PRACTICES, NEEDS AND METHODOLOGIES FOR HUMAN EXPOSURE ASSESSMENT AT Cal/EPA: REPORT OF THE MMRA PROJECT TEAM

FINAL INTERIM REPORT

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Hazardous Waste Toxicology Section
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency

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Identification of Practices and Needs for Human Exposure Assessment at Cal/EPA: Report of the MMRA Project Team

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CHAPTER 1

INTRODUCTION

1.1 Background of the Project

The Multimedia Risk Assessment (MMRA) Project developed as a result of findings and recommendations of the Risk Assessment Advisory Committee (RAAC). This committee of scientists with expertise in risk assessment was convened to conduct external peer review of risk assessment practices in the boards, departments and offices (BDOs) comprising the California Environmental Protection Agency (Cal/EPA). The committee held its first public meeting in June 1995 and published its report, *A Review of the California Environmental Protection Agency's Risk Assessment Practices, Policies, and Guidelines*, in October 1996 (RAAC, 1996).

The RAAC concluded "Cal/EPA's risk assessment products are of good quality both from the perspective of scientific credibility and professional practice." However, the Committee stated that "Cal/EPA does not appear to be aware of some of the leading edge modeling techniques available and some of these may be superior in performance to the models routinely used." The Committee also noted that there were some differences in risk assessments performed by boards and departments in Cal/EPA and their counterparts at the U.S. Environmental Protection Agency (U.S. EPA).

The committee recognized the efforts of the Department of Toxic Substances Control (DTSC) to develop the multimedia approach of *CalTOX, A Multimedia Total Exposure Model for Hazardous Waste Sites* (DTSC, 1993). The Committee also recognized the efforts of the Air Resources Board (ARB) and the Office of Environmental Health Hazard Assessment (OEHHA) to develop the multimedia *Air Toxics "Hot Spots" Program Risk Assessment Guidelines* (CAPCOA Guidelines) methodology (CAPCOA,1993). However, it noted that "there are two processes, driven by two groups within Cal/EPA and two different statutory authorities" with different goals to accomplish, and each focused on the fate and transport of chemicals following emission into one environmental medium: soil, in the case of *CalTOX*, and air, in the case of *Air Toxics "Hot Spots" Program Risk Assessment Guidelines*. Neither deals with releases into multiple environmental media. The RAAC also noted that some programs in Cal/EPA do not use multimedia fate and transport modeling or human health risk assessment.

The RAAC report contains a number of recommendations that are directly related to multimedia risk assessment. One of the recommendations highlighted in the report is that "Cal/EPA should take steps to integrate fate and transport modeling efforts with human exposure assessment." Other highlighted recommendations are that "Cal/EPA should put more emphasis on receptor-based exposure assessment when it is appropriate and cost-effective" and that "Cal/EPA should improve the characterization of uncertainty and variability in risk assessments and in communication of this information to risk managers and the public."

1.2 Overview of Project Goals and Organization

The goal of the project is first to identify methodologies for predicting multimedia environmental fate and transport and to identify algorithms for all significant routes of exposure to environmental contaminants. The methodologies and algorithms that are consistent with the above RAAC recommendations and also are appropriate for use in the majority of human health risk assessments reviewed in programs in Cal/EPA will be recommended for inclusion in a model integrating multimedia fate and transport with human exposure assessment.

One objective of the MMRA Project is to identify appropriate methodologies for predicting multimedia fate and transport of chemical contaminants. Tasks required to reach this objective are being performed by staff of the Department of Civil and Environmental Engineering at the University of California, Davis. Information from tasks focusing on fate and transport modeling is not contained in this report but is available in a separate report (Uddameri and Young, 1999).

In 1998 the MMRA Project Team comprised of OEHHA staff with technical expertise in human health risk assessment was established to work toward the goal of the MMRA Project. In the same year, an Inter-Agency Work Group comprised of employees of the boards and departments of Cal/EPA and members of the MMRA Project Team was established to provide input on risk assessment practices and needs throughout Cal/EPA and to provide critical review of MMRA Project products.

Two tasks to be completed during the first year of the project (Phase 1) were to identify both current uses and needs of Cal/EPA programs for exposure assessment methodologies and to identify documents on exposure assessment methodologies developed by U.S. government agencies, by California government agencies and by other organizations. A third task initiated during Phase 1 was the comparison of exposure algorithms recommended for use in several Cal/EPA programs.

The following three chapters summarize the results of three distinct Phase 1 tasks. Chapter 2 discusses the survey of exposure assessment practices and perceived needs by the BDOs of Cal/EPA. Chapter 3 contains summaries of guidance documents used in risk assessments submitted to, or used by programs within the BDOs of Cal/EPA. This chapter also summarizes certain "leading edge" methodological approaches. Chapter 4 presents results of a task undertaken as a pilot project for a major Phase 2 task: the detailed comparison of exposure algorithms in three documents summarized in Chapter 3. The pilot project is a comparison of *CalTOX*; the Air Toxic "Hot Spots" or CAPCOA Guidelines; and *Technical Support Document: Exposure Assessment and Stochastic Analysis* (TSD/EASA) algorithms and procedures (OEHHA, 2000). Chapter 5 summarizes results of certain Phase 1 tasks and describes major Phase 2 tasks.

CHAPTER 2

SURVEY OF EXPOSURE ASSESSMENT PRACTICES AND NEEDS AT CAL/EPA

2.1 Background Information

A recurring theme in the RAAC report is that Cal/EPA should address consistency in risk assessment practices across Cal/EPA programs. An investigation of exposure and risk assessment methodologies and guidelines used in certain Cal/EPA programs appears in the 1996 RAAC report. The MMRA Project Team elected to update the survey of current guidance for exposure assessment methodologies and to survey needs for exposure assessment guidance in Cal/EPA programs. The results of these surveys will help to define the exposure assessment component of a multimedia risk assessment model appropriate for use in many of the risk assessments coming to the attention of Cal/EPA programs. It will also help to identify highly specialized applications of human exposure assessment not easily incorporated into a general model.

A survey was provided to MMRA Inter-Agency Work Group members requesting information on their use(s) of exposure assessment, including the methodologies, guidance documents and computer models used in their individual programs. A copy of the survey is included as the Appendix, and the survey results are summarized in this chapter.

2.2 Survey Results

The following information was obtained from surveys completed by the Air Resources Board's (ARB) Emissions Evaluation Section (herein referred to as ARB); the Department of Pesticide Regulation's (DPR) Medical Toxicology Branch, Health Assessment Section (DPR/MTBHAS) and DPR's Worker Health Branch (DPR/WHB); the Regional Water Quality Control Boards (RWQCB/Regions 1, 5 and 6); the Department of Toxic Substances Control's (DTSC) Human and Ecological Risk Division (herein referred to as DTSC), and OEHHA's Hazardous Waste Toxicology Section (OEHHA/HWTS), Air Toxicology and Epidemiology Section (OEHHA/ATES), and Pesticide and Environmental Toxicology Section (OEHHA/PETS). The Integrated Waste Management Board does not formally conduct exposure assessment.

1. ***Does your program conduct exposure assessment, and if so, for what purpose?***
   As shown in Table 2-1, exposure assessment is widely used by Cal/EPA programs as part of the review of site-specific health risk assessments (HRAs). Examples of this include OEHHA/ATES's and ARB's review of "Hot Spot" facility HRAs and review of leaking underground storage tank sites by the RWQCBs. These HRAs are often used as a basis for developing cleanup criteria/standards and prioritizing sites for remedial action. Exposure assessment is also a component of chemical-specific HRAs, such as when OEHHA/PETS evaluates worker exposure to new pesticide active ingredients and when DPR/WHB makes regulatory decisions on registration and use of pesticides. Another example of chemical-specific HRAs include ARB's process of evaluating risks posed by toxic air contaminants. Exposure assessment is a key part in developing health-based standards or criteria, such as the RWQCB

water quality objectives, OEHHA/PETS Public Health Goals for drinking water, and DTSC's waste classification standards. DPR/MTBHAS estimates acute and chronic exposures to pesticides from daily ingestion of contaminated foods.

Table 2-1. Applications/Uses of Exposure Assessment in Cal/EPA Programs

Organization	Site-specific HRAs	Chemical-specific HRA	Health-based Standards/Criteria	Pesticide Exposure from Contaminated Foods	Research and Development
DTSC/HERD	Hazardous waste site cleanup		Waste classification		
OEHHA/ HWTS	Review of HRAs submitted to other State organizations		Reference dose development		Multimedia Risk Assessment Project
OEHHA/PETS	Fish consumption advisory levels	Exposure to new pesticide active ingredients	Development of Public Health Goals (PHGs)		
OEHHA/ATES	Assessing “hot spots” facilities	Evaluating toxic air contaminants and AB2588-listed substances	Development of acute/chronic reference exposure levels (RELs) and unit risk factors		
RWQCBs	Assessing leaking underground storagepl tanks and SLIC sites		Water quality objectives		
DPR/WHB		Registration and use of pesticides			
DPR/MTBHAS				Guidelines for acute/chronic exposures	
ARB	Assessing “hot spots” facilities	Evaluating toxic air contaminants			

2. Which approaches does your program use for exposure assessment – screening, detailed-deterministic, detailed-probabilistic?

Table 2-2 summarizes the responses to question 2. Most programs conduct or review screening or detailed deterministic assessments on a regular basis. In most programs, probabilistic assessments are only occasionally performed or reviewed.

Table 2-2. Approaches used in Cal/EPA Programs for Exposure Assessment

Organization	Screening	Detailed Deterministic	Detailed Probabilistic
DTSC/HERD	REG [1]	REG	OCC [2]
OEHHA/HWTS	REG	REG	OCC
OEHHA/PETS	REG	REG	OCC
OEHHA/ATES		REG	OCC
RWQCB-R1	REG	REG	OCC
RWQCB-R5	REG	OCC	NEVER
RWQCB-R6	OCC	OCC	NEVER
DPR/WHB	OCC	REG	OCC
DPR/MTBHAS	REG	REG	OCC
ARB	REG	REG	NEVER

[1] Regularly (REG)
[2] Occasionally (OCC)

3. Identify computer models or software programs that you use for exposure assessment and how frequently they are used.

A variety of computer software models are used for conducting exposure assessment at various Cal/EPA programs. Table 2-3 lists computer models and software programs used for exposure assessment by the Cal/EPA BDOs. From DTSC's *Preliminary Endangerment Assessment* (PEA) *Guidance Manual* (DTSC, 1994) and "*Leadspread"*, found in *Supplemental Guidance for Human Health Multimedia Risk Assessments* (DTSC, 1992*)*, spreadsheets have been developed to calculate exposure intake and blood lead concentrations, respectively. The DTSC *CalTOX* model presents the methods, assumptions, and inputs used for making exposure and dose estimates. The Health Risk Assessment Version 2.0 Program used by ARB and OEHHA/ATES incorporates algorithms and default values contained in the CAPCOA Guidelines and *Health Risk Assessment Guidelines for Nonhazardous Waste* Incinerators (ARB, 1990). ARB is currently developing a software program entitled *Hot Spots Analysis and Reporting Program* (HARP), which will incorporate Geographic Information Systems and exposure analysis using the probabilistic approach. The HARP program starts with emissions estimates and runs through air dispersion modeling, exposure assessment, and risk assessment (including stochastic module). The beta version of the model is currently being tested. The DPR programs and OEHHA/PETS utilize exposure assessment software programs specific to individuals ingesting foodstuffs containing pesticide residues and to pesticide workers.

Table 2-3. Computer Models and Software Programs Used for Exposure Assessment

Organization	Screening Assessment	Deterministic Assessment	Probabilistic Assessment
DTSC/HERD	Preliminary Endangerment Assessment Guidance Manual (PEA Manual); Leadspread	Leadspread	Multimedia Exposure Model for Hazardous Waste Sites (*CalTOX*); *CalTOX*, Part 3
OEHHA/HWTS	PEA Manual; Leadspread	Leadspread	
OEHHA/PETS		USEPA Pesticide Handlers Exposure Database (PHED) TAS, Exposure 1&2, *CalTOX*, Stella	Crystal Ball
OEHHA/ATES ARB		Health Risk Assmt. Version 2.0; Air Toxics Hot Spots Program Risk Assmt Guidelines for Nonhazardous Waste Incinerators; CAPCOA ACE 2588	Crystal Ball HARP
DPR/WHB		PHED	Crystal Ball; @Risk
DPR/MTBHAS		TAS, Exposure 1, Chronic Dietary Exposure Analysis	TAS, Exposure 4, Detailed Distributional Dietary Exposure Analysis

4. Identify any exposure pathways that you consider in exposure assessment and how frequently.
Exposure pathways evaluated by Cal/EPA BDOs depend to a large extent on individual program mandates. Table 2-4 shows the exposure pathways that are generally considered by the Cal/EPA programs that were surveyed.

Table 2-4. Exposure Pathways Typically Considered by Cal/EPA Programs

	INHALATION			INGESTION							DERMAL		
ORGANIZATION	Outdoor	Indoor	Shower	Soil	Surface Water	Ground Water	Homegrown Produce	Meat & Dairy	Fish & Shellfish	Breast Milk	Soil	Water	Foliage
DTSC/HERD	√	√	√	√	√	√	√	√	√		√	√	
OEHHA/HWTS	√	√	√	√	√	√	√	√	√	√	√	√	
OEHHA/PETS	√	√	√	√	√	√	√	√	√	√	√	√	
OEHHA/ATES	√	√		√	√		√	√	√	√	√		
ARB	√	√		√	√		√	√	√	√	√		
RWQCBs	√	√	√	√	√	√			√		√	√	
DPR/WHB	√			√			√	√			√		√
DPR/MTBHAS					√	√	√	√					

5. ***In estimating exposure dose, please identify which of the following is used and how frequently – biomarker of exposure, personal monitor data, actual measured concentration at the point of contact, estimates from ambient monitoring data, estimates from fate and transport modeling, assumed concentration at the point of contact.***

   Methods for estimating exposure dose vary widely across Cal/EPA programs. Measured environmental contaminant concentrations, ambient monitoring data, and fate and transport modeling are used for estimating contact-point concentrations either regularly or occasionally by the survey respondents. An assumed concentration at the point of contact is occasionally used in some programs and regularly used by DPR/WHB (*e.g.*, using Pesticide Handlers Exposure Database, or PHED values, and other surrogates). Personal monitoring data is used by OEHHA/PETS, DPR/MTBHAS and DPR/WHB (e.g., patches). Blood lead level is a biomarker of exposure that is occasionally used for exposure assessment purposes by OEHHA/HWTS. Blood lead level on a population mean basis is used as a point of departure in determining the impact of lead in OEHHA/ATES. OEHHA/PETS occasionally uses actual administered doses, primarily from animal studies, when developing public health goals for drinking water.

6. ***Identify any source/reference documents that you use for exposure factors and how frequently they are used.***

   References used by Cal/EPA programs for obtaining exposure factor values are primarily U.S. EPA or Cal/EPA guidance documents. Table 2-5 lists the reference documents used as sources of exposure factor values by the surveyed programs.

Table 2-5. Sources of Exposure Factors for Health Risk Assessments Reviewed in Cal/EPA

Exposure Factor Source	Cal/EPA Organization						
	DTSC HERD	**OEHHA HWTS**	**OEHHA PETS**	**OEHHA ATES/ARB**	**RWQCB Region 5**	**DPR WHB**	**DPR MTBHAS**
USEPA EFH (a)	Ö	Ö	Ö			Ö	Ö
USEPA RAGS (b)	Ö	Ö					
USEPA Fish Guidance (c)			Ö				
USEPA Livestock Dietary Exposure (d)							Ö
USEPA Pesticide Residue Tolerances Guidance (e)							
USEPA Drinking Water Health Advisory (f)			Ö		Ö		
USEPA Ambient Water Quality Guidance (g)			Ö		Ö		
ASTM RBCA (h)		Ö					
CMA/Versar Exposure Assumptions Analysis (I)		Ö					
AIHC Exposure Factors (j)		Ö					
CAPCOA Hot Spots Guidelines (k)		Ö		Ö			
***CalTOX* Model (l)**	Ö		Ö				
DPR HS-1612 (m)						Ö	
DTSC Supplemental Guidance (n)	Ö	Ö					
Prop 65 Regulations (o)			Ö		Ö		
OEHHA Exposure Assessment and Stochastic Analysis (p)				Ö			

a. U.S. EPA (1997a) *Exposure Factors Handbook*
b. U.S. EPA (1991a) *Risk Assessment Guidance for Superfund*
c. U.S. EPA (1995a) *Fish Sampling and Analysis Guidance*
d. U.S. EPA (1994a) *Procedure for Calculating Livestock Dietary Exposure*
e. U.S.EPA (1994b) *Guidance on the Number and Location of Domestic Crop Field Trials for Establishment of Pesticide Residue Tolerances*
f. U.S. EPA (1999a) *Drinking Water Regulations and Health Advisories*
g. U.S. EPA (1999b) *National Recommended Water Quality Criteria*
h. ASTM (1995a) *Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites*
i. CMA (1990) *Analysis of the Impact of Exposure Assumptions on Risk Assessment of Chemicals in the Environment*
j. AIHC (1994*) Exposure Factors Sourcebook*
k. CAPCOA (1993) *Air Toxics "Hot Spots" Program Risk Assessment Guidelines*
l. DTSC (1993) *CalTOX*
m. DPR-WHB (1993) *Guidance for the Preparation of Human Pesticide Exposure Assessment Documents*
n . DTSC (1992) *Supplemental Guidance for Human Health Multimedia Risk Assessment of Hazardous Waste Sites and Permitted Facilities*
o. Proposition 65 Regulations (Title 22, Cal. Code Regulations, Sec. 1200 et seq.)
p. OEHHA (2000) *Technical Support Document for Exposure Assessment and Stochastic Analysis*

7. ***Which of the following best describes the type of exposure factors you use – central tendency (mean, median), high-end (90-95th percentile), bounding estimate (99.99th percentile)?***
   Most of the surveyed Cal/EPA programs use both central tendency and high-end estimates of an exposure factor value. A bounding estimate is also occasionally used by DTSC, RWQCB/Region 5, OEHHA/PETS, OEHHA/HWTS, and regularly by DPR/WHB ("not necessarily a quantitative value"). OEHHA/ATES recommends using both a central tendency and a high-end estimate.

