildlife Exposure Factor and Toxicity Database (Cal/Ecotox)

OEHHA is currently developing an electronic database (Cal/Ecotox) which will contain exposure factor (*i.e.*, species-specific parameters used in estimating exposure of animals to environmental contaminants) and toxicity data for California species. This project is being conducted in collaboration with the University of California at Davis. Cal/Ecotox was designed to augment the US EPA Wildlife Exposure Factor Handbook (US EPA, 1993) and the Terretox database (US EPA, 1995) by emphasizing California's need for western species. The database, containing data from the primary literature, is intended to furnish the risk assessment community with a convenient source of basic scientific information on California wildlife species and contaminants effects. Any database user must use his/her own data quality objectives to determine which data will be useful in an ERA. This approach was selected because data quality objectives may vary considerably among users. While the database will initially be developed using terrestrial animal data, it is anticipated that data for aquatic species will be incorporated in the future. Guidance on the use of this database for risk assessment purposes will be provided with the database.

Toxicity Extrapolation

This document will discuss considerations for the selection and use of statistical models and uncertainty factors for the extrapolation of toxicity data to species of concern in ERAs. Guidance will be provided for various types of extrapolations, including extrapolations between taxa, between responses, between field and laboratory data, and among geographic locations. Examples of toxicity extrapolations for a suite of specific chemicals and California wildlife species will be developed. This document will complement and utilize the Cal/Ecotox database.

Population Model for Ecological Risk Assessment

Due to the complexity of assessing some ecological effects of contaminants by field methods, and the requirement in some situations to conduct prospective assessments, the incentive to use modeling to aid in characterization of ecological hazards is considerable. The need for appropriate mathematical models, in particular those describing population and community level effects, was identified earlier by OEHHA. Consequently, OEHHA is developing a model that will have potential utility for both predictive and retrospective risk assessments. This model, developed in conjunction with the University of California at Davis, is

capable of predicting population effects on member species of a complete foodweb in relation to exposure to chemical toxicants. Utilizing available site-specific data inputs and/or estimates, the model can evaluate the effects of multiple toxicants impacting the ecosystem through a variety of pathways and can address sublethal, as well as lethal, toxicity endpoints. For initial calibration exercises, the model has been configured to simulate population level effects associated with pesticide exposure in an agroecosystem. However, the model is flexible and may be configured for other ecosystems, including aquatic, and contaminant effect scenarios. External peer review by modeling experts has been conducted. Verification studies will be conducted prior to release of the model. It is anticipated that, together with the appropriate guidance on model use provided by OEHHA, the model will be a valuable predictive tool applicable to problem formulation, analysis, and risk characterization phases. It is also anticipated that definition and documentation of the relative advantages and disadvantages of the model will provide a benchmark against which the utility of alternative models may be evaluated.

Proposed documents:

Measurement Endpoint Test Methods

As a technical support document for the California endpoint selection guidelines described above, this document will review current endpoint test methodologies with respect to their relevance to California ecological endpoints, and provide guidance on their appropriate use and interpretation. Criteria for selecting relevant laboratory and field tests will be provided, as well as lists of, and references for, selected aquatic and terrestrial protocols. Problems of measuring effects at different scales (*e.g.*, individual *vs*. population *vs*. community) will be discussed. Particular attention will be paid to tests developed for California receptors.

Non-Chemical Stressors

Non-chemical stressors include biological (e.g., exotic species) or physical factors (e.g., drought) that may have adverse effects on ecological resources and may pose equal or greater risks than chemical stressors. Omitting consideration of non-chemical stressors during an ERA could result in inadequate risk assessments since assessment of risks posed by chemicals will be of little scientific validity without concurrent assessment of the effects, both interactive and independent, of non-chemical stressors. Based upon these scientific principles, as well as Cal/EPA's mandates, the Cal/EPA guidelines will provide guidance on non-chemical stressors by adopting US EPA's proposed guidance on this subject and by developing additional guidance, if necessary, on non-chemical stressors where they influence toxicity of chemicals to ecological resources. Extensive guidance on non-chemical stressors or guidance on assessment of non-chemical stressors in the absence of chemical stressors will not be provided. Rather, the Cal/EPA guidelines will include a technical document which will

address factors and ecosystem characteristics that can influence exposure to and effects of chemicals. A bibliography of selected case studies from California (and appropriate examples from other locations) will be included. These examples will illustrate how site-specific ecological and historical factors are taken into consideration during an ERA, and depict potential effects on risk assessment outcomes when non-chemical factors are not properly included in analyses. In addition, a summary section will outline the principles illustrated by the case studies as well as how these can be used to reduce uncertainty in the overall assessment.