8. ***Describe the relative importance of the following sources of uncertainty on your program's exposure assessments – temporal dimensionality (e.g., short-term exposures, age of exposure), spatial dimensionality (e.g., migration over distance), environmental migration/transport/dispersion, environmental fate (e.g., biodegradation), exposure assessment modeling, receptor-related (e.g., exposure factors).***
   Environmental fate, exposure assessment modeling, environmental migration, transport, and dispersion and receptor-related uncertainty were rated as contributing the most to uncertainty in exposure assessment. Except for OEHHA/PETS who frequently evaluate short-term exposures, spatial dimensionality and temporal dimensionality are reported to contribute marginally less to uncertainty in exposure assessment.

9. ***Does your program use a probabilistic approach in exposure assessment? Are there plans in your organization to consider probabilistic (stochastic, Monte Carlo) methods as an improvement for exposure and risk assessment?***
   Senate Bill 1731 amends the Air Toxics "Hot Spots" Information and Assessment Act of 1987 to require OEHHA to prepare probabilistic risk assessment guidelines for facilities subject to the Act. The 1996 *Draft Technical Support Document for Exposure Assessment and Stochastic Analysis* (TSD/EASA) was released for public comment in December 1996. ATES responded to public comment and revised the document accordingly. It has been reviewed by the State's Scientific Review Panel on Toxic Air Contaminants and was finalized in October 2000.

   Cal/EPA programs using the stochastic approach include DTSC, DPR/MTBHAS, DPR/WHB, OEHHA/HWTS, and OEHHA/PETS. Most programs describe this as occasional use and that they anticipate using the probabilistic approach more in the future. ARB, the local air districts and OEHHA/ATES are mandated to use the OEHHA guidelines for probabilistic risk assessment, once finalized. The RWQCBs surveyed are not using the probabilistic approach and either do not plan to use this approach or are not sure whether it will be considered in their programs.

10. ***Identify the guidance documents that you use in your probabilistic approach, and the relative frequency***.
    DTSC regularly uses *CalTOX* as guidance in generating exposure factor distributions and for conducting stochastic analyses using the Monte Carlo method. DPR/MTBHAS uses the *Draft Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Program* (U.S. EPA, 1998c). OEHHA/PETS uses the *Santa Monica Bay Seafood Consumption Study* (SCCWRP/MBC, 1994) for generating probability density functions for fish consumption. ARB defers stochastic analysis to OEHHA/ATES. OEHHA/ATES is using the U.S. EPA Exposure Factors Handbook while revising their technical support document.

OEHHA/HWTS uses U.S. EPA guidance, Regional U.S. EPA guidance documents, and a number of reports and textbooks for probabilistic exposure and risk assessment. The Federal documents include: the *Draft Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs* (U.S. EPA, 1998a); *Policy for Use of Probabilistic Analysis in Risk Assessment* (U.S. EPA, 1997b); *Exposure Factors Handbook; Guiding Principles for Monte Carlo Analysis* (U.S. EPA, 1997c); and *Characterization of Uncertainties in Risk Assessment with Special Reference to Probabilistic Uncertainty Analysis* (U.S. Dept. of Energy, 1996a). The Regional U.S. EPA documents include *Use of Monte Carlo Simulation in Performing Risk Assessments* (U.S. EPA, 1995b) and *Use of Monte Carlo Simulation in Risk Assessments* (U.S. EPA, 1994c). Other occasional guidance documents are *Exposure Factors Sourcebook* (AIHC, 1994) and the *Analysis of the Impact of Exposure Assumptions on Risk Assessment of Chemicals in the Environment* (CMA, 1990).

11. Identify the software that you use in your probabilistic approach, and the relative frequency.

Commercial software used by various Cal/EPA programs (DPR/WHB, OEHHA/HWTS, OEHHA/PETS) for conducting Monte Carlo variance propagation analysis include Crystal Ball and @RISK.

DPR/MTBHAS uses the Exposure software program and plans to use DEEM in the future.

BestFit and C-Fit are used by OEHHA/HWTS for developing the exposure factor probability density functions used in the Monte Carlo simulations.

ARB, the local air districts and OEHHA/ATES will be using the ARB program HARP following its revision after beta testing.

12. Briefly identify the issues – and their relative priorities- in screening, site-specific, probabilistic exposure assessment, and "others" that in your opinion we should address as part of the MMRA project.

Table 2-6 summarizes issues in exposure assessment that the Cal/EPA BDOs have brought forward to the MMRA Project Team for consideration.

Table 2-6. Suggested Issues in Screening, Site-Specific, and Probabilistic Exposure Assessment

Organization	Screening Exposure Assessment	Site-Specific Exposure Assessment	Probabilistic Exposure Assessment
OEHHA/HWTS	Exposure algorithms & factors must have sound technical basis		Data reporting guidance and interpretation
OEHHA/PETS	Comprehensive list of default factors and single (or limited) exposure media models	Give priority to standard of data quality; evaluate models using sensitivity analyses	Generate California and ethnic-specific distributions
OEHHA/ATES		Consider half-lives, bioaccumulation factors, plant uptake factors	Increase research for determining variability distributions and longitudinal studies
RWQCB/Region 5	Minimum data quality requirements	Tiered approach using conservative default values; consider background exposure (e.g. metals)	Define science policy goals from probability output
DPR/MTBHAS	Address dietary exposure using tiered approach		Give priority to quality of data sets used to generate probability values
DPR/WHB	Exempt some data or consider insignificant exposure; use conservative deterministic approach	Site-and pesticide-specific data for pesticide users	Use as a tool to integrate multimedia sources

Other issues were identified by the Cal/EPA programs with respect to the exposure assessment component of the MMRA Project. DTSC suggests working to achieve agreement between DTSC and RWQCBs on a model for measuring subsurface transport of chemicals. ARB recommends that all MMRA information should interface with the future HARP and OEHHA TSD/EASA guidelines. The information should include cumulative facility exposure, indoor air exposure, balancing the practical and academic need for mass conservatism, and improving deposition velocity information. DPR/WHB gives high priority to the use of biomonitoring as the ultimate tool for integrating multimedia sources. RWQCB/Region 5 noted that, in complying with water quality objectives from water quality control plans, the State and RWQCB's aims are to achieve compliance throughout the water body. They also suggest that populations with higher than average exposures (e.g., subsistence fishers) be addressed.

OEHHA/HWTS views the use of Data Quality Objectives (e.g., number of samples, sample location, quality of analytical method, and statistical analysis) as a critical component of exposure assessment. For screening exposure assessment, OEHHA/PETS would like to see a consistent set of exposure

values for both human and animal parameters and some way to account for exposure to background chemicals. For probabilistic exposure assessment, PETS is interested in joint probability distribution functions and using ranges of dermal exposure for different pesticide handling activities and exposures from contaminated foods. Another issue OEHHA/PETS reported is what constitutes a "chronic" exposure when they are confronted with effects from repeated intermittent (e.g., annual seasonal) exposures. For example, how long would individual exposures have to be (e.g., total days per year) to be considered chronic exposures?

13. Identify the issues in exposure assessment that in your opinion are not important to address as a component of the MMRA Project.

(i) DTSC commented that they have the PEA Guidance and *CalTOX* for use in screening and site-specific/probabilistic exposure assessments, respectively.

(ii) DPR/WHB identified the use of the probabilistic approach and biomonitoring as issues not important to screening exposure assessment. They identified the inclusion of drinking water and dietary intake as not important with respect to site-specific exposure assessment in their program. For probabilistic exposure assessment, DPR/WHB does not consider knowledge of probability density functions for every exposure-related factor as being an important issue. They also describe use of biomonitoring calculations of exposure from different sources as not being important to this project.

(iii) OEHHA/PETS Fish Team states that it is not important to have agency - or program-specific models for screening exposure assessments.

14. If you have any additional comment or suggestion related to the exposure assessment component of the MMRA project, please let us know.

(i) OEHHA/ATES commented that the MMRA Project needs to develop more focus and that the purpose of the project needs to be better defined.

(ii) DPR/WHB noted that biomonitoring seems to be the best assessment tool provided the underlying pharmacokinetics are well understood. They believe this approach would eliminate a lot of uncertainties inherent in MMRA, such as dermal absorption, whether events should occur concurrently, etc.

(iii) RWQCB/Region 5 commented that compliance with environmental standards does not necessarily hinge on risk assessment methods. Responsible parties often try to use the results of HRAs to justify noncompliance with environmental standards. The MMRA guidance document should clearly differentiate between these.

(iv) RWQCB/Region 6 doubts that there is or soon will be expertise in their office to properly model exposure assessment.

(v) RWQCB/Region 1 noted that U.S. EPA-Region 9 Preliminary Remediation Goals (PRGS), or chemical concentrations that correspond to fixed levels of risk in soil, air, and water, are frequently used by consultants to support closure requests. RWQCB warns that these values are not usually protective of water quality.

(vi) OEHHA/PETS cited a need to develop approaches to characterize cumulative (exposures to chemicals with similar mechanisms of action) and aggregate (exposures to the same chemical from different sources) exposures for various pesticides.

(vii) OEHHA/PETS suggests that the project address how to handle data points below the limit of detection, acknowledging that extrapolation methods need to account for different patterns of data distributions.

2.3 Conclusions

The survey results clearly indicate that Cal/EPA BDOs use exposure assessment for a variety of purposes. Exposure assessment is conducted to define the baseline risk and mitigation objectives in site-specific risk assessment, or to establish health criteria in chemical-specific risk assessment. While site-specific exposure assessments require site-specific environmental and receptor data, chemical-specific exposure assessments generally use default exposure factors. A tiered approach – from screening to refined analysis – is used by most BDOs when conducting exposure assessment. Models used by Cal/EPA for exposure assessment address contaminant releases (scheduled such as stack emissions or unscheduled such as a spill) to a single environmental medium rather than releases to multiple environmental media. Although most programs rely on deterministic exposure assessment, there is a trend towards using the probabilistic approach as a further refinement of the deterministic approach.

Cal/EPA programs performing site-specific risk assessment require sampling and monitoring data to estimate site contaminant concentrations. Even when fate and transport modeling is employed to estimate environmental concentrations, emissions data from sampling are used. On the other hand, default assumed values are generally used for exposure parameters in site-specific risk assessment. Similar or identical default values are used for quantifying human exposure in chemical-specific risk assessments that are used to support advisory or regulatory chemical levels.

Each Cal/EPA program considers exposure pathways that are germane to its program mandate for conducting exposure assessment. The exposure pathways listed in Table 2-4 will be considered as the MMRA Project attempts to address all relevant exposure pathways resulting from contaminant releases into multiple environmental media. Refinement of the intake algorithms describing these pathways will require ongoing interaction with the Cal/EPA programs.

Most Cal/EPA programs rely on U.S. EPA guidance documents for conducting or reviewing exposure assessment. In general, most of the surveyed Cal/EPA programs use both central tendency and high-end estimates of an exposure factor value. A necessary project will involve compiling exposure factor values listed in the guidance documents and noting when different default values are identified for the same parameter. This task will be followed by an evaluation of the basis for using different values for a particular parameter in different programs within Cal/EPA.

There is a trend in Cal/EPA towards using the probabilistic approach when conducting exposure assessment. Both U.S. EPA and the State of California (OEHHA/ATES and DTSC/HERD) have been developing probabilistic exposure assessment guidance in recent years. Given the increased application of the probabilistic approach, the MMRA Project will be following its further development.

Several important issues concerning the MMRA Project emerged from the survey (see Table 2-6). Most programs stressed the importance of the quality of data used to estimate exposure and some suggested that Data Quality Objectives be required for the environmental sampling and analysis process. A few survey respondents indicated that exposure assessment could be improved through refinements specific to their programs. For example, DPR would like to address dietary exposure using a tiered approach (screening assessments) and also give high priority to addressing specific pesticide uses (site-specific assessments). OEHHA/PETS is interested in the ability to generate California-specific and ethnic-specific distributions in probabilistic exposure assessment. RWQCB/Region 5 suggests that more consideration be given to natural background levels of exposure to chemicals, especially metals. Finally, OEHHA/ATES noted the importance of continued research on the half life of chemicals in the atmosphere, on fish bioaccumulation factors and on plant uptake factors for use in site-specific exposure assessment. It is clear that there are many outstanding issues that will require attention as we progress towards building an exposure assessment model that can be used for most Cal/EPA programs.

CHAPTER 3

DOCUMENTS ON EXPOSURE ASSESSMENT METHODOLOGY AND PARAMETERS

3.1 Background

This chapter describes documents that may be useful sources of methodology or data for multimedia human exposure assessment. They were identified from several sources. The first source was the surveys, discussed in Chapter 2, of exposure assessment practices in the BDOs of Cal/EPA. The second was a systematic literature search for U.S. government documents on topics related to exposure assessment. The third was professional experience of scientists at Cal/EPA who review risk assessment documents prepared outside Cal/EPA.

From the documents identified, 33 were selected as being likely to contain information that is relevant to the goals of the MMRA Project. Criteria for this selection include (1) publication by an agency with experience in exposure assessment, (2) current use for exposure assessment guidance by an agency of the U.S. or California government, and (3) presentation of information being developed to improve exposure assessment methodology. Each of the selected documents is summarized, and its potential significance for the MMRA Project is highlighted.

These documents have been reviewed and summarized in order to facilitate the task of evaluating alternative methodologies for exposure assessment. Accordingly, the summaries note if formal exposure algorithms are included and if an algorithm is described for each major exposure pathway. Data input requirements and availability of software for calculating exposure are noted when information is available in a document.

The reviewed documents have been placed in several categories. Documents in the first group address exposure to contaminants released into an environmental medium and their subsequent inter-media transfer. This category is subdivided into documents that address releases into air and those that address releases into soil or groundwater. Documents in the second category discuss principles or methodologies for estimating systemic absorption by a specific route. Documents in the third category contain information on exposure factors, and those in the fourth discuss the probabilistic approach for characterizing uncertainty and variability in exposure assessment. The final, fifth category includes guidance for assessing health risks resulting from exposure to chemical mixtures.

3.2.1 Guidance Documents for Contaminants Released into Air

(a) ***Air Toxics "Hot Spots" Program Risk Assessment Guidelines***. Revised 1992. Toxics Committee of the California Air Pollution Control Officers Association (CAPCOA). 1993.

Status of the Document

No record of peer review or public comment appears in the document.

Purpose of the Document

The purpose of the document is to provide risk assessment procedures for use in the preparation of the health risk assessments required under the Air Toxics "Hot Spots" Information and Assessment Act of 1987. These procedures and guidelines are for estimating human health risks due to chemicals released from a site into ambient air.

Contents

The document contains an overview describing the stages of risk assessment, a section on risk assessment procedures, a section on organization of health risk assessments and several appendices. Information on algorithms for exposure assessment is in Appendix E.

Data Inputs

Assessments prepared under these guidelines require data on chemical emissions and release parameters, meteorological data, and receptor locations.

Intake Algorithms

In most cases, the exposure algorithms are identical to those published by the South Coast Air Quality Management District (1988). This document is summarized in Section 3.2.1(b). There are, however, a number of modifications listed in Appendix E of CAPCOA (1993).

Model Output

From the results of a fate and transport model, estimates of exposure for each chemical emitted are specified for each receptor considered.

Potential Significance for MMRA Project

Each of the algorithms in this document for estimating exposure and uptake should be considered when evaluating methodology for estimating multi-pathway, multi-route exposure.

(b) ***Multi-Pathway Health Risk Assessment Input Parameters Guidance Document***. South Coast Air Quality Management District (SCAQMD). Prepared by Clement Associates. 1988.

Status of the Document

No record of peer review or public comment appears in the document.

Purpose of the Document

The purpose of the document is to describe an approach for conducting the exposure assessment component of a multiple pathway health risk assessment for chemicals emitted into air.

Contents

The document discusses the estimation of chemical concentrations in soil, food, surface water, indoor dust and mother's milk. It also contains exposure algorithms for estimating uptake of chemicals in these media as well as ambient air and aerosol.

Data Inputs

Assessments prepared under these guidelines require data on chemical emissions and release parameters, meteorological data, and receptor locations.

Intake Algorithms

This document contains an algorithm for the mother's milk pathway. A factor describing bioavailability is included in most algorithms. Exposure algorithms are similar in most cases to those later published by U.S. EPA (1989a), and exposure parameters recommended are similar, but not always identical to, those in U.S. EPA (1989a).

Model Output

From the results of a fate and transport model, estimates of exposure for each chemical emitted are specified for each receptor considered.

Significance for the MMRA Project

Each of the algorithms in this document for estimating exposure and uptake should be considered when evaluating methodology for estimating multi-pathway, multi-route exposure.

(c) ***Air Toxics Hot Spots Program Part IV: Technical Support Document. Exposure Assessment and Stochastic Analysis.*** California Environmental Protection Agency, Office of Environmental Health Hazard Assessment, Sacramento, CA. October, 2000.

Status of the Document

This document was released for public review and comment on March 10, 2000. The document, along with submitted comments, was considered by the Scientific Review Panel (SRP) of the Air Resources Board in a public meeting on July 16, 2000. The SRP agreed to accept the document when certain additions and changes were made. The revised document was submitted to the Lead Panel Member for approval and released in October 2000.

Purpose of the Document

The Air Toxics Hot Spot Information and Assessment Act (SB 1731) requires that OEHHA develop risk assessment guidelines for the Air Toxics Hot Spots program using a "likelihood of risks" approach to health risk assessment. This document describes methodology both for a deterministic approach for estimating exposure and risk and a stochastic approach for estimating exposure and risk. The stochastic approach leads to a distribution of exposure estimates in a risk assessment, and such a distribution of exposures can be used to characterize the likelihood of risks.

Content

This document describes air dispersion modeling of substances released into air from stationary sources. Three types of models are described: models used for screening purposes, refined models, and models describing special components of air dispersion such as building downdrafts.

The document describes algorithms for estimating human exposure to a substance that is present in several environmental media. Point estimates for exposure parameters in exposure algorithms are recommended, and for certain parameters a distribution is described.

A tiered approach to air toxics risk assessment is described in the document. In tier 1, default values for exposure parameters are used to characterize potential risks from air emissions. In tier 2, site-specific parameters are used if site-specific data are available for estimating these parameters. In tier 3, stochastic methods are used to sample distributions of parameters described in the document. Default values for exposure parameters are used when no distribution is described. In tier 4, site-specific data describing distributions of exposure parameters are used in the stochastic modeling of exposure.

Data Inputs

Data input requirements for air emissions are described as are data requirements for air dispersion modeling.

Intake Algorithms

The algorithms recommended in this document are similar in form to those used in the U.S. EPA *Risk Assessment Guidance for Superfund* (U.S. EPA, 1989a). Default values for exposure parameters are different in some cases from those recommended by U.S. EPA as are some of the exposure-scenario parameters describing human activity.

Software Used

In addition to the commercial software available for conducting a stochastic analysis, OEHHA and ARB have developed computer software that will perform the point estimate and stochastic assessments.

Data Output

The output from exposure calculations described in this document are expressed in milligrams per kilogram per day (mg/kg/day).

Significance for the MMRA Project

This document describes algorithms for multimedia exposure assessment along with default exposure parameters that will soon be published as guidance for risk assessments reviewed in the Air Toxics "Hot Spots" Program. These algorithms and default parameters will be considered for incorporation into the multimedia model. Distributions of data recommended in this document will also be considered in developing recommendations for stochastic exposure assessment using the multimedia model.

(d) ***Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities***. Peer Review Draft. Office of Solid Waste and Emergency Response, U.S. EPA. EPA-530-D-98-001A, B, C (three-volume set). July 1998.

Status of the Document

The *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* was prepared by the Multimedia Planning and Permitting Division, U.S. EPA Region 6, acting as lead organization, with the assistance of numerous other U.S. EPA offices, private business, and

academia. It has undergone extensive internal peer review and is being released for public comments.

Purpose of the Document

Regulatory agencies have published sufficient guidance for conducting evaluation of carcinogenic risks and non-carcinogenic hazards from direct exposure to released contaminants, but the evaluation from indirect exposures is more complex. The *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* is intended as guidance for performing human health risk assessment associated with direct and indirect exposure pathways from emissions from hazardous waste combustion units. The overall purpose of this document is to explain how risk assessments should be performed at hazardous waste combustion facilities. The *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* has been developed as national guidance to consolidate information presented in other risk assessment guidance and methodology documents previously prepared by U.S. EPA and state environmental agencies.

Performance of an exposure and risk assessment is necessary to determine whether the presence or release of a hazardous waste may present a substantial hazard, or to determine if permit conditions or additional permit conditions are necessary to protect human health and the environment.

Contents

In addition to direct exposure pathways as detailed in *Risk Assessment Guidance for Superfund* (U.S. EPA, 1989a), there can be significant risks from indirect exposure pathways (i.e., pathways other than direct inhalation) from hazardous waste combustion facilities. The food chain appears particularly important for bioaccumulation contaminants emitted from such units. The *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* is divided into three lengthy volumes.

Data Inputs

Volume 1 contains guidance on exposure scenario identification; exposure setting characterization; estimation of media concentrations and calculation of chemical concentrations in air, soil, produce, beef and dairy products, pork, chicken and eggs and drinking water and fish; quantifying exposure with generic exposure rate equations, consumption rates, exposure frequency and duration, averaging time and body weight; risk and hazard characterization with individual risk and hazard estimation; uncertainty interpretation; and limitations of the risk assessment.

Chemical-specific data are extensively presented in Volume 2. Topics include chemicals for consideration as compounds of potential concern; target organs and critical effects for compounds with reference doses; compounds-specific parameter values (physical and chemical properties, biotransfer factors for plants and animals, and human health benchmarks), and acute benchmarks.

Data Output

Estimation of media concentration equations, variable values, and intake of contaminants in soil, water, air, fish, produce and animal products, are extensively detailed in Volume 3. Contaminants are followed from their deposition on soil, to their movement in the environment (runoff, erosion, leaching, volatilization), uptake in plants, and intake in animals. Algorithms and description of variables and values are extensively documented, including references and recommendations on exposure scenarios and exposure factor values.

Intake Estimation

Algorithms, input data, values recommended, and output results, are thoroughly described. There is no software associated with this manual, and although some calculations are complex, commercial spreadsheet programs can handle them. The data outputs are clearly described, and the algorithms for the exposure pathway are well documented and easy to follow.

Significance for the MMRA Project

The Protocol is a comprehensive, thorough guidance document. It represents the next generation of the *Multipathway Health Risk Assessment Input Parameters Guidance Document* (U.S. EPA, 1988) that served as the basis for the development of the CAPCOA (1003) "Hot Spots" guidelines. It should be given close consideration for the MMRA Project.

(e) ***Methodology for Assessing Health Risks Associated with Multiple Pathways of Exposure to Combustor Emissions***. Update to EPA/600/6-90/003 Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions. U.S. EPA National Center for Environmental Assessment (NCEA), Cincinnati, OH. Publication No. EPA 600/R-98/137. December 1998.

Status of the Document

This report (MPECE) was prepared in response to the May 1993 Combustion Strategy for Hazardous Waste Incinerators released by the Administrator of U.S. EPA. The MPECE report supersedes the *Methodology for Assessing Health Risks Associated with Indirect Exposure to Combustor Emissions* (U.S. EPA, 1990) and the November 1993 Addendum to the 1990 report, both of which were reviewed by the U.S. EPA's Science Advisory Board and the public. The report also incorporates information from the Dioxin Reassessment Document (1994), the Mercury Report to Congress (1997), and the Utility Boiler Report to Congress (1997). Earlier versions of the *Methodology* report underwent internal Agency and external peer review.

Purpose of the Document

The purpose of the methodology is to provide a set of algorithms for assessing human exposures to atmospheric pollutants emitted from stationary combustion sources. The methodology also provides procedures to estimate indirect exposures that may result from uptake and transfer of atmospheric

agents through the terrestrial or aquatic food chains. The report provides ample information on how to apply the methodology.

Contents

The MPECE methodology includes analytical procedures and models for estimating exposures through direct and indirect pathways and risks resulting from atmospheric pollutants (*excluding incinerator ash*) that are emitted from a stationary combustion source. Direct exposures normally result from inhalation of combustor products. Indirect exposures result when the products of the combustor are transferred through the atmosphere and deposited downwind to environmental media (soil and water) and biota. Humans are secondarily exposed to multiple media (multimedia) by dermal contact, direct ingestion and/or ingestion of foods grown in the contaminated soil or water. The methodology is descriptive in nature, and requires other documents for performing tasks that require step-by-step guidance. For example, the methodology provides the algorithms and describes the parameters for calculating media concentrations, but it does not provide default values for these parameters. The methodology begins with designing an exposure scenario and ends with a presentation of risk characterization.

The methodology is not prescriptive, but rather provides procedures that the risk assessor can draw upon. The methodology provides numerous exposure scenarios, ranging from a screening framework to an in-depth analysis, a large number of selectable exposure pathways, and makes use of atmospheric dispersion models (ISC3 recommended), and extra sources of exposure such as background. The key assumptions and limitations associated with various environmental migration models, various exposure pathways, and intake algorithms, are clearly described. The methodology is supported with a model validation included in the report.

Data Inputs

The MPECE methodology requires a large number of chemical-specific, site-specific and exposure-pathway-specific factors. The document describes critical inputs, and key input parameters, providing the risk assessor with *a priori* guidance on *sensitive* parameters. Relevant input information for conducting indirect risk assessments includes the U.S. EPA Exposure Factors Handbook. A number of human exposure factors are presented as central tendency (mean or median) and upper end (90^{th} or 95^{th} percentiles) values. Default values are not recommended, but instead ranges of default are under development in a companion document.

Intake Algorithm

The methodology makes use of highly specific algorithms. The algorithms may be considered the next generation of the methodology developed for the South Coast Air Quality Management District in 1988 (Multi-Pathway Health Risk Assessment Input Parameters Guidance Document), and go a large step ahead of the current U.S. EPA RAGS methodology.

Software Used

No software is associated with this methodology. The approach can be constructed in a spreadsheet, but it would be tedious due to the large number of algorithms for fate and transport and exposure assessment.

Data Output

Dose estimates are normalized over body weight to express them in a manner that is consistent with dose-response relationships.

Significance for the MMRA Project

The methodology presented in the MPECE document should be evaluated to determine its applicability to the MMRA model. All pathways and contaminated media considered are relevant and appropriately discussed and updated for use as a sound scientific approach.

3.2.2 Guidance Documents for Contaminants Released into Soil and Groundwater

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(a) ***CalTOX, A Multimedia Total Exposure Model for Hazardous-Waste Sites.*** California Environmental Protection Agency, Office of Scientific Affairs, California Department of Toxic Substances, Sacramento, CA. 1993.

Status of the Document

This document is described as a "final draft" and as a "technical report," and it is labeled "Technical Report – Do Not Quote, Cite, or Use for Regulatory Action." It has undergone external peer review and has been released for public comment. It is the subject of a published review by an expert panel, the Committee on Risk-Based Criteria for Non-RCRA Hazardous Waste of the National Research Council (NRC, 1999).

Purpose of the Document

The document is to "build on and extend" U.S. EPA (1989a) guidance for risk assessment at contaminated sites. "The major objective of *CalTOX* is to provide risk managers and other decision makers with a more complete picture of both how potential human exposure comes about and how precisely it can be quantified for soil-bound contaminants." The model described in the document was developed to estimate human exposure to chemicals initially released into soil.

Contents

The document is divided into four parts. Part 1 contains an overview of the multimedia transport and transformation model and the human exposure model integrated into *CalTOX*. It also contains

discussions of data inputs and outputs and of capabilities and limitations of the model. Part 2 contains the equations used in the transport and transformation model. Eight environmental compartments are included in the model. Transfer of chemicals between compartments depends on transfer coefficients and concentration differences in boundary layers. Partitioning of a chemical between two phases in a compartment (*e.g.*, soil water and soil gas) is determined by thermodynamic equilibrium assuming that fugacity is directly proportional to concentration. Part 3 describes the multi-route exposure model integrated into *CalTOX*. Part 4 contains public comments and responses.

Data Inputs

The model requires three types of data: chemical-specific data, landscape data and exposure scenario data. Chemical data include concentration, molecular weight, octanol-water partition coefficient, Henry's law constant, molecular weight and solubility in water. Landscape data requirements include average annual wind speed, temperature, mixing layer thickness, rainfall, runoff, surface water depth, soil density, porosity, soil water content and root zone depth. Exposure parameters required as inputs include activity patterns, averaging time, soil ingestion, consumption rates of several categories of food, and parameters describing a residence.

Intake Algorithms

With the exception of dermal uptake, algorithms appear to be equivalent to those specified by U.S. EPA (1989a). However, in *CalTOX* physiological parameters are normalized to body weight and a range of values for these ratios is considered. This may not be completely consistent with the U.S. EPA methodology. For dermal exposure, *CalTOX* contains factors for calculating intake from water or soil in contact with skin.

Calculations

Calculations are performed by a spreadsheet that is available at no cost. CALTOX can be used stochastically if software for uncertainty analysis such as Crystal Ball or @RISK is added to the Excel spreadsheet.

Model Output

The model estimates human exposure from contact with multiple environmental media including soil, air, suspended particles, surface water and several categories of food.

Significance for the MMRA Project

Components of the *CalTOX* transport and transformation model may be useful in a screening level model. The algorithms for dermal uptake in *CalTOX* should be considered when evaluating methodology for estimating uptake by this route.

(b) ***Preliminary Endangerment Assessment Guidance Manual.*** California Department of Toxic Substances Control, 1994.

Status of the Document

This is a final document. No information on the extent of peer review is presented in the document.

Purpose of the Document

The PEA Manual offers guidance for conducting a "Preliminary Endangerment Assessment," or a screening evaluation that estimates the potential chronic health hazard from contamination at a site. The anticipated use of the evaluation is to assist the risk manager in deciding whether further site characterization, risk assessment, or remediation is necessary.

Contents

The PEA exposure assessment can be categorized as "screening-deterministic-generic." Although the evaluation is generally used for purposes of health risk assessment, it can also be used to calculate preliminary remediation goals (PRGs) by establishing an accepted risk level or hazard quotient, and back calculating to a concentration of contaminant in an environmental medium. The risk/hazard estimates are calculated for exposure pathways most frequently encountered at a residential setting. Health-conservative exposure factors are used. However, not all potential exposure pathways are included (*e.g.*, contaminant uptake by homegrown produce, ingestion of mother's milk).

The PEA exposure assessment is based on a number of methods, models, and assumptions commonly used by U.S. EPA to quantify risk/hazard. The manual makes assumptions about chemical groups and certain chemicals to simplify the evaluation (e.g., inorganic lead concentrations less than 130 ppm in soil constitutes an acceptable health risk). Maximum contaminant values reported from environmental sampling are recommended for use as the exposure point concentration. The default exposure factors are those recommended by U.S. EPA to represent a reasonable maximum exposure in a residential setting at Superfund sites. Finally, "reduced" risk and hazard equations (*i.e.*, equations in which exposure factors are combined into a single coefficient) are provided for easy hand or spreadsheet calculation of hazard and risk. The PEA methodology, including derivations of the risk/hazard algorithms, is clearly outlined in the text and appendices of the assessment manual.

Significance for the MMRA Project

The screening approach of the PEA methodology might be a useful resource for the screening portion of the multimedia risk assessment (MMRA) model. The basic approach to estimating chemical exposure is clearly outlined and user-friendly. Fate and transport models recommended in the PEA document may or may not be appropriate for use in the MMRA model. Exposure pathways would need to be evaluated for compatibility with the MMRA model. Default exposure factors would have to be updated to be consistent with current U.S. EPA and Cal/EPA practices.

(c) ***Supplemental Guidance for Human Health Multimedia Risk Assessments of Hazardous Waste Sites and Permitted Facilities***. California Environmental Protection Agency, Department of Toxic Substances Control, Office of the Scientific Advisor, 1992.

Status of the Document

This document consists of several chapters prepared by DTSC staff and scientists from Lawrence Livermore National Laboratory. Three chapters were removed from the document when *CalTOX* was issued. The report is identified as "interim final." No information on the extent of peer review is presented in the document.

Purpose of the Document

This guidance manual supplements U.S. EPA guidance by providing recommendations on specific technical issues that may be encountered when preparing multimedia risk assessment reports for submittal to DTSC.

Contents

Chapter 1: Default exposure parameters for residential, commercial/industrial, agricultural, and recreational exposure scenarios were excerpted from 1992 U.S. EPA reports and listed.

Chapter 2: Provides principles and methods for deriving the soil concentration term for use in pathway equations involving direct exposure to soil. Methods include data requirements, calculation of the source terms, use of negative analytical results, and correction for background. In addition to using U.S. EPA RAGS as a reference, the authors cite DTSC technical draft documents, journal articles, and other reports for developing their methodologies.

Chapter 5: Describes an indicator chemical approach for estimating exposures to complex waste mixtures when site-related chemicals exceed a manageable number or when toxicity data are not available for individual chemicals. Examples of how to determine chemical class and how to select indicator chemicals are presented. The approach is intended to be consistent with U.S. EPA RAGS.

Chapter 7: Guidance is provided for estimating blood lead concentrations in children and adults based on a multi-pathway analysis. Each pathway is represented by an equation relating incremental blood lead increase to a concentration in an environmental medium, using contact rates and empirically determined ratios. This approach ("Leadspread") is similar to that used by U.S. EPA in their IEUBK model.