Risk Characterization

Risk characterization is the final phase of a risk assessment and consists of two processes: risk estimation, in which exposure and effects analyses are compared to estimate the likelihood of an effect, and risk description, which summarizes the risk estimation, addresses the uncertainties in the assessment and interprets the ecological significance of the identified risks. Under risk description, ecological risks must be adequately described and communicated to the risk manager. Good risk communication requires that the risk assessor fully discloses the strengths and weaknesses of risk assessment methods used as well as any assumptions made during the risk assessment, and that the risk manager understands the impact of these assumptions. Workshop participants and several external peer reviewers recommended developing guidance on various areas pertaining to risk characterization, including the need to improve communication between risk manager and risk assessor. OEHHA will therefore develop a technical resource document to assist communication of risk assessment findings between the risk assessor and risk manager (see proposed document below). For other areas of risk characterization (e.g., weight of evidence approach) Cal/EPA will incorporate, and potentially build upon, US EPA's guidance on risk characterization (contained in the US EPA proposed guidelines), since guidance in this area is more likely to be applicable to a wide variety of situations, thus requiring less interpretation for California-specific needs.

Proposed document:

Communication of Risk Assessment Findings

Adequate guidance in this area of ERA is not readily available at this time. Therefore, this technical resource will be developed to provide guiding principles for use by risk assessors when communicating risk assessment findings to risk managers. The document will include explanation of the kinds of information that must be included in a risk characterization document, standards for effective and clear description of risk assessment findings, as well as a bibliography of helpful resources on this topic.

Guidelines Review and Interested Party Input

To ensure that the guidelines meet the needs of the Cal/EPA ERA community, OEHHA will continue to seek input from interested parties. Depending upon factors such as available resources and level of interest, this may include further workshops on ERA guidance topics and issues. Opportunity for input will also be provided through several levels of review. The review process will help ensure that the proposed guidelines incorporate the best available science and are useful to the Boards and Departments and the regulated community. There will be two levels of review: expert technical review and public review. Technical review will provide an objective and thorough evaluation of scientific aspects of the guidelines, whereas public review will deliver comments on both scientific and non-scientific issues. All input will be carefully considered in the context of Cal/EPA goals and mandates, as well as available resources.

Technical review. For each technical resource document, a detailed outline will be developed by OEHHA and commented on internally by the IAWG. This will provide the foundation for writing the document, which will undergo OEHHA internal review, and further IAWG review. Each document will then undergo technical review by external peer reviewers selected on an *ad hoc* basis (See Figure 2). Criteria for reviewer selection will include area and level of expertise, recognition in specific technical area and familiarity with the ecological risk assessment process. To ensure balanced representation, technical reviewers from government institutions, academia, non-profit/environmental groups and the private sector will be invited. The use of *ad hoc* peer reviewers who are experts from outside of California state government will provide independent recommendations on technical and scientific aspects of the guidelines, and may also provide review in areas of expertise not widely available within Cal/EPA. Due to the broad range of topics that the guidelines will potentially encompass, *ad hoc* groups of experts from various fields rather than a standing review committee will be more appropriate for peer review purposes. This peer review process will conform to all applicable requirements of Senate Bill 1320 (SB 1320, Statutes of 1997, Chapter 295).

Public review. Each technical document that has undergone peer review and subsequent appropriate revisions will be released for a 60-day public comment period (Figure 2). Availability of documents will be announced through publication in the California Regulatory Notice Register, through posting on OEHHA's web site (www.calepa.cahwnet.gov/oehha), and by mailing announcements to individuals on mailing lists maintained for this purpose. The public review process is designed to provide ample opportunity for public input by releasing technical documents in a phased manner and by soliciting feedback from interested parties on an on-going, periodic basis.

TIMELINE FOR DEVELOPMENT

Anticipated timelines for current and proposed guideline components are summarized in Figure 3. Completion of documents will depend upon release of US EPA proposed guidelines as well as available resources within OEHHA.

Guideline Components	1998	1999	2000	2001-2003
General Guidelines - Adopt US EPA proposed guidelines for ERA				
California Ecological Endpoint Selection (Problem Formulation)				
Wildlife Exposure Factor/Toxicity Database (Analysis)				
Toxicity Extrapolation (Analysis)				
Population Model for ERA (Analysis)				
Measurement Endpoint Test Methods (Analysis)				
Non-Chemical Stressors (Analysis)				
Communication of Risk Assessment Findings (Risk Characterization)				

Figure 3. Anticipated timeline for initial Cal/EPA Ecological Risk Assessment Guidelines development

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California Department of Toxic Substances Control. 1996. Draft Guidance for Ecological Risk Assessment at Hazardous Waste Sites and Permitted Facilities, Parts A and B. California Environmental Protection Agency. Sacramento, CA.