Chapter 8: Describes how to estimate health risks from exposure to soil contaminated with DDT, DDD, and/or DDE. Exposure scenarios were developed assuming contamination is on agricultural land being developed for new uses. Exposure factors are recommended for soil ingestion rates, contact rates of soil with skin, and absorption of soil-borne DDT across skin. Factors are given fir estimating gastrointestinal absorption of DDT from ingested soil. Other exposure routes (dust, ingestion of homegrown produce) are also considered.

Data Input

The guidance provides default values that generally represent the reasonable maximum exposure and usually consistent with U.S. EPA values. Each chapter of the document identifies the sources of the input data.

Intake Algorithms

Algorithms are unique in the assessment of intake using Leadspread (Chapter 7). Each pathway relates incremental blood lead to a concentration in a medium (e.g., µg lead/dl blood per µg lead/day) and multiplies by contact rates and lead concentrations in that medium to obtain intake. Chapter 8 provides intake algorithms for many different scenarios (e.g., homemaker, children, community park) that estimate intake of DDT via soil ingestion, dermal absorption, and inhalation exposures. Algorithms are consistent with those used in U.S. EPA RAGS.

Software Used

The Leadspread model for estimating exposure to lead has been adapted to a spreadsheet, hence, the name. The software for this spreadsheet is easy to use and can be obtained from DTSC.

Data Output

The output from exposure calculations described in this document (except for Leadspread calculations) are expressed in milligrams per kilogram per day (mg/kg/day).

Significance for the MMRA Project

Chapter 1: The default exposure parameters are extracted from 1992 documents, therefore updates are inevitable.

Chapter 2: The methods used to derive a soil concentration might be useful because they looked at sources other than U.S. EPA RAGS.

Chapter 5: The indicator chemical approach described here might be useful for purposes of the multimedia model. A lot of chemical information was reported and could save some work.

Chapter 7: Leadspread might be considered for use in the multimedia model, however, DTSC should be consulted regarding the status of revisions, validation, etc.

Chapter 8: This chapter should be consulted if the multimedia model incorporates exposure to soil-borne DDT and exposure from other sources.

(d) ***Public Health Assessment Guidance Manual.*** U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR), Atlanta, Georgia. PB92-147164. March 1992.

Status of the Document

This document is the result of a cooperative effort of ATSDR, Oak Ridge National Laboratory, and state health departments participating in the ATSDR Public Health Assessment Cooperative Agreement Program. A draft was released in the *Federal Register* for public comment and was distributed to federal, state, and local entities, private consultants and corporations, and trade/professional organizations. Comments received were considered in finalizing the document.

Purpose of the Document

This guidance document addresses issues of quality assurance in the process of conducting health assessments. While U.S. EPA's risk assessment characterizes the nature and magnitude of risks to public health from exposure to hazardous substances, ATSDR's health assessment addresses specific community concerns by defining public health implications of a specific site. Accordingly, the health assessment not only characterizes the exposure, it also reviews specific community concerns and available health outcome data (medical records, morbidity and mortality data, tumor and disease registries).

Contents

The ATSDR document provides guidelines for evaluating site data, responding to community health concerns, determining contaminants of concern, identifying and evaluating exposure pathways, and determining public health implications. Toxicological data, human exposure information and health outcome data are reviewed in evaluating public health implications.

With respect to quantifying exposure, algorithms are provided for the following pathways: dermal (soil and water), ingestion (food, soil, and water), and inhalation. Default values for various parameters are also given. In particular, parameters for children as a sensitive sub-population are underscored. The U.S. EPA Exposure Factors Handbook is cited as a reference for default values not provided by ATSDR.

Significance for the MMRA Project

ATSDR's algorithms and default values should be compared and contrasted with those from other relevant documents.

(e) ***Risk Assessment Information System: Risk Assessment Strategy at DOE-ORO***. U.S. Department of Energy, Oak Ridge Operations. Publication No. ES/ER/TM-180, 1996.

Status of the Document

The U.S. Department of Energy contracted with Lockheed Martin Energy Systems, Inc. for the preparation of this document. There is no indication that the document has been reviewed by a third party.

Purpose of the Document

The document is developed to ensure that all risk assessments and related activities throughout the Oak Ridge Operations are carried out in a consistent and technically defensible manner. The manual defines the risk assessment strategy for DOE's Oak Ridge Operations in the CERCLA RI/FS process. It is for use in decontamination and decommissioning activities.

Contents

This document focuses on the baseline risk assessment and relies on existing U.S. EPA risk assessment guidance documents to provide specific details on conducting baseline risk assessment. It lays out a decision-tree to define the role and steps of risk assessment in the RI/FS process. Briefly, the process begins with a review similar to that of the DTSC Preliminary Endangerment Assessment. But in this case, it calls for using PRGs as a screen. RI is triggered when potential hazard is identified. The RI workplan will incorporate the Data Quality Objective of the baseline risk assessment. Data obtained from the RI will be used for the baseline risk evaluation.

The document also defines what exposure pathways will need to be considered under different land use scenarios- industrial, residential, and recreational. In addition, it gives algorithms and default parameters for calculating exposure doses. These algorithms and default values come from U.S. EPA RAGS (U.S. EPA, 1989a).

Because DOE facilities may handle radioactive materials, the assessment of radio-nuclides is also discussed. The manual further notes that RAGS does not address the food pathway. As such, Appendix F provides a discussion on food-chain modeling, including applicable transfer coefficients.

Significance for the MMRA Project

Since the objective is to provide guidance to environmental restorations at Oak Ridge facilities, and because it is based on U.S. EPA RAGS, the focus of the document is on soil cleanup. The document basically follows RAGS in providing guidelines for consideration of primary and secondary exposure pathways. However, it takes one step further than RAGS by addressing the food path in more detail.

The default values for various exposure parameters are somewhat dated. Data from the U.S. EPA Exposure Factors Handbook have not been included.

This document would be a useful resource for research and development efforts on the food pathway. While the document has not received extensive review, it provides another source of information for evaluation.

(f) ***U.S. EPA Guidelines for Exposure Assessment***. U.S. Environmental Protection Agency. 57 *Federal Register* 22888-22938. May 29, 1992.

Status of the Document

This document was reviewed by the Risk Assessment Forum, the Risk Assessment Council, subjected to an external public peer review, and presented to the EPA Science Advisory Board for final comment. In addition, the guidelines were reviewed by the Working Party on Exposure Assessment, an interagency working group under the Subcommittee on Risk Assessment of the Federal Coordinating Committee on Science, Engineering and Technology. The document is identified as "final guidelines."

Purpose of the Document

This document is intended to convey the general principles of exposure assessment. It is not a detailed instructional guide such as U.S. EPA's *Risk Assessment Guidance for Superfund.*

Contents

Consistent with its stated purpose, the document provides an overview of the general concepts in exposure assessment, covering topics such as exposure, intake, uptake, and dose. It also provides the guidance for planning an exposure assessment. Various considerations are discussed. First, it deals with developing data for estimating contact-point concentrations. The needs for establishing sampling strategies, data quality objectives, and modeling strategies are outlined. Second, it covers the application of data. Caveats associated with applying short-term sampling data to long-term exposure assessment are presented. Intake and uptake considerations are also discussed. Finally, the document provides some guidelines on uncertainty analysis and the communication of exposure assessment results.

Significance for the MMRA Project

This is a general guidance document, which provides the audience a feel for what needs to be considered in planning or conducting an exposure assessment. It does not discuss specific exposure assessment methods and algorithms, nor does it provide or discuss default exposure parameters. Therefore, it may be of limited use for the MMRA Project.

(g) ***Guidance for Conducting Remedial Activities and Feasibility Studies Under CERCLA***. Office of Emergency and Remedial Response, U.S. EPA. Publication No. EPA/540/G-89/004. Washington, D.C. 1988.

Status of the Document

This document is an Interim Final version. Training classes on its use were still being given to project managers four or five years ago, and it is in use by many project managers doing site investigation for remedial action.

Purpose of the Document

The purpose of this guidance is to provide the user with an overall understanding of the RI/FS process. Expected users include U.S. EPA personnel, State agencies responsible for coordinating or directing activities at National Priorities List (NPL) sites, potentially responsible parties (PRPs), Federal facility coordinators, and consultants or companies contracted to assist in RI/FS-related activities at NPL sites.

Contents

The document states that baseline risk assessments provide an evaluation of the potential threat to human health and the environment in the absence of any remedial action. It states that exposure assessment identifies actual or potential exposure pathways, characterizes the potentially exposed populations, and determines the extent of the exposure. The document describes in explicit text the purpose and steps in an exposure assessment, it describes Data Quality Objectives, identification of exposure pathways in a site conceptual model, and the need for quality assurance/quality control. But, it states that a detailed guidance is given in the "Superfund Public Health Evaluation Manual."

Significance for the MMRA Project

This document does not contain any risk assessment methodology *per se* and will be of limited use for the MMRA Project.

(h) ***Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual, Part A - Baseline Risk Assessment***. Interim Final. OSWER 9285.701A, EPA/540/1-89/002. Office of Emergency and Remedial Response, U.S. EPA. Washington, D.C. 1989.

Status of the Document

The Risk Assessment Guidance for Superfund (RAGS) is a thorough document that has undergone extensive peer review at U.S. EPA and nationwide. It is defined as "interim final" since final guidance will be issued when revisions to the National Oil and Hazardous Substances Pollution Contingency Plan become final.

Purpose of the Document

The RAGS document provides guidance for developing health risk information at Superfund sites, although the analytical framework and specific methods may also be applicable to other assessments of hazardous wastes/materials. The guidance is for conducting refined deterministic site-specific risk assessments.

Contents

U.S. EPA RAGS exposure assessment methodology follows the scientific principles described in the *Guidelines for Exposure Assessment* (U.S. EPA, 1992). The RAGS methodology calls for characterizing exposures from groundwater, surface water, sediment, air (outdoor only), soil, resuspended soil (dust), and food, making it appropriate for assessing exposure from multiple contaminated media. The exposure assessment process and individual steps are clearly described and include flow charts, summary tables, and examples. Issues that are critical to exposure assessment (e.g., characterizing potentially exposed populations, data quality, evaluating uncertainty) are clearly described. Information on exposure factors may require updating, but they can be found elsewhere, e.g., in Exposure Factors Handbook (U.S. EPA, 1997).

Data Input

Data input requirements for calculating exposure intake are clearly specified for each pathway. Default exposure factor values are provided in the required units, with percentile values and references cited. Median (50^{th} percentile) and upper-bound (90^{th} percentile) values are recommended for calculating typical reasonable maximum exposures. Pathway-specific values are recommended in cases where numbers will depend on specific site conditions (*e.g.*, local weather conditions) or human activity patterns (produce or fish consumption).

Intake Algorithms

The RAGS intake algorithms are universally used by federal and state risk assessors for conducting exposure assessments. The RAGS algorithms do not include factors accounting for *bioavailability* (the fraction of ingested contaminant that is released from the environmental matrix and is available for absorption). Default values for frequency (days/year), duration (years), and length (averaging time) of exposure are assumed. The RAGS algorithms for calculating ingestion of chemicals in soil and contaminated foods include the variable "*fraction ingested from the contaminated source.*"

Data Output

Intake values are expressed in milligrams per kilogram body weight per day (mg/kg·day). These units are universally used; they can be easily compared with reference doses, or with other measurements of internal doses expressed in mg/kg·day. Because cancer potency values are expressed as 1/(mg/kg·day), this allows for easy calculation of lifetime excess cancer risk.

Significance for the MMRA Project

U.S. EPA RAGS exposure assessment methodology follows sound scientific principles and the original recommendations made in the National Research Council (NRC, 1983). Despite its age, this RAGS document is the unquestionable reference document for the health risk assessment of contaminated sites. The RAGS methodology will be evaluated in the course of the MMRA Project.

(i) ***Risk Assessment Guidance for Superfund. Volume 1 - Human Health Evaluation Manual, Part B, Development of Risk-based Preliminary Remediation Goals***. Interim. Office of Emergency and Remedial Response, U.S. EPA. Washington, D.C. EPA/540/R-92/003, Publication 9285.7-01B. 1991.

Status of the Document

This document was developed by U.S. EPA's Office of Emergency and Remedial Response, with assistance and input from various offices of U.S. EPA. No reference was made with respect to any public review prior to the release of this interim guidance. By distributing the manual as an interim document, U.S. EPA intends to allow a period of field testing and review. U.S. EPA will revise and finalize the document at a later date.

Purpose of the Document

The purpose of the document is to assist risk assessors and remedial project managers involved in waste site cleanup to develop preliminary remediation goals (PRGs). In general, PRGs are contact-point environmental concentrations that serve as preliminary cleanup targets. They are developed early in the decision-making process (before the RI/FS and the baseline risk assessment are completed) to streamline the consideration of remedial alternatives.

Contents

A PRG is a health-based concentration for a specific chemical in a given environmental medium under a particular land use scenario. For example, a PRG in micrograms per liter (µg/l) for benzene in groundwater under a residential land use scenario can be established. There are two general methods for establishing PRGs - one is based on existing health standard, and the other is based on risk assessment. This document provides guidance on using the risk assessment method in developing PRGs.

Data Input

The main input is the acceptable risk level. The default value is 10^{-6} for cancer risk, or a hazard index of one for adverse health effects other than cancer.

Intake Algorithms

Algorithms for calculating PRGs are based on the equations given in U.S. EPA's Risk Assessment Guidance for Superfund, Volume 1, Part A. However, the terms in those equations have been re-arranged so that the risk-based contact point concentrations (PRGs) can be computed. Standard default assumptions for residential, commercial and industrial land use scenarios, instead of site-specific parameters, are also provided.

The equations for calculating ground or surface water PRGs take into account two exposure pathways - ingestion of water and inhalation of volatiles. The equations for soil PRGs, on the other hand, consider ingestion of soil, inhalation of volatiles, and inhalation of particulates.

Significance for the MMRA Project

This document together with other parts of the Risk Assessment Guidance for Superfund Volume 1, Part A, should be considered and evaluated in developing the MMRA Project.

(j) ***Risk Assessment Guidance for Superfund, Volume 1 – Human Health Evaluation Manual, Part C- Risk Evaluation of Remedial Alternatives***. Interim. Office of Emergency and Remedial Response, U.S. EPA. Washington D.C. Publication 9285.7-01 C. 1991.

Status of the Document

This document was developed by U.S. EPA's Office of Emergency and Remedial Response, with assistance and input from various offices of U.S. EPA. No reference was made with respect to any public review prior to release of this interim guidance. By distributing this manual as an interim document, U.S. EPA intends to allow a period of field testing and review. U.S. EPA will revise and finalize the document at a later date.

Purpose of the Document

This guidance was developed to assist project managers and risk assessors in using exposure and risk information at hazardous waste sites to evaluate remedial alternatives during the feasibility study and human health risks associated with selected remedial alternatives.

Contents

The guidance addresses short- and long-term health risks associated with a remedial activity. Evaluation of short-term risks associated with implementing remedial alternatives follow the same general steps as a baseline risk assessment and should follow guidance provided in RAGS Part A [see review in section 3.2.2(h)]. This Part C guidance contrasts exposure assessment when evaluating remedial alternatives versus that which occurs in a baseline risk assessment (e.g., exposure pathways may be added or removed as a result of remediation technologies). The identification and quantification of potential releases from selected remediation technologies is detailed in appendices. The document also provides guidance on the evaluation of long-term risks, which involves evaluating residual risk and the remedial alternative's ability to provide protection

over time. In these instances, PRGs [see review in section 3.2.2 (i)] usually provide the standard for evaluating long-term health risks.

Intake Algorithms

Algorithms for calculating intake from short-term exposures are based on the equations given in U.S. EPA's RAGS, Volume 1, Part A.

Significance for MMRA Project

This guidance will be useful to the MMRA Project if we incorporate into the model evaluation of risks associated with remedial activities at hazardous waste sites.

(k) ***Risk Assessment Guidance for Superfund. Volume 1 - Human Health Evaluation Manual, Part D - Standardized Planning, Reporting, and Review of Superfund Risk Assessments***. Interim. Office of Emergency and Remedial Response, U.S. EPA, Washington, D.C. Publication 9285.7-01 D. 1998.

Status of the Document

This interim document is a culmination of the U.S. EPA risk assessors' efforts to promote standardization in risk assessment review. Prior to release of this version, two earlier drafts were released for review by various U.S. EPA regions. While not a final document, U.S. EPA encourages its regions to use this guidance in their review of risk assessments.

Purpose of the Document

The main purpose of this document is to provide guidance to U.S. EPA staff in their review of risk assessments. The objective is to achieve review consistency among U.S. EPA regions through use of standard tools. Qualitative guidance is also given to encourage project managers to involve risk assessors even after the remediation investigation phase.

Contents

A total of 10 standard tables and one worksheet which correspond to data collection, data evaluation, exposure assessment, toxicity assessment, and risk characterization are described. These tables are in the form of a checklist to assist a reviewer in evaluating the proposed exposure pathways, the quality and appropriateness of environmental data, the proposed chemicals of concern, the values used for daily intake calculations, the computation of contact-point concentrations, the toxicity data, the calculation of hazard indices and carcinogenic risks, and the characterization of receptor risks.

Significance for the MMRA Project

While the current focus is to develop a MMRA method and guidelines for the conduct of MMRA, it would be desirable to develop additional guidance to standardize the review of multimedia risk assessments at a later stage. This document will be a useful reference at that juncture.