Office of Environmental Health Hazard Assessment (OEHHA). 1995. Ecotoxicological Risk Assessment Workshop Series: Workshop Summaries. Submitted as a report to the Office of Environmental Health Hazard Assessment, Cal/EPA. Sacramento CA.

SB 1320. Statutes of 1997, Chapter 295.

US EPA. 1993a. Wildlife Exposure Factors Handbook. Volume I. EPA/600/R-93/187a. Washington, DC.

US EPA. 1993b. Wildlife Exposure Factors Handbook. Volume II. Appendix: Literature Review Database. EPA/600/R-93/187b. Washington, DC.

US EPA. 1996. Proposed Guidelines for Ecological Risk Assessment. Office of Research and Development. EPA/630/R-95/002B. Washington, DC.

Appendix 1. Cal/EPA Ecotoxicological Risk Assessment Workshop Series Recommendations

Source:
Recommendations below were reproduced verbatim from: Office of Environmental Health Hazard Assessment (OEHHA). 1995. Ecotoxicological Risk Assessment Workshop Series: Workshop Summaries. Submitted as a report to the Office of Environmental Health Hazard Assessment, Cal/EPA. Sacramento CA. pp. 99-104.[2]

Recommendations for Ecological Risk Assessment Guidelines and Practices.

One of the goals of this workshop series on ecological risk assessment practices is to provide Cal/EPA with a set of recommendations for how to prioritize their efforts in development of guidelines. A list of recommendations had been generated during the previous two workshops. These lists were not prioritized nor were they consensus views of all the participants. Attendees at this third workshop were divided into four breakout groups and asked to review these recommendations in order to add any additional ones and to put them into a general priority order. Breakout groups had 1.5 hours for discussion and then reported back to the general session. Cal/EPA regards these prioritized recommendations as one source of input to the process of determining the best approach to guideline development. Other input will be included as well as the process moves forward.

Workgroup Reports

General Recommendations
Twelve recommendations were selected as high priority. They were not prioritized further and are listed here in random order:

- make guidelines scientifically defensible
- provide clear definitions of terms
- use a tiered approach
- put the ecological risk assessment into the context of natural variability (spatial and temporal); this may require long term data sets.
    - ◊ currently, ecology often does not play a role. Ecological risk assessments really are toxicological exposure assessments.
- guidelines should be broad and flexible and incorporate subsections with case histories. Examples of subsections are:
    - ◊ point vs. nonpoint sources

[2] The views expressed in the workshops and workshop summaries are those of the speakers/authors and do not necessarily represent those of the Office of Environmental Health Hazard Assessment, the California Environmental Protection Agency or the State of California.

- ◊ prospective vs retrospective
- ◊ emergency versus deliberative

- include stakeholders in the risk assessment process
- provide guidelines on how to address and express uncertainty
- support the conduct of ecological risk assessments with population, community and ecosystem level studies
- use an interdisciplinary approach
- provide criteria for reference site selection
- consider cumulative (direct and indirect) impacts in an ecological risk assessment
- study design and analysis approaches need to be site-specific

A general discussion occurred of the need to take a holistic view of ecosystem processes. Some felt that this would be delimited by the definition of the Assessment Endpoints. The effects of a small site to a larger ecosystem in which it is imbedded should be covered under the "cumulative impact" assessments that are required. The comment was made that effects at one ecological scale above and below the level of study should always be done. Finally, the group concluded that a list of applicable or relevant and appropriate requirements (ARARs) would also be helpful.

Endpoint Recommendations

This presentation began with a discussion of Assessment *versus* Measurement Endpoints. Assessment endpoints depend on values and must be developed within a humanistic context. The guidance must explicitly define the two types of Endpoints, with examples of how they are related. In addition, guidance should provide examples of both good and bad endpoints in order to anticipate errors. The list of recommendations was separated into three groups: high, medium, and low priority. They were not further prioritized within each group. However, consensus was reached for which group each recommendation belonged in.

High Priority:

- develop guidance on endpoint selection, including definitions, populations, processes, and indirect effects
- develop guidance on how to develop "benchmark" doses/concentrations and/or the need to establish reference doses
- develop guidelines for selection of indicator species, guilds, or target species.
- consider indirect effects
- develop guidance on how to use and interpret sublethal endpoints, including growth, reproduction, behavior, and biomarkers.