(l) ***U.S. EPA Soil Screening Guidance: Technical Background Document***. Second Edition. U.S. EPA Solid Waste and Emergency Response, Washington, D.C. Publication No. EPA/540/R95/128. May 1996.

(m) ***U.S. EPA Soil Screening Guidance: User's Guide***. Office of Solid Waste and Emergency Response. Publication No. EPA/540/R-96/018. PB96-963505. July 1996.

Status of the Documents

The policies in the Soil Screening Guidance: User's Guide and the supporting Technical Background Document are intended solely as guidance to U.S. EPA personnel; they are not final U.S. EPA actions and do not constitute rulemaking. These policies are not intended to create any rights enforceable by any party in litigation with the US Government. U.S. EPA officials may decide to follow the guidance or act at variance with the guidance, based on an analysis of specific site circumstances. U.S. EPA also reserves the right to change the guidance at any time without public notice.

Purpose of the Documents

The Soil Screening Guidance is a tool that U.S. EPA developed to help standardize and accelerate the evaluation and cleanup of contaminated soils at sites on the National Priorities List (NPL) with future residential land use. The guidance provides a methodology to calculate risk-based, site-specific, soil screening levels (SSLs) for contaminants in soil that may be used to identify areas needing further investigation at NPL sites. It does not replace the Remedial Investigation/Feasibility Study (RI/FS) or risk assessment, but it can focus the RI and risk assessment on aspects of the site likely to be of concern.

Contents

The soil screening process is a step-by-step approach for evaluating soil contamination at residential sites. The methodology includes developing a conceptual site model (CSM), comparing the CSM to the SSL scenario, defining data collection needs, sampling and analyzing soils at the site, calculating site-specific SSLs, comparing site soil contaminant concentrations to calculated SSLs, and determining which areas of the site require further study. The potential pathways of exposure to contaminants in soil in the SSL scenario are direct ingestion, inhalation of volatiles and fugitive dusts, ingestion of contaminated groundwater, dermal absorption, ingestion of homegrown produce, and migration of volatiles into basements. The ingestion, inhalation, and migration to groundwater pathways are treated quantitatively, while the potential for dermal absorption and plant uptake are qualitative and based on more limited empirical data. The Technical Background Document

analyzes the use of the Johnson and Ettinger Model for estimating the pathway for indoor inhalation of volatile organic compounds from subsurface soils. It suggests that use of this Model is limited due to its sensitivity to a number of parameters such as distance from the source to the building, building ventilation rate, and the number and size of cracks in a basement wall. Thus, instead of relying exclusively on the Model, data from a comprehensive soil-gas survey are recommended to address the potential for migration of VOCs in the subsurface. Soil gas data and site-specific information on soil permeability can be used to replace default parameters in the Johnson and Ettinger Model to obtain a more reliable estimate for the impact of this pathway on site risk. A simplified equation from the Jury Model describes a soil-to-air Volatilization Factor (VF) which defines the relationship between the concentration of the contaminant in soil and the flux of the volatilized contaminant to air. Pathways that involve surface water, local rivers and lakes, fish consumption, terrestrial or aquatic ecological concerns, and some subsurface geological conditions are omitted.

SSLs are risk-based concentrations based on future residential land use assumptions and related exposure scenarios, and are derived from equations which combine exposure information assumptions with U.S. EPA toxicity data. The generic SSLs use default assumptions chosen to be protective of human health for most site conditions in a residential setting, but site-specific SSLs involving 110 chemicals can be calculated. To calculate SSLs, the exposure equations and pathway models based on RAGS HHEM are run in reverse to back-calculate an "acceptable level" of a contaminant in soil. For the ingestion, dermal, and inhalation pathways, toxicity criteria are used to devise an acceptable level of contamination in soil, based on a one-in-a-million (10^{-6}) individual excess cancer risk for carcinogens and a hazard quotient (HQ) of 1 for non-carcinogens. SSLs are back-calculated for migration to groundwater pathways using groundwater concentration limits [nonzero maximum contaminant level goals (MCLGs), maximum contaminant levels (MCLs), or health-based limits (10^{-6} cancer risk or a HQ of 1) where MCLs are not available.]

Toxicity data are provided for 110 compounds in order to calculate SSLs. Only pentachlorophenol shows greater than 10% dermal absorption, which the guidance reports is necessary for absorption via the dermal route to equal or exceed the ingestion route. Therefore, pentachlorophenol is the only chemical for which the Soil Screening Guidance directly considers dermal exposure. In this case the ingestion SSL is divided in half to account for equivalent dermal exposure. Likewise, generic fugitive dust SSLs are several orders of magnitude greater than generic ingestion for semivolatile organics and metals. Ingestion SSLs are considered adequate protection for inhalation exposures to fugitive dusts and metals (except for chromium).

Data Input

The guidance provides a subsurface soil sampling strategy which follows the Data Quality Objective (DQO) process and recommends taking two or three soil borings that penetrate through the entire source area without going below the water table in the areas suspected of having the highest contaminant concentrations. Soil gas surveys and soil matrix sampling are recommended. The maximum contaminant concentration from composite samples is used as a conservative estimate of the mean. The highest mean subsurface soil boring concentration among a set of borings taken from the source area represents the mean of the entire source area. In contrast, quantitative baseline

human health risk assessment usually requires discrete environmental concentrations, rather than composites.

Intake Algorithms

The algorithms are based on the U.S. EPA Risk Assessment Guidance for Superfund Human Health Evaluation Manual, Part B. However, the approach for calculating non-carcinogenic SSLs leads to screening levels that are approximately three times more conservative than PRGs. The generic SSLs are based on a conservative "childhood only" exposure with an averaging time of six years. For carcinogens, the total dose is averaged over a lifetime of 70 years.

Significance for the MMRA Project

This guidance provides a strategy for evaluating the impact of soil contamination. The methodology will be evaluated for its applicability to the soil component of the MMRA model.

The applicability of the principle of DQOs will also be assessed. This includes sampling surface soil using DQOs to collect data needed to evaluate exposures via direct ingestion, dermal absorption, and inhalation of fugitive dust. An individual is assumed to move randomly across an exposure area (EA) of 0.5 acre or less over time, spending equivalent amounts of time in each location. The concentration contacted over time is represented by the spatially averaged concentration over the EA. Because determination of the "true" mean would require extensive sampling, the maximum contaminant concentration from composite samples is used as a conservative estimate of the mean. The strategy includes data quality assessment (DQA) with a false negative error rate of five percent (soil concentrations appear to be below the SSL when they are really above the SSL) and a 20% false positive error rate (soil concentrations appear above the SSL when they are really below it). A coefficient of variation (CV) based upon 250% variability in contaminant values (CV=2.5) requires six samples in each of four grids per 0.5 acre, with compositing of four samples, #1 from each grid, #2 from each grid, etc. A table of probabilities for error rates with CVs from 2.5 – 4.0 vs sample sizes from 6-9 per 0.5 acre is provided.

(n) ***Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities***. Revised Interim. OSWER Directive #9355.4-12. Office of Solid Waste and Emergency Response, U.S. EPA. Washington, D.C. July 14, 1994.

(o) ***Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities.*** Clarification to the 1994 Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities. U.S. Environmental Protection Agency. 1998.

Status of the Documents

These documents are policy directives issued by U.S. EPA's Office of Solid Waste and Emergency Response (OSWER) to EPA Regional Administrators. They are labeled as interim documents.

Purpose of the Documents

The directives establish and clarify OSWER's approach to assessing risks from lead in soil at CERCLA and RCRA sites.

Contents

In these directives, OSWER recommends a 400 ppm screening level for lead in soil at residential properties. These documents also describe how to develop both site-specific Preliminary Remediation Goals (PRGs) at CERCLA sites and media cleanup standards for residential land use at RCRA Corrective Action facilities. A third topic addressed in these documents is a strategy for management of sites that may have multiple sources of lead contamination.

This document uses EPA's Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children to identify a screening level of lead in soil at residential sites. The IEUBK model predicts blood lead concentrations in children exposed to lead in soil. The screening level of 400 ppm is the concentration of lead in soil predicted by the model to produce a blood lead level at or above 10 micrograms per deciliter (µg/dl) in no more than 5% of exposed children.

Significance for the MMRA Project

The methodology used in these documents for predicting blood lead levels in children should be evaluated for possible incorporation into the MMRA model.

(p) ***Standard Guide E1739-95e1 for Risk-Based Corrective Action Applied at Petroleum Release Sites (RBCA).*** West Conshohocken, PA: American Society for Testing and Materials (ASTM), Version dated September 10, 1995.

(q) ***Standard Guide for Risk-Based Corrective Action (RBCA)***. *Final Standard Version 4.0.* American Society for Testing and Materials (ASTM). West Conshohocken, PA. 1995.

Status of the Documents

These documents are reviewed together since they are essentially similar, differing primarily in that the first is applied to petroleum products and the second includes other chemicals. The first guide is under the jurisdiction of ASTM Committee E-50 on Environmental Assessment and is the direct responsibility of Subcommittee E50.01 on Storage Tanks.

The second document is part of the ASTM standards process and was reviewed by experts in an ASTM Technical Committee from U.S. and state government agencies, academic institutions, and the private sector. It is not an ASTM standard; it is under consideration within an ASTM technical committee but has not received all approvals required to become an ASTM standard. It is being balloted concurrently by the subcommittee and main committee and will be included in Standardization News for Society Review.

Purpose of the Documents

The first document was developed as a guide to risk-based corrective action (RBCA), a consistent decision-making process for assessment of and response to a petroleum release, based on the protection of human health and the environment. Since sites vary greatly in terms of complexity, physical and chemical characteristics and risk, the RBCA process uses a tiered approach where corrective action activities are tailored to site-specific conditions and risks.

The second document extends the RBCA process to halogenated and non-halogenated volatile organic compounds, alkylated benzenes, chlorinated benzenes, phenols, phthalate esters, PCBs and organochlorine pesticides, organic acids and bases, polycyclic aromatic hydorcarbons, and metals. Many of the components of U.S. EPA RAGS have been integrated into the RBCA framework.

Contents

A tiered approach is presented in these documents. Tier 1 evaluations utilize non-site-specific corrective action goals for complete and potentially complete direct and indirect human exposure pathways and qualitative ecological screening evaluation for complete and potentially complete exposure pathways for relevant ecological receptors and habitats. The non-site-specific corrective action goals for human exposure pathways assume that the receptor and the source are in the same location and are based on "conservative" deterministic assumptions. Fate and transport of petroleum products and exposure pathways are "hardwired" into the Tier 1 Risk-Based Screen Levels (RBSL) "look-up" tables.

The Tier 2 evaluation for human exposure pathways is an incremental refinement of Tier 1 methodology to develop site-specific corrective action goals. It may include:

1) developing statistically representative concentrations of chemical(s) of concern for comparison to the Tier 1 corrective action goals,
2) back-calculating Site Specific Target Levels (SSTLs) by applying a direct exposure pathway corrective action goal from Tier 1 to site-specific determined point(s) of exposure using site-specific conditions and Tier 1 methodology, or
3) developing SSTLs for complete or potentially complete exposure pathways using site-specific conditions, or
4) a combination of alternatives.

The Tier 2 evaluation for some chemicals(s) of concern and exposure pathways may also be based on comparison of site conditions to Other Relevant Measurable Criteria (ORMC) such as regulatory standards, groundwater protection criteria, consensus criteria, or aesthetic criteria.

Tier 3 evaluation involves a significant incremental effort over Tier 2 evaluation to develop site-specific corrective action goals. Tier 3 evaluations use probabilistic exposure assessment methods, bioavailability data, and advanced fate and transport modeling to develop SSTLs for potential direct and indirect exposure pathways at the point(s) of exposure based on site-specific conditions. Evaluation of ecological receptors and habitats is more quantitative in nature and uses more site-

specific data than previous tiers. Tier 3 evaluation for some chemicals of concern and exposure pathways may also be based on comparison of site conditions to ORMC.

RBSLs and SSTLs use slope factors and reference doses selected from IRIS, HEAST, and peer-reviewed sources and employ upper-bound conservative deterministic exposure parameters and a constant, non-diminished source. Default values are used to determine the levels of chemical(s) of concern in environmental media and the likely physical distribution of the chemical(s) of concern in development of RBSLs and SSTLs for Tier 1 and Tier 2. Determination of Tier 1 RBSLs and Tier 2 and 3 SSTLs generally involves the use of 1) chemical fate and transport models, 2) exposure assessment models, and 3) dose-response assessment models. Tier 2 SSTLs are consistent with U.S. EPA-recommended practices.

Data Input

Input data are concentrations of chemicals in groundwater or soil. Data quality objectives (DQOs), target risk levels, appropriate statistics and sample sizes for calculating exposure concentrations, selection of exposure assumptions, determining when and how to account for cumulative risks, and additive effects among chemicals(s) of concern are all considered "technical policy decisions" that must be made separately to implement RBCA. Chemical fate and transport models, exposure assessment models, and dose-response assessment models are part of RBCA. RBCA is a self-contained program that lacks the quality assurance/quality control (QA/QC) that is required for risk assessment.

The exposure algorithms are designed to protect groundwater and people from direct exposure to contaminants in soils or groundwater. Software is necessary and commercially available.

The output may be a RBSL, a non-site-specific human health risk-based value for chemical(s) of concern that are protective of human health for specified exposure pathways utilized during the Tier 1 evaluation. It may also be SSTLs, or risk-based values for chemical(s) of concern that are protective of human health for specified exposure pathways under the Tier 2 or Tier 3 evaluations. Exposure is not cumulative as RBSLs and SSTLs are based on single chemicals.

Significance for MMRA Project

This methodology and documents are somewhat complementary to the MMRA model, although the model was developed for leaking underground tank applications and it lacks applicability for 1) other sources, 2) receptors some distance from a source and 3) data quality assessment needed for quantitative human health risk assessment. The RBCA process is a self-contained process that incorporates fate and transport and exposure assessment into corrective action decisions from a specific source-type, leaking underground storage tanks.

3.3 Guidance Documents for Estimating Exposure Dose

(a) ***Dermal Exposure Assessment: Principles and Applications.*** U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. Publication No. EPA/600/8-91/011B. 1992.

Status of the Document

Experts from U.S. government agencies, academic institutions and the private sector reviewed this document in 1991. It is identified on the title page as an "interim report."

Purpose of the Document

The purpose of this document is to describe the principles of dermal uptake of chemicals and to show how to apply these principles in actual human exposure scenarios. It is intended for use in scenarios where soil is the medium that is initially contaminated. It is not intended for consumer or occupational scenarios where there is dermal contact with chemicals on or in products.

Contents

The document summarizes the state of knowledge in 1992 concerning dermal exposure to water, soil and vapor media. It presents methods for estimating dermal absorption resulting from contact with these media. It summarizes available chemical-specific experimental data describing their dermal absorption properties and provides predictive techniques to use where data are not available. It also describes procedures for evaluating experimental data for application to exposure assessments.

The first part of the document addresses principles of dermal exposure assessment. Physical and biological properties of skin that are of major importance in dermal absorption are discussed in the chapter on mechanisms. Properties of skin that vary with location, age and individual are discussed in the chapter on factors that influence percutaneous absorption. Experimental design of dermal absorption studies is discussed in a chapter on techniques for measuring dermal absorption, and the quantitative description of uptake through skin is discussed in a chapter on mathematical description of dermal exposure. This chapter contains a table listing dermal uptake parameters for a number of environmental pollutants. Considerations relevant to dermal absorption from specific environmental media are discussed in chapters on dermal absorption of compounds from water, soil, and air.

The second part of the document addresses applications of dermal absorption to exposure assessment. One chapter discusses dermal exposure scenarios. A second chapter discusses the relative contribution of dermal exposure to total exposure, and a third discusses a stepwise approach to dermal exposure assessment.

Significance for the MMRA Project

This document does not recommend any specific dermal exposure assessment algorithms or dermal uptake algorithms. It does, however, present information on the scientific basis for estimating dermal uptake, and this information is appropriate for evaluating methods of estimating dermal uptake and for evaluating scientific judgement used in assessing risks from chemicals absorbed through skin.

(b) ***Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry***. U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. Publication No. EPA/600/8-90/066F. 1994.

Status of the Document

An external review draft version of this document (Interim Methods for Development of Inhalation Reference Doses. Interim Report. Office of Health and Environmental Assessment, U.S. EPA, Washington, D.C. EPA/600/8-88/066F. 1989) underwent external peer review in 1987. In 1990, the Scientific Advisory Board (SAB) reviewed this draft, and a revised draft was reviewed by the SAB in 1993.

Purpose of the Document

The purpose of the document is to describe U.S. EPA methodology for deriving inhalation reference air concentrations (RfCs) as benchmark estimates of the quantitative dose-response assessment of chronic non-cancer toxicity for individual inhaled chemicals. While human respiratory exposure assessment is not the main purpose of this document, it does discuss methodology for comparing respiratory exposure in humans with respiratory exposure in laboratory rodents.

Contents

The document discusses criteria and information to be considered in selecting key studies for RfC derivation, provides an overview of the respiratory system and its intra- and interspecies variability and discusses areas of uncertainty and data gaps in relation to the proposed methodology.

Of particular interest for human exposure assessment are the sections on default dosimetric adjustments and physiological parameters and the section on dosimetric adjustments for particle exposures. The report also contains an appendix on a U.S. EPA particle deposition dosimetry model.

Significance for the MMRA Project

The potential relevance to the MMRA Project is limited to this document's methodology for estimating internal dose resulting from respiratory exposure. This methodology will be evaluated for use in estimating absorbed dose when it is appropriate to do so and when an estimate of the absorbed fraction has not been made in chemical-specific assessments, *e.g.*, RELs, adopted under OEHHA programs.

3.4 Guidance Documents for Exposure Factors

(a) ***Risk Assessment Guidance for Superfund. Volume 1 – Human Health Evaluation Manual Supplemental Guidance, Standard Default Exposure Factors***. Office of Solid Waste and Emergency Response, Toxics Integration Branch, U.S. EPA. Washington, D.C. OSWER Directive 9285:6-03. 1991.

Status of the Document

This document was published as "interim final" guidance. It is the product of an inter-agency work group formed in March 1990 to address concerns regarding inconsistencies in exposure assumptions used in Superfund risk assessments. A draft version was reviewed by technical staff and management in U.S. EPA and discussed at two EPA-sponsored meetings.

Purpose of the Document

The purpose of the document is "to transmit the Interim Final Standard Exposure Factors guidance to be used in the remedial investigation and feasibility study process. This guidance supplements the Risk Assessment Guidance for Superfund: Human Health Evaluation Manual, Part A that was issued October 13, 1989."

Contents

The document contains guidance on when residential, recreational, commercial/industrial and agricultural scenarios should be considered. For residential, agricultural and industrial scenarios, default exposure factors are listed for water ingestion, soil ingestion and inhalation of air. These factors include the quantity per day, frequency (days per year) and duration. For agricultural sites, exposure factors are listed for consumption of home-grown fruits and vegetables and for consumption of locally caught fish. For recreational scenarios, factors are listed for consumption of fish.

Significance for the MMRA Project

The exposure factors in this document should be considered as possible values for default exposure factors.

(b) ***Exposure Factors Handbook.*** Volume 1: General Factors, EPA/600/P-95/002Fa. Volume II: Food Ingestion Factors, EPA/600/P-95/002Fb. Volume III: Activity Factors, EPA/600/P-95/002Fc. Office of Research and Development, U.S. EPA, Washington, D.C. 1997.

Status of the Document

This document was reviewed by experts in U.S. EPA. A panel of experts from government, industry and academic institutions reviewed a draft of this document at a peer review workshop in 1995. It is published as a final document.

Purpose of the Document

The purpose of the document is to summarize data on parameters describing human characteristics which affect exposure to chemicals in the environment and to recommend values for these parameters.

Contents

The document is published in three volumes. Volume I contains parameters described as "general factors." Examples include breathing rate and tapwater intake per day. Volume II contains data on food ingestion parameters. Volume III contains data on human activity parameters.

Significance for the MMRA Project

This document does not recommend any specific exposure algorithms. It does, however, contain distributions of parameters that may be appropriate sources of mean and high-end estimates of parameters for exposure algorithms as well as input data for Monte Carlo simulation of the variability in exposure.

(c) ***Exposure Factors Sourcebook***. American Industrial Health Council (AIHC), Washington, D.C. 1994.

Status of the Document

It is stated that "This document has been peer reviewed by representatives of academia, government, private consulting, and industry." It is stated that future editions will extend and update material in the document.

Purpose of the Document

The purpose of the document is to expand data initially published in U.S. EPA's Exposure Factors Handbook.

Contents

Exposure factor data are presented in chapters on receptor physiologic parameters, time activity patterns, and receptor contact rates. Chapters on good risk assessment practices and probability distributions are included in the document.

Significance for the MMRA Project

This document does not recommend any specific exposure algorithms. It does, however, contain distributions of parameters that may be appropriate sources of mean and high-end estimates of parameters for exposure algorithms as well as input data for Monte Carlo simulation of the variability in exposure.

3.5 Guidance Documents for Assessing Uncertainty and Variability

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(a) ***Characterization of Uncertainties in Risk Assessment with Special Reference to Probabilistic Uncertainty Analysis.*** Office of Environmental Policy and Assistance, U.S. Department of Energy. U.S. DOE Publication No. EH-413-068-0496. 1996.

Status of the Document

This document is identified as a "RCRA/CERCLA information brief." No record of internal or external peer review appears in the document.

Purpose of the Document

The purpose of the document is to explain concepts that are important in uncertainty analysis as it pertains to health risk assessment.

Contents

This document poses six questions that it attempts to answer. The questions are: "What are the sources of uncertainty in a risk assessment? How do standard default exposure factors or scenario assumptions affect uncertainty? Why is uncertainty analysis an important component of risk assessment? What approaches are used to characterize uncertainty or to make risk assessment more understandable? What is Monte Carlo Simulation (MCS)? What are the advantages and disadvantages of performing MCS?"

Significance for the MMRA Project

This document does not recommend any specific procedures or distributions for Monte Carlo analysis.

(b) ***Guiding Principles for Monte Carlo Analysis.*** U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. U.S. EPA Publication No. EPA/630/R-97/001. 1997.

Status of the Document

This document is published as the report of a technical panel established by U.S. EPA's Risk Assessment Forum following a May 1996 workshop convened to discuss principles appropriate for reviewing risk assessments based on Monte Carlo analysis. No record of internal or external peer review appears in the document.

Purpose of the Document

The purpose of the document is to provide guidance for the use of probabilistic techniques in U.S. EPA risk assessments.

Contents

The document discusses the use of Monte Carlo methods to characterize variability and uncertainty in estimates of exposure and risk. It also discusses the use of Monte Carlo methods in identification and quantification of major sources of variability and uncertainty. The 16 guiding principles in the document are grouped into categories. The first is selecting input data and distributions for use in Monte Carlo analysis. The second is evaluating uncertainty and variability, and the third is presenting the results of a Monte Carlo analysis.

Significance for the MMRA Project

This document does not recommend any specific procedures or distributions for Monte Carlo analysis. It does present principles that can be used to evaluate proposed guidelines or recommendations concerning methodology for probabilistic risk assessment.

(c) ***Policy for Use of Probabilistic Analysis in Risk Assessment at the U.S. Environmental Protection Agency***. U.S. Environmental Protection Agency, Office of Research and Development, Washington, D.C. 1997.

Status of the Document

This document is published as a policy statement attached to the document *Guiding Principles for Monte Carlo Analysis*, the report of a technical panel established by U.S. EPA's Risk Assessment Forum following a May 1996 workshop convened to discuss principles appropriate for reviewing risk assessments based on Monte Carlo analysis. No record of internal or external peer review appears in the document.

Purpose of the Document

The purpose of the document is to state U.S. EPA's policy on the use of probabilistic analysis in risk assessment.

Contents

The document contains the policy statement: "It is the policy of the U.S. Environmental Agency that such probabilistic techniques as Monte Carlo techniques, given adequate supporting data and credible assumptions, can be viable statistical tools for analyzing variability and uncertainty in risk assessments."

The document also contains eight conditions for acceptance of a risk assessment that uses probabilistic techniques. These include clear statement of the purpose and scope, identification of models, data and assumptions used, presentation and discussion of results of a sensitivity analysis, a discussion of correlations between input variables, information describing each input and output distribution, calculation of exposure and risk using deterministic methodology, and information on the stability of the estimates of central tendency and higher end estimates of risk.

The document discusses the use of Monte Carlo methods to characterize variability and uncertainty in estimates of exposure and risk. It also discusses the use of Monte Carlo methods in identification and quantification of major sources of variability and uncertainty.

Significance for the MMRA Project

This document does not recommend any specific procedures or distributions for Monte Carlo analysis. It does present principles that can be used to evaluate proposed guidelines or recommendations concerning methodology for probabilistic risk assessment.

(d) ***Use of Monte Carlo Simulation in Risk Assessment.*** U.S. Environmental Protection Agency, Region III, Philadelphia, PA. U.S. EPA Publication No. EPA/903/F-94/001. 1994.

Status of the Document

This document is a technical guidance manual. No record of internal or external peer review appears in the document.

Purpose of the Document

The purpose of the document is to state conditions for acceptance of risk assessments that use Monte Carlo analysis in U.S. EPA Region III.

Contents

This document lists several limitations of current usefulness of Monte Carlo simulations in risk assessment and states guidelines for using Monte Carlo simulations. Limitations include the inability of available software to distinguish between uncertainty and variability, ignoring correlations between exposure variables, using exposure factors from short-term studies to simulate exposure over long time periods, and the dependence of the area in the tail of a distribution generated by Monte Carlo simulations (sensitivity of the tail) on the shape of input distributions.

Guidelines for accepting risk assessments using Monte Carlo simulations include simulating exposure only for human receptors; submitting a workplan stating software to be used for simulations together with fate and transport models, routes and input data; simulating the variability resulting only from variability of exposure parameters; using simulations only to analyze uncertainty and variability; and presenting graphs showing distributions of each input variable and distributions of both total risk and route-specific risk.

Significance for the MMRA Project

This document does not recommend any specific procedures or distributions for Monte Carlo analysis. It does present principles that can be used to evaluate proposed guidelines or recommendations concerning methodology for probabilistic risk assessment, and lists restrictions on the types of data to be used as input distributions.

(e) ***Use of Monte Carlo Simulation in Performing Risk Assessments.*** U.S. Environmental Protection Agency, Region VIII Superfund Technical Guidance, Denver, CO. 1995.

Status of the Document

This document is a technical guidance manual. No record of internal or external peer review appears in the document.

Purpose of the Document

The purpose of the document is to state conditions for acceptance of risk assessments that use Monte Carlo analysis in U.S. EPA Region VIII. The document includes the information in document 3.4 (d). It contains additional information noted below.

Contents

This document lists several limitations of current usefulness of Monte Carlo simulations in risk assessment and states guidelines for using Monte Carlo simulations. Limitations include the inability of available software to distinguish between uncertainty and variability; ignoring correlations between exposure variables; using exposure factors from short-term studies to simulate exposure over long time periods; and the dependence of the area in the tail of a distribution generated by Monte Carlo simulations (sensitivity of the tail) on the shape of input distributions.

Guidelines for accepting risk assessments using Monte Carlo simulations include simulating exposure only for human receptors; simulating the variability resulting only from variability of exposure parameters; using only significant exposure scenarios and using the reasonable maximum exposure estimate for calculating risks for all routes of exposure; using simulations only to analyze uncertainty and variability; and presenting graphs showing distributions of each input variable and distributions of both total risk and route-specific risk.

This document contains an example of Monte Carlo simulations used in a human health risk assessment.

Significance for the MMRA Project

This document does not recommend any specific procedures or distributions for Monte Carlo analysis. It does present principles that can be used to evaluate proposed guidelines or recommendations concerning methodology for probabilistic risk assessment, and lists restrictions on the types of data to be used as input distributions.

(f) ***Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs.*** Draft. Office of Pesticide Programs, Health Effects Division, U.S. Environmental Protection Agency, Washington, D.C. 1998.

Status of the Document

This document is a revision and expansion of the U.S. EPA document *Pesticide Assessment Guidelines, Subdivision K*. It is denoted "working draft – do not cite or quote."

Purpose of the Document

The purpose of the document is to assist the regulated community in designing and implementing studies required under the Federal Insecticide, Fungicide and Rodenticide Act.

Contents

Part A of the document contains background material. Part B contains instructions on study design and conduct. Part C contains information on quality assurance and quality control. Part D contains guidance on methodology for estimating exposure and risk.

Part D discussed methodology for estimating internal dose from applied dose. It also discussed the use of transfer factors in exposure assessment involving food pathways.

Significance for the MMRA Project

This document contains information and methodology that should be considered when methodology for estimating exposure and uptake via food pathways is addressed by the MMRA Project.

(g) ***Analysis of the Impact of Exposure Assumptions on Risk Assessment of Chemicals in the Environment.*** VERSAR for the Chemical Manufacturers Association (CMA), Washington, D.C. 1990.

Status of the Document

This document was prepared for the Chemical Manufacturers Association.

Purpose of the Document

The stated overall purpose of the project is identification of the means for reducing uncertainty in exposure assessment and documentation of alternative approaches that provide more realistic measures of exposure.

Contents

The document is divided into three parts. Phase I contains a discussion of the factors contributing to uncertainty and factors contributing to variability in risk assessment. It also contains a discussion of the range of exposure parameters used in risk assessment and a qualitative description of resulting variability in exposure estimates. Phase II selects scenarios and exposure algorithms and specifies distributions of input parameters. The results of Monte Carlo simulations are presented for each scenario. Phase III consists of recommendations.

Significance for the MMRA Project

This document does not recommend any specific exposure algorithms. It does, however, specify distributions of parameters that should be evaluated to determine if they may be appropriate sources of input data for Monte Carlo simulation of the variability in exposure.

3.6 Guidance Documents for Chemical Mixtures

(a) ***Guidance for Conducting Health Risk Assessment of Chemical Mixtures.*** External Scientific Peer Review Draft. Risk Assessment Forum Technical Panel. U.S. EPA, Washington, D.C. Publication NCEA-C-0148, April 1999.

Status of the Document

This document was developed by a Technical Work Panel to ensure that advances in the area of chemical mixtures health risk assessment are reflected in the Agency's guidance materials. The document is an External Scientific Peer Review Draft and is intended as a supplement to the *Guidelines for the Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1986) and *Technical Support Document on Health Risk Assessment of Chemical Mixtures* (U.S. EPA, 1990).

Purpose of the Document

This document was designed to supplement the broad concepts related to mixtures exposure and toxicity in the 1986 Guidelines and subsequent documents with information that is organized according to the type of data available to the risk assessor, which ranges from data-rich to data-poor situations. This document has been developed as a procedural guide that emphasizes broad underlying principles of the various science disciplines necessary for providing information on the relationship between multi-chemical exposure and potential health effects.

Contents

The guidance proposes a decision tree approach for the selection of a methodology for assessment of a chemical mixture. The approach can be outlined as follows:

- An assessment of data quality - determine if a quantitative or only qualitative assessment can be made. This assessment itself appears somewhat qualitative and does not mention indicators such as detection limit, precision and accuracy, etc., but only the presence or absence of needed information on exposure, health effects, and interactions.
- The data is whole mixture data
  Is there information directly available on the mixture of concern?
  Is there information only on similar mixtures?
- The data is mixture component data
  Are interactions data available?
  Do the components act by a similar mode of action?
  Can the components be thought of as belonging to a chemical class?

The default methods that can be applied to each situation are as follows:

- No interactions information is available, exposure levels are low – use an additivity assumption
- Components show dissimilar toxicity – use response addition. Determine the risks per the exposure for the individual components which act independently; the mixtures risk is then estimated by adding the individual risks together.
- Components show similar toxicity – use dose addition. Scale the doses of the components for potency and add the doses together to get an equivalent dose in terms of an index chemical; the mixtures response is then estimated for the combined mixtures dose. Assume that all the components have similar uptake, pharmacokinetics and toxicological processes, and that the log-probit dose-response curves of the components are parallel.
- Interactions data are available
- Incorporate them into the risk assessment either by using the interactions based hazard index (Section 4.4.2) or by including a qualitative assessment of the direction and magnitude of the impact of the interaction data.
- Data are available on the chronic, subchronic, or carcinogenic effects of mixtures such as coke oven emissions, so procedures similar to single compounds are followed.
- Data are available on similar mixtures, but if compositions vary with time or different emission sources, ranges of risk can be estimated if components are significantly different, or a single risk assessment may be adequate if components have toxicological similarity. Toxicological

similarity can be supported if: 1) there is a common mode of action; 2) short-term screening assays show consistency; 3) chemical class or structure is similar; 4) common components are present in similar proportions; 5) there is a common source of formation or emission; and, 6) statistical criteria for similarity exist.

Significance for the MMRA Project

The guidance discusses the rationale for each default method in detail, as well as evidence to support the default method. Examples of application to specific mixtures such as Arochlor, coke oven emissions, roofing tar, diesel exhaust, and cigarette smoke; current data limitations and uncertainties in both exposure and dose-response; and future directions are discussed. The guidance also indicates that data for health risk assessment of chemical mixtures, except for those noted, is still very limited. The type of logic followed in discussing the rationale for each default method may be useful for future discussions of choices in multi-media risk assessment methods.

CHAPTER 4

COMPARISON OF CAL/EPA EXPOSURE ASSESSMENT APPROACHES

4.1 Background

A major Phase 2 task for the MMRA Project is a detailed review of multimedia exposure assessment methodologies. Because it is a goal of the project to identify a comprehensive methodology or methodologies appropriate for use in many risk assessments reviewed or performed by Cal/EPA programs, multimedia exposure assessment methodologies developed wholly or partially within this agency were selected for a pilot task during Phase 1. The methodologies developed to date are the *Air Toxics "Hot Spots" Risk Assessment Guidelines* (CAPCOA, 1993), *CalTOX: A Multimedia Total Exposure Model for Hazardous Waste Sites* (DTSC, 1993) and the *Technical Support Document: Exposure Assessment and Stochastic Analysis* (OEHHA, 2000). The RAAC (1996) report includes a comparison of the *CalTOX* and CAPCOA methodologies in its review of exposure assessment practices of Cal/EPA, U.S. EPA, and the National Research Council (NRC). The MMRA Project Team has extended this comparison to include the OEHHA stochastic analysis document (OEHHA, 2000). A comparison of the three Cal/EPA exposure assessment methodologies is presented in the tables that follow.