Medium Priority:

- develop guidance on using California species or surrogates for bioassays

Low Priority:

- Define "death", especially for plants
- provide guidance on the use of QSARs

In addition the group recommended that ASTM develop guidelines for:

- bioassessments in bays and estuaries
- terrestrial in situ assays and community analysis methods

Finally, the group suggested that the following recommendations were relatively high priorities but belonged under other topics:

General Recommendations:

- develop guidance on selection and definition of reference sites

Exposure Recommendations:

- develop toxicity data for reptiles, amphibians, decomposers, birds, and California plant species
- develop guidance on how to extrapolate toxicity data among species, acute to chronic exposures, and LOAEL to NOAEL values
- develop guidance for difficult exposure assumptions

Further discussion of benchmark criteria revealed that everyone wants them but no one likes them. Some would like a table of values but others requested that guidance be provided for how to develop site-specific values.

Exposure Recommendations

The following points were discussed by the exposure assessment discussion group which consisted of 4 agency representatives, 4 consultants, and 2 DoD representatives. They are listed in priority order. Exposure data and guidelines for California species, including:

- uptake / intake factors (aquatic and terrestrial)
    - ◊ guidance for evaluating "internal dose" versus conducting a paper study on chemical intake / uptake
    - ◊ toxicity bioassays approaches with California species for both laboratory and field tests to determine bioaccumulation uptake / intake
- guidance for how to deal with spatial and temporal considerations in exposure assessments, variability in contaminant concentrations, and short-term "pulse" exposures versus continuous, long-term exposures including:
    - ◊ models
    - ◊ chemical fate and transport
    - ◊ data and methods for probabilistic assessments

    - ◊ QA/QC protocols (lab and field)
    - ◊ species selection
- methods and guidelines for selection of reference sites, including guidance on statistical methods for comparison of reference and study sites
- data and guidelines for chemical bioavailability factors
- trophic transfer factors, particularly for terrestrial systems
- information on characteristics and behavior of species life history, habitat preferences, feeding behaviors, etc. i.e., an Exposure Factors Handbook for California
- A reference list for literature, guidance documents, models, etc. that are appropriate for use in ecological risk assessments.

Other issues of lower priority were discussed. These included:

- information / guidelines on what methods will be acceptable to OEHHA
- justifications for species selection
- data on addressing avoidance, recovery, attractiveness issues
- BCFs (which ones should be used?)
- background concentration data for naturally-occurring inorganics in California
- appropriate surrogate species
- site size and a definition of how far “off-site” assessments should go
- methods, data, and guidelines for evaluating impacts to populations and communities
- evaluation of resident versus migrant versus native versus introduced species -- which have higher priority?
- watershed issues
- establishing DQOs for field data
    - ◊ sample size
    - ◊ natural variability
    - ◊ replicates
    - ◊ detection limits
    - ◊ controls
    - ◊ references

- duration of exposure -- default assumptions for how long an exposure to use
- consideration of nonpoint sources, including historical use of pesticides, background concentrations, urban issues, growth
- how to "frame" the ecological risk assessment to consider non-chemical stressors
- consideration of species that may not be onsite even though you may "expect" them to be onsite on basis of information from the California natural diversity database (CNDDB)
- guidance on when to consider the most sensitive species and life stages
- chemical concentration data to use (mean? 95% UCL? max? distribution?)
- information on critical habitats, ecosystems, species distributions
- modeling considerations of chemical bioconcentration, bioaccumulation, biomagnification

A suggestion was made during discussion to look at the information produced by the International Biome Program in order to get background ecological data (e.g., nutrient cycling rates). For example, the Desert Biome Project was run collaboratively by UCLA, Utah State, BYU, and U. of Nevada.

Risk Characterization and Communication Recommendations

Separate lists were drafted for risk characterization and risk communication. There was considerable discussion within this group of whether it is appropriate to have communication guidance in an ecological risk assessment as it really is part of the larger RI/FS process. Also, the use of professional communicators and facilitators should be encouraged. Therefore, the discussion focused on communication outside the assessment process. The group felt that all the points on the list of risk characterization and communication recommendations developed from previous meetings were valid. In addition, they identified the following priority items:

Risk Characterization:

- define risk characterization approach in the Problem Formulation step. You need to know where you are going before you start.
- Make sure there is a balance between ecology and toxicology
- terminology is very important. We need good definitions of ecology, toxicology, ecotoxicology and so on.
- define whether or how indicator species will or will not be used in risk characterization
- define how to characterize risk associated with chemical mixtures
- define how non-chemical stressors will be characterized

Risk Communication:

- determine whether risk communication guidance should be in an ecological risk assessment guidance document
- if yes, define how, by whom, to whom, and when to communicate risk
- every ecological risk assessment should contain some risk communication (e.g., interpretation of results, how to place results in perspective)
- recognize education (risk communication) is never complete