4.2 Comparison of Cal/EPA Exposure Assessment Approaches

As noted in the RAAC (1996) report, the *CalTOX* model and CAPCOA risk assessment guidelines were developed for very different purposes. The *CalTOX* model was developed for DTSC as a spreadsheet model to assist in health risk assessments that address contaminated soils and the contamination of air, surface water, sediments, and groundwater by chemicals migrating from the initial site of contamination. The modeling effort includes a multimedia transport and transformation model, specified exposure scenarios, and distributions of data for use in estimating uncertainty and variability in the model's exposure estimates. The CAPCOA guidelines were designed to provide risk assessment procedures for use in the preparation of the health risk assessments required under the Air Toxics "Hot Spots" Program. The OEHHA/ATES technical support document was also developed for this purpose. It contains methodology for calculating both point estimates of exposure and distributions of estimates (a stochastic approach). This approach utilizes data that OEHHA has evaluated for a number of human intake factors and in some cases probability distributions are provided for certain intake factors. A comparison of major features of the three risk assessment methodologies is presented in
Table 4-1.

The MMRA Project will have to address exposure assessment model components summarized in Table 4-1 that differ across individual methodologies. For example, the model will have to include both acute and chronic exposures. Fractional intake of exposure media (*e.g.*, 50 percent of ingested produce is homegrown produce) and potential effect of correlations between input variables in stochastic analysis will also be addressed. A major consideration will be use of data

Table 4-1. Comparison of the *CalTOX* Model, CAPCOA Guidelines, and Exposure Assessment and Stochastic Analysis Report

Exposure Model	***CalTOX* Model**	**CAPCOA Guidelines**	**OEHHA Exposure Assessment & Stochastic Analysis**
Source of Contamination	Soil (one year after spill)	Air (facility air emissions data)	Same as CAPCOA
Chemicals Evaluated	Only chemicals which display fugacity	Only those on "Hot Spots List"	Same as CAPCOA
Fate and Transport Model	Fugacity determines chemical distribution between 7 environ. Compartments	Fate & transport models from Clement Assoc., 1986 document	Not Applicable
Length of Exposure Modeled	Chronic exposures	Chronic and acute exposures	Same as CAPCOA
Human Receptors and Activities Modeled	Adults and infants Childhood exposures are considered for non-carcinogens	Adults Infants (ingestion of mother's milk)	Adults and children Infants (mother's milk)
	Residential and off-site worker exposures are considered	Residential and off-site worker exposures are considered	Same as CAPCOA
Intake Equations	Environmental concentrations measured or determined using *CalTOX* "transport and transformation model"	Facility air emissions data or USEPA air dispersion models/SCAQMD air, soil, and water algorithms	Same as CAPCOA
	Input parameters are probability density functions	Input parameters are high-end estimates	Point estimate (mean/high-end) and distributions of estimates
	Fractional intake is considered in all exposure pathways	Fractional intake is considered in food ingestion pathways	Same as CAPCOA
	Correlation of contact rate and body weight is assumed	Default values of body surface area and body weight are "matched"	Correlation of contact rate and body weight is assumed
Intake Factors, Exposure Frequencies and Durations	Refer to Table 4-4	Refer to Table 4-4	Refer to Table 4-4

for point estimates (i.e., mean versus high-end) and use of exposure parameter distributions for purposes of estimating exposure using the stochastic approach.

The *CalTOX* Model, CAPCOA Guidelines and OEHHA/ATES Exposure Assessment and Stochastic Analysis evaluate exposures from multiple pathways and routes of exposure. Program mandates largely dictate which exposure pathways are to be evaluated. Table 4-2 compares exposure pathways evaluated by the three approaches under consideration.

Table 4-2. Exposure Pathways – Comparison of the *CalTOX* Model with CAPCOA Guidelines and OEHHA Exposure Assessment and Stochastic Analysis Report

***CalTOX* Model**	**CAPCOA Guidelines and OEHHA Exposure Assessment and Stochastic Analysis**
Inhalation of airborne vapors including volatile organic compounds from soil and contaminated tap water; inhalation of airborne particulates	Inhalation of airborne vapors and particulates
Incidental ingestion of soil/dust	Incidental ingestion of soil
Dermal contact with soil	Dermal contact with soil
Ingestion of mother's milk	Ingestion of mother's milk
Ingestion of fruits, vegetables and grains	Ingestion of root crops, leafy crops, and vine crops (CAPCOA)/exposed, protected, leafy, root (OEHHA)
Ingestion of meat, milk, eggs, fish and sea food (shellfish)	Ingestion of meat (poultry, cattle, goats, pigs and sheep), milk, eggs and fish
Ingestion of tap water and surface water during swimming or other water recreation	Ingestion of surface water
Dermal contact with surface water while swimming and contaminated water in baths and showers	Not Considered (a)

a. While the Air Toxics "Hot Spots" Program does not estimate the exposure dose from these pathways, the Public Health Goals (PHG) Program in OEHHA does.

Table 4-3 lists the inter-media transfer routes considered by *CalTOX* and the CAPCOA and OEHHA guidelines. *CalTOX* describes a method for computing contaminant concentrations in "exposure media" (e.g., inhaled air, ingested water) that are derived from concentrations in environmental compartment media (e.g., ambient air, surface soil, groundwater). The model uses "inter-media transfer factors" (*i. e*., the ratio of chemical concentration in the exposure medium to the chemical concentration in the environmental compartment) to determine the chemical concentration in the exposure medium. The MMRA Project will have to further investigate the extent of Cal/EPA program needs concerning inter-media transfer and the underlying data used for developing inter-media transfer factors.

Table 4-3. Inter-media Transfer Routes Recommended in the *CalTOX* Model, CAPCOA Guidelines, and OEHHA Exposure Assessment and Stochastic Analysis Report

Inter-media Transfer Route	*CalTOX* Model	CAPCOA Guidelines and OEHHA Exposure Assessment & Stochastic Analysis
Wet and dry deposition of particle-bound chemicals from air to surface soil and surface water	Yes	Yes
Wet and dry deposition of particle-bound chemicals from air to plants (grass, vegetables, and fruits)	Yes	Yes
Partition of chemical vapors from air to plants (grass, vegetables, and fruits)	Yes	Not Considered
Uptake of chemicals from soil to plant through the root system	Yes	Yes
Transport of particle-bound chemicals from soil to plant surface through rainsplash	Yes	Not Considered
Transfer of chemicals from grass to milk and beef through grass and hay ingestion	Yes	Yes
Transfer of chemicals from soil to milk and beef through soil ingestion	Yes	Yes
Transfer of chemicals from air to milk and beef through inhalation	Yes	Yes
Transfer of chemicals from water to milk and beef through water ingestion	Yes	Yes
Transfer of chemicals from water to fish through absorption	Yes	Yes
Transfer of chemicals from water to plant through irrigation	Yes	Not Considered
Transfer of chemicals from mother to infant through breast milk	Yes	Yes
Degradation and transformation in the environment	Yes	Yes

Exposure intake is determined by algorithms that include physiological parameter values (*e.g.*, breathing rate) for each exposure pathway of concern. Whereas the deterministic approach uses point values for individual exposure parameters, the stochastic approach makes use of probability distributions of the parameters to estimate dose. In its list of parameter values, *CalTOX* reports the arithmetic mean and the coefficient of variation (CV) for the individual values. Parameter mean values and CVs are presented for the various exposure media and for human activity parameters (e.g. exposure duration) in Table 4-4. The table also lists parameter values for point estimates recommended in the CAPCOA Guidelines and OEHHA Exposure Assessment and Stochastic Analysis Report.

Table 4-4. Comparison of Human Exposure Factor Values Recommended by *CalTOX* Model, CAPCOA Guidelines, and OEHHA Exposure Assessment and Stochastic Analysis Report Residential Exposure Scenario (Adult)

Exposure pathway	Exposure parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Analysis
General	Body weight (kg)	71 (16-70 years of age) 62 (child/adult combined)	70 (adult, average)	63 (ages 0-70)
	Exposure duration	30 [CV=1] (a)	Chronic exposure: 70 years; acute: 1 hr	9, 30 and 70 years
	Averaging time for non-carcinogens (years)	30	Chronic exposure: 70 years; acute: 1 hr	
	Averaging time for carcinogens (years)	70	70	70
Inhalation exposure	Inhalation rate (m^3/day)	10.2 (resting) and 30.7 (active) (16-70 years of age) (b)	20	17 (ave), 25 (high-end)
	Exposure frequency (days/year)	NA (c)	365	350
Soil dermal contact	Surface area of exposed skin (cm^2/day)	5112 (d)	4656	4700 (ave), 5500 (high-end)
	Soil loading on skin (mg/cm^2)	0.5 [CV=0.4]	0.5	0.2 (ave), 1.0 (high-end)
	Fraction of soil from contaminated source (e)	NA	1	1
	Exposure frequency (days/year)	137 events/year [CV= 0.6]	365	121 (ave), 350 (high-end)
	Dermal absorption	Chemical specific (provided in document)	Chemical specific	Chemical specific (provided in document)

Table 4-4, continued

Exposure pathway	Exposure parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Analysis
Soil Ingestion	Soil ingestion rate (mg/day)	10 (f)	110 (lifetime average)	107
	Fraction ingested from contaminated source	NA	1	1
	Exposure frequency (days/year)	137 events/year [CV=0.6]	365	350
Water ingestion	Drinking water ingestion rate (l/day)	1.4 (g)	2 (lifetime average)	1.5 (ave), 3.4 (high-end)
	Exposure frequency (days/year)	NA	365	365
Vegetable ingestion	Vegetable ingestion rate (kg/day) (wet weight)	Fruits and vegetables: 0.3 Exposed produce: 0.34 Protected produce: 0.16 (h)	Root crop: 0.05 Vine crop: 0.25 Leafy crop: 0.01	Exposed: 0.22 (average), 0.76 (high-end) Leafy: 0.18 /0.67 Protected: 0.09 /0.31 Root: 0.20 /0.66
	Exposure frequency (days/year)	NA	365	350
	Fraction ingested from contaminated source	Fruits and vegetables: 0.24 [CV=0.7]	Site specific	Site specific
Milk ingestion	Milk ingestion rate (kg/day)	Milk and dairy: 0.26 (I)	0.3	0.34 (ave), 1.1 (high-end)
	Exposure frequency (days/year)	NA	365	350
	Fraction ingested from contaminated source	0.4 [CV=0.7]	Site specific	Site specific

Table 4-4, continued

Exposure pathway	Exposure parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Analysis
Meat ingestion	Meat ingestion rate (kg/day) (wet weight)	Meat: 0.18 (j)	0.1	Beef: 0.14 (ave); 0.43 (high-end) Chicken: 0.09 (ave); 0.32 (high-end) Pork: 0.09 (ave), 0.29 (high-end)
	Exposure frequency (days/year)	NA	365	350
	Fraction ingested from contaminated source	0.44 [CV=0.5]	Site specific	Site-specific
Fish ingestion	Fish ingestion rate (kg/day) (wet weight)	0.02 (k)	0.024	Fisher-caught fish: 0.03 (ave), 0.09 (high-end)
	Exposure frequency (days/year)	NA	365	350
	Fraction ingested from contaminated source	0.7 [CV=0.3]	Site specific	Site specific
Showering	Inhalation exposure (m^3/hr)	1.33 m^3/hr [CV=0.3]	NA	NA
	Skin surface area exposed (cm^2)	17040 (I)	NA	NA
	Exposure time (hr/day)	0.27 [CV=0.6]	NA	NA
	Exposure frequency (days/year)	NA	NA	NA
Water ingestion during swimming	Water ingestion rate	50 ml/day (m)	NA	NA
	Exposure time (hr/day)	0.5 [CV=0.5]	NA	NA
	Exposure frequency (day/year)	15 [CV=4]	NA	NA

Table 4-4, continued

Exposure Pathway	Exposure Parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Analysis
Dermal contact with chemicals in water during swimming	Skin surface area available for contact (cm^2)	17040 (i)	NA	NA
	Exposure time (hr/day)	0.5 [CV=0.5]	NA	NA
	Exposure frequency (day/year)	15 [CV=4]	NA	NA

Industrial/Commercial Exposure Scenario

Exposure Pathway	Exposure Parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment & Stochastic Guidelines Ages 0-9
Inhalation	Inhalation rate (m^3/day)	NA	20 m^3/8 hr-workday	Not specified
Drinking water ingestion	Drinking water ingestion rate (l/day)	NA	NA	NA
Ingestion of soil and dust	Soil ingestion rate (mg/day)	NA	NA	Offsite worker: 100
General	Exposure frequency (days/year)	NA	260	250 (offsite soil ingestion)
	Exposure duration (years)	NA	46	46 (offsite soil ingestion)

Table 4-4, continued

Residential Exposure Scenario (Child)

Exposure Pathway	Exposure Parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment & Stochastic Guidelines Ages 0-9
General	Body weight of an infant (kg)	7.2 [CV=0.3] (0-1 year)	6.5 (0-1 year)	18 (child 0-9 yrs)
	Body weight of a child (kg)	29 [CV=0.24] (0-15 yr)	NA	
	Exposure frequency (days/year)	NA	NA	365
Soil ingestion	Soil ingestion rate (mg/day)	64 (0-15 years) (n)	NA	107
	Fraction ingested from contaminated source	Site specific	NA	1.0
	Exposure frequency (days/year)	NA	NA	350
Soil dermal contact	Surface area of exposed skin (cm^2/day)	2784 (0-15 years) (o)	NA	2000
	Soil loading on skin (mg/cm^2)	0.5 [CV=0.4]	NA	0.2 (average) 1.0 (high-end)
	Fraction of soil from contaminated source	NA	NA	1.0
	Exposure frequency (days/year)	137 [CV=0.6]	NA	350
Mother's milk ingestion	Breast-milk ingestion rate (kg/day)	0.8 (p)	0.9	0.66 (average) 0.90 (high-end)
	Frequency of exposure (days/year)	365	365	365
	Breast-feeding period (year)	1	1	1

Table 4-4, continued

Exposure Pathway	Exposure Parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Guidelines
Inhalation exposure	Inhalation rate (m^3/day)	5.6 (resting, 0-15 years) 16.0 (active, 0-15 years) (q)	NA	8.1 (average) 10.4 (high-end)
Drinking water ingestion	Drinking water ingestion rate (l/day)	0.8 (r)	NA	0.72 (average) 1.7 (high-end)
	Exposure frequency (days/year)	NA	NA	350
Meat ingestion	Meat ingestion rate (kg/day) (wet weight)	0.13 (0-15 years) (s)	NA	Beef: 0.04 (ave), 0.14 (high-end) Chicken: 0.03 (ave), 0.09 (high-end) Pork: 0.02 (ave), 0.09 (high-end)
	Exposure frequency (days/year)	NA	NA	350
	Fraction ingested from contaminated source	0.44[CV=0.5]	NA	Site-specific
Vegetable ingestion	Vegetable ingestion rate (kg/day) (wet weight)	Fruits and vegetables: 0.22 Exposed produce: 0.32; Protected produce: 0.12 (0-15 years) (t)	NA	Exposed: 0.07 (average), 0.28 (high-end) Leafy: 0.05/ 0.20 Protected: 0.03 / 0.12 Root: 0.07 / 0.27
	Exposure frequency (days/year)	NA	NA	350
	Fraction ingested from contaminated source	0.24[CV=0.7]	NA	Site-specific

Table 4-4, continued

Exposure Pathway	Exposure Parameter	*CalTOX* Model	CAPCOA Guidelines	OEHHA Exposure Assessment and Stochastic Guidelines
Milk ingestion	Milk ingestion rate (kg/day)	0.5 (0-15 years) (u)	NA	0.20 (ave) 0.93 (high-end)
	Exposure frequency (days/year)	NA	NA	350
	Fraction ingested from contaminated source	0.4[CV=0.7]	NA	Site-specific
Fish ingestion	Fish ingestion rate (kg/day) (wet weight)	0.01 (0-15 years) (v)	NA	Fisher-caught fish: 0.01 (ave), 0.02 (high-end)

a. Parameter values listed under *CalTOX* are averages, values in parentheses are coefficients of variation (CVs) of the parameters. CV is a measure of uncertainty and/or variability of a parameter relative to its mean value; it can be calculated by dividing the arithmetic standard deviation by the arithmetic mean.
b. Based on an average active breathing rate of 0.018 m^3/kg-hr [CV=0.3] and an average resting breathing rate of 0.006 m^3/kg-hr [CV=0.2], assuming an average body weight of 71 kg
c. Not available (NA)
d. Based on an average total skin surface area of 0.024 m^2/kg [CV=0.06] and an average fraction of body surface that may come into contact with soil of 0.3 [CV=0.04], it was assumed that the average body weight of an adult is 71 kg.
e. The fractional intake is designed to account for considerations of exposure frequency. Please note that for all exposure pathways in *CalTOX*, either an exposure frequency or a fractional intake value is used to account for less-than-full-time exposure.
f. Based on an average soil ingestion rate of 1.4E-7 kg/kg-day [CV=2] (16-70 years) and an average body weight of 71 kg.
g. Based on an average water ingestion rate of 0.02 l/kg-day [CV=0.2] and an average body weight of 71 kg.
h. Based on an average fruits and vegetables ingestion rate of 0.0042 kg/kg-day [CV=0.2]; average exposed produce ingestion rate of 0.0048 kg/kg-day [CV=0.2]; average protected produce ingestion rate of 0.0022 kg/kg-day [CV=0.2]; and an average body weight of 71 kg. *
i. Based on an average milk and dairy products ingestion rate of 0.0037 kg/kg-day [CV=0.2] and an average body weight of 71 kg.
j. Based on an average meat ingestion rate of 0.0026 kg/kg-day [CV=0.2] and an average body weight of 71 kg.
k. Based on an average fish ingestion rate of 0.00028 kg/kg-day [CV=0.3] and an average body weight of 71 kg.
l. Based on an average exposed skin surface area of 0.024 m^2/kg [CV=0.06] and an average body weight of 71 kg.
m. Based on an average ingestion rate of 0.0007 l/kg-day [CV=1] and an average body weight of 71 kg.
n. Based on an average soil ingestion rate of 2.2E-6 kg/kg-day [CV=3] (0-15 years) and an average body weight of 29 kg.
o. Based on an average skin surface area of 0.032 m^2/kg [CV=0.09] (child) and an average fraction of body surface come into contact with soil of 0.3 [CV=0.04], it is assumed that the average body weight of a child is 29 kg.
p. Based on an average breast-milk ingestion rate of 0.11 kg/kg-day [CV=0.2] and an average body weight of 7.2 kg.
q. Based on an average resting breathing rate of 0.008 m3/kg-hr [CV=0.2] and an average acting breathing rate of 0.023 m3/kg-hr [CV=0.3], assuming an average body weight of 29 kg.
r. Based on an average water ingestion rate of 0.029 L/kg-day [CV=0.2] and an average body weight of 29 kg.
s. Based on an average meat ingestion rate of 0.0043 kg/kg-day [CV=0.2] and an average body weight of 29 kg.
t. Based on an average fruit and vegetable ingestion rate of 0.0075 kg/kg-day [CV=0.2]; an average exposed produce ingestion rate of 0.011 [CV=0.2]; an average protected produce ingestion rate of 0.004 [CV=0.2]; and an average body weight of 29 kg.
u. Based on an average milk ingestion rate of 0.017 kg/kg-day [CV=0.2] and an average body weight of 29 kg.
v. Based on an average fish ingestion rate of 0.00035 kg/kg-day [CV=0.4] and an average body weight of 29 kg.

4.3 NRC Review of *CalTOX*

Following the comparison of *CalTOX*, CAPCOA and the Exposure Assessment and Stochastic Analysis documents, a review of the use of CalTOX for hazardous waste classification came to the attention of the MMRA Project Team. The report by the National Research Council (NRC) Committee on Risk-Based Criteria for Non-RCRA Hazardous Waste, *Risk-Based Waste Classification in California* (NRC, 1999), reviews both the DTSC's use of the methodology in *CalTOX* and in the Preliminary Endangerment Assessment Guidance Manual (PEA) spreadsheet to classify hazardous waste. Comments of the committee that are specific to the use of *CalTOX* and that appear to be of major concern are listed in Table 4-5. These comments have been listed for use by the MMRA Project Team to apply the underlying concerns of the NRC committee to Phase 2 evaluations of other guidance documents and to the development of recommendations by the team.

Table 4-5. Use of *CalTOX* in the Preliminary Endangerment Assessment Methodology

Page Citation	Comment from NRC (1999) report
Page 38/39	The committee stated: The statement of the protection goals should address such questions • What population is to be protected and what level of protection is to be provided? • What level of protection is to be provided to the most-exposed individuals? • Which sensitive populations are to be considered and what level of protection is to be provided to them?
Page 47	The committee stated that information in the document should include: • "A complete (mathematical) description of the models that are used; and a specification of which models are used in which scenarios to match which physical processes;" • "A complete specification of each parameter value used in the document, together with references allowing retrieval of the method of its measurement or of its calculation."
Page 67	The committee questioned the use of deposition velocity for ambient dust to predict deposition of wind-blown dust from an adjacent site.
Page 69	The committee stated that "the treatment of variability and uncertainty is inadequate in the DTSC report. No distinction is drawn between the two."

Table 4-5 (continued)

Page 70	The committee recommended using sensitivity analysis to: • "Identify the dominant factors that most influence the model's results;" • "Focus attention on assumptions concerning dominant pathways and improve efforts to reduce the uncertainty associated with them."
Page 73	The committee stated that "There appears to have been very little validation of any of the models used by DTSC, in any sense of the term" and provided detailed suggestions.
Page 79	The committee questioned whether food intake data used are relevant to the California population.
Pages 80	The committee noted that a large fraction of food is assumed to be produced at an adjacent residence.
Pages 90	The committee criticized the modeling of dust deposition.
Page 100	The committee criticized the approximations used to model soil transport stating: • "The model might predict short-term emission rates that are substantially lower than actual rates." • "Soil concentrations in the top few millimeters are substantially lower than values predicted by CALTOX."

CHAPTER 5

SUMMARY OF PHASE 1 TASKS AND PHASE 2 PLANS

5.1 Highlights of Phase 1 Tasks

The survey discussed in Chapter 2 generated information on current exposure assessment practices and needs as perceived by staff in Cal/EPA programs. The information obtained includes the extent of use of human exposure assessment in 11 individual programs. It also includes program-specific use of guidance documents, the use of probabilistic approaches to assess variability, and the use of specific software programs for exposure assessment. In addition, survey responders identified topics in exposure assessment that responders wanted the MMRA Project to address.

The survey results indicate that developing a MMRA model that will meet the needs of all Cal/EPA programs will be a challenging task. Although there is general agreement among the programs about certain issues (*e.g.*, use of a tiered approach to exposure assessment and data quality objectives), there are requirements and practices unique to certain programs that may be difficult to incorporate into a unified model. For example, DPR evaluates exposure to pesticide residues in foods and on plant foliage, which requires exposure assessment data and assumptions that are not found in standard exposure assessment guidelines. OEHHA/PETS is interested in incorporating ethnic-specific exposure factors for California in the evaluation of exposure from ingesting contaminated fish. The next phase of the MMRA Project will require a more comprehensive investigation into some of these individual program needs in exposure assessment.

A number of documents summarized in Chapter 3 were not published at the time of the RAAC review of risk assessment methodologies used in Cal/EPA and U.S. EPA programs. Some of these recently published documents appear to be particularly useful references for data and methodology supporting multimedia risk assessment. One example is *Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities* (U.S. EPA, 1998), which contains information on inter-media transfer and physical properties of individual chemicals as well as values for intake parameters and receptor activity.

Documents on uncertainty and variability summarized in Chapter 3 include recent publications by U.S. EPA that articulate policy and guidance for the use of stochastic analysis in human health risk assessment. This policy and guidance may be appropriate for risk assessments containing stochastic analysis that are reviewed by programs in Cal/EPA. The U.S. EPA (1997) *Exposure Factors Handbook* summarized in Chapter 3 contains distributions of input parameters for exposure assessment that may in some cases be appropriate for risk assessments reviewed by Cal/EPA programs.

The comparison of exposure assessment models developed by California government programs reveals numerous differences. Many of the differences in the value of a specific input parameter of an algorithm are small. However, some of the differences are greater than a factor of two. In addition, there are differences in the exposure pathways included in the models.

5.2 Major Phase 2 Tasks

A major task in Phase 2 will be to extend the comparison of exposure algorithms described in Chapter 4. Algorithms recommended by U.S. EPA for assessing sites where contaminated soil or groundwater is the primary concern will be compared with algorithms in *CalTOX*. The task will be divided into the comparison of algorithms for screening analysis and those intended for a more detailed analysis. The MMRA Project Team will identify those algorithms (or components of algorithms) where there is agreement. In cases where there is disagreement, the Team will investigate whether differences can be explained by differences in policy goals.

A second major task for Phase 2 is comparison of appropriate methodologies for estimating inter-media transfer of environmental contaminants. The Project Team will use an approach for this task that parallels the approach used for comparing exposure algorithms. Development of methodology for estimating inter-media transfer is a concern that was prominent in the RAAC (1996) report.

A third major task is to work toward defining criteria for an adequate site conceptual model for most risk assessments reviewed by Cal/EPA programs. As part of this task, the Project Team will review proposed criteria for deciding when an exposure pathway is complete. The Project Team will also review exposure scenarios specified by California and U.S. government agencies. Following the lead of the NRC committee (NRC, 1999), exposure scenarios proposed for use in programs with similar policy goals will be compared, and significant differences that can not be supported by differences in policy will be analyzed. This will be conducted with opportunities for input from the Inter-Agency Work Group and programs in Cal/EPA concerned with specification of exposure scenarios.

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APPENDIX A:

ABBREVIATIONS AND ACRONYMS

AIHC	American Industrial Health Council
ARB	Air Resources Board
ASTM	American Society for Testing and Materials
ATES	Air Toxicology and Epidemiology Section
ATSDR	Agency for Toxic Substances and Disease Registry
BDOs	Boards, Departments, and Offices
Cal/EPA	California Environmental Protection Agency
Cal/TOX	California Department of Toxic Substances Control
CAPCOA	California Air Pollution Control Officers Association
CAQMD	Coast Air Quality Management District
CERCLA	Comprehensive Environment Response and Clean-up Liability Act
CMA	Chemical Manufacturers Association
COPC	Chemicals of Potential Concern
CSM	Conceptual Site Model
CV	Coefficient of Variation
DOE/ORO	Department of Energy, Oak Ridge Operations
DPR	Department of Pesticide Regulation
DTSC	Department of Toxic Substances Control
DQA	Data Quality Assessment
DQOs	Data Quality Objectives
EA	Exposure Area
HARP	Hot Spots Analysis and Reporting Program
HBLs	Health-Based Limits
HERD	Human and Ecological Risk Division
HEAST	Health Effect Assessment Summary Table
HHEM	Human Health Evaluation Manual
HQ	Hazard Quotient
HRAs	Health Risk Assessments
HWTS	Hazardous Waste Toxicology Section
IEUBK	EPA's Integrated Exposure Uptake Biokinetic
IRIS	Intergrated Risk Information System
MCLs	Maximum Contaminant Levels
MCLGs	Maximum Contaminant Level Goals
MCS	Monte Carlo Simulation

MMRA	Multi-Media Risk Assessment
MPECE	Multiple Pathways of Exposure to Combustor Emissions
MTBHAS	Medical Toxicology Branch Health Assessment Section
NCEA	National Center for Environmental Assessment
NPL	National Priorities List
OEHHA	Office of Environmental Health Hazard Assessment
ORMC	Other Relevant Measurable Criteria
OSWER	Office of Solid Waste and Emergency Response
PEA	Preliminary Endangerment Assessment
PETS	Pesticide and Environmental Toxicology Section
PHED	Pesticide Handlers Exposure Database
PHGs	Public Health Goals
PRGs	Preliminary Remediation Goals
PRPs	Potentially Responsible Parties
QA/QC	Quality Assurance/Quality Control
R&D	Research and Development
RAAC	Risk Assessment Advisory Committee
RAGS	Risk Assessment Guidance Document for Superfund
RBCA	Risk-Based Corrective Action
RBSLs	Risk-Based Screening Levels
RCRA	Resource Conservation and Recovery Act
RELs	Reference Exposure Levels
RfCs	Reference Air Concentrations
RfD	Reference Dose
RI/FS	Remedial Investigation/Feasibility Study
RWQCB	Regional Water Quality Control Boards
SAB	Scientific Advisory Board
SCAQMD	South Coast Air Quality Management District
SN	Standardization News
SSL	Soil Screening Levels
SSTL	Site Specific Target Levels

TACs	Toxic Air Contaminants
TMD	Technical Background Document
TSD/EASA	Technical Support Document for Exposure Assessment and Stochastic Analysis
U.S. EPA	U.S. Environmental Protection Agency
VF	Volatilization Factor
VOCs	Volatile Organic Compounds
WHB	Worker Health Branch

APPENDIX B:

EXPOSURE ASSESSMENT WORK GROUP SURVEY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT
CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

MULTIMEDIA RISK ASSESSMENT PROJECT
EXPOSURE ASSESSMENT WORKGROUP SURVEY

Name: _____

Board or Department:_____

Position: _____

Please return your completed survey by February 18, 1999, to:

Karen Randles
OEHHA, HWTS
301 Capitol Mall, Second Floor
Sacramento, CA 95814-4327
E-mail: krandles@sactopo.cahwnet.gov
Fax: (916) 322-9705
Phone: (916) 322-5657 [Karen] or call Sharon or Tonya: (916) 324-2829

In order to achieve the project's goals, we need information regarding *human exposure assessment* approach that you and your organization use at present and may need in a near future. Your experience and opinions on this topic are very important to us, so we can understand what you do, how you do it, and what your needs are. We will attempt to address your comments by incorporating this input in the appropriate exposure assessment module. If you need more room for your answers, please continue them on the last sheet. Please let us know if you would like to receive this survey also as an electronic file.

Please score your responses as : **1=Regularly; 2=Occasionally; 3=Never** (unless specified otherwise).

1. Does your program perform or review exposure assessment? Yes:…… No:……

If yes, for what purpose (e.g., remediation, clean-up, developing advisory levels, developing standards and criteria, etc.) and how frequently?

_____ 1 2 3

_____ 1 2 3

_____ 1 2 3

2. Which of the following approaches does your program use for exposure assessment?

- Screening (e.g., Preliminary Remediation Goals, etc.) 1 2 3
- Detailed-deterministic (e.g., Superfund Risk Assessment Guidance) 1 2 3
- Detailed-probabilistic 1 2 3

3. Please identify any computer model(s) or software programs that you use for exposure assessment and how frequently these are used:

_____ 1 2 3

_____ 1 2 3

_____ 1 2 3

4. Please identify any exposure pathways that you consider in exposure assessment and how frequently:

- Inhalation of vapors/gases 1 2 3
- drinking water 1 2 3
- incidental ingestion of soil 1 2 3
- dermal contact with soil 1 2 3
- ingestion of homegrown produce 1 2 3
- ingestion of homegrown animal products 1 2 3

other (specify) _____ 1 2 3

_____ 1 2 3

_____ 1 2 3

_____ 1 2 3

5. In estimating exposure dose, please identify which of the following information is used and how frequently:

- biomarker of exposure 1 2 3
- personal monitor data 1 2 3
- actual measured environmental concentrations at the point of contact 1 2 3
- estimates from ambient monitoring data 1 2 3
- estimates from fate and transport modeling 1 2 3
- assumed concentration at the point of contact 1 2 3

other (specify) _____ 1 2 3

_____ 1 2 3

6. Please identify any source/reference document(s) that you use for exposure factors (e.g., inhalation rates, body weight, exposed dermal area) and how frequently these are used:

_____ 1 2 3

_____ 1 2 3

_____ 1 2 3

7. Which of the following best describes the type of exposure factors you use? Please indicate all that apply:

- central tendency (mean, median) 1 2 3
- high end (90-95th percentile) 1 2 3
- bounding estimate (99.99th percentile) 1 2 3

8. Describe the relative importance of the following sources of uncertainty on your program's exposure assessments (**1**=very important; **2**=relatively important; **3**=not important):

- temporal dimensionality (e.g., short-term exposures, age of exposure) 1 2 3
- spatial dimensionality (e.g., migration over distance, contaminated area) 1 2 3
- environmental migration/transport/dispersion 1 2 3
- environmental fate (e.g., biodegradation, chemical reactions) 1 2 3
- exposure assessment modeling 1 2 3
- receptor-related (e.g., exposure factors, intake) 1 2 3

9. Please provide us the following information (**1**=Yes; **2**=No; **3**=Not sure):

(a) Does your program use a probabilistic approach in exposure assessment? 1 2 3

(b) Are there plans in your organization to consider probabilistic (stochastic, Monte-Carlo) methods as an improvement for exposure and risk assessment? 1 2 3

10. Identify the guidance document(s) that you use in your probabilistic approach, and the relative frequency:

- for the Monte Carlo method:

_____ 1 2 3

_____ 1 2 3

- for the exposure factors probability density functions (PDFs):

_____ 1 2 3

_____ 1 2 3

11. Please identify the software that you use in your probabilistic approach, and the relative frequency for:

- running Monte Carlo simulations:

_____ 1 2 3

_____ 1 2 3

- developing the exposure factors probability density functions (PDFs):

_____ 1 2 3

_____ 1 2 3

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12. Please briefly identify the issues – and if possible their relative priorities - in the following categories of exposure assessment that in your opinion we <u>should</u> address as part of the MMRA project:

- screening exposure assessment:

_____ 1 2 3

_____ 1 2 3

- site-specific exposure assessment:

_____ 1 2 3

_____ 1 2 3

- probabilistic exposure assessment:

_____ 1 2 3

_____ 1 2 3

- others:

_____ 1 2 3

_____ 1 2 3

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13. Please identify the issues in exposure assessment that in your opinion are <u>not</u> important to address as component of the MMRA Project.

- screening exposure assessment:

_____ 1 2 3

_____ 1 2 3

- site-specific exposure assessment:

_____ 1 2 3

_____ 1 2 3

- probabilistic exposure assessment:

_____ 1 2 3

_____ 1 2 3

- others:

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14. If you have any additional comment or suggestion related to the exposure assessment component of the MMRA project, please let us know.

